



Original article

[Translated article] Real-world effectiveness and safety of atezolizumab-carboplatin-etoposide regimen in extensive-stage small-cell lung cancer

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ABSTRACT

Objective: The objective is to describe the real-world effectiveness and safety of atezolizumab in combination with carboplatin and etoposide as first-line treatment for patients with extensive-stage small-cell lung cancer.

Methods: We conducted a retrospective observational study of 48 patients with extensive-stage small-cell lung cancer treated with atezolizumab, carboplatin, and etoposide between March 2022 and May 2024 at a tertiary care center. The primary endpoints were progression-free survival and overall survival, analyzed using the Kaplan–Meier method. Safety outcomes and clinical predictors of survival were also assessed using software SPSS v26.

Results: After a median follow-up of 7.6 months (range: 1.5–28.4), median progression-free survival was 5.8 months and median overall survival was 7.1 months. Baseline ECOG performance status (ECOG 1 and 2) and the presence of brain metastases were associated with reduced overall survival. Patients who received ≤ 2 cycles of maintenance atezolizumab showed inferior survival outcomes. Grade 3–4 treatment-related adverse events occurred in 60.4% ($n = 29$) of patients, with hematologic toxicity being the most frequent.

Conclusions: In this real-world cohort, atezolizumab in combination with carboplatin and etoposide demonstrated feasibility and a manageable safety profile in first-line treatment of extensive-stage small-cell lung cancer. Longer follow-up and larger sample sizes are warranted to confirm these findings and further define prognostic markers in clinical practice.

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Efectividad y seguridad en vida real de atezolizumab-carboplatino-etopósido en cáncer de pulmón microcítico de enfermedad extendida

RESUMEN

Objetivo: analizar la efectividad y la seguridad en vida real de atezolizumab combinado con carboplatino y etopósido para el tratamiento de primera línea en cáncer de pulmón microcítico de enfermedad extendida.

Método: estudio observacional y retrospectivo que incluyó pacientes con diagnóstico de cáncer de pulmón microcítico de enfermedad extendida tratados con atezolizumab combinado con carboplatino y etopósido desde marzo de 2022 hasta mayo de 2024 en un hospital de tercer nivel. Los objetivos primarios fueron la supervivencia libre de progresión y la supervivencia global. El análisis estadístico se realizó mediante el método Kaplan–Meier. El software estadístico utilizado fue SPSS v26.

Resultados: se incluyeron un total de 48 pacientes. La mediana de seguimiento fue de 7,6 meses (rango: 1,5–28,4). La mediana de supervivencia libre de progresión y supervivencia global fue de 5,8 meses y 7,1 meses, respectivamente. Las metástasis cerebrales y el ECOG 1 y 2 al diagnóstico se asociaron con una supervivencia global reducida. Los pacientes que recibieron 2 o menos ciclos de atezolizumab en mantenimiento

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obtuvieron tanto una supervivencia libre de progresión como una supervivencia global inferiores. El 60,4% ($n = 29$) de los pacientes experimentaron algún efecto adverso de grado 3–4, siendo la toxicidad hematológica el efecto adverso más común.

Conclusiones: atezolizumab, combinado con etopósido y carboplatino, muestra ser una estrategia de tratamiento eficaz y con un perfil de seguridad tolerable para el cáncer de pulmón microcítico de enfermedad extendida en un entorno de práctica clínica real. Sin embargo, el periodo de seguimiento es una limitación, por lo que se requieren estudios con mayor tamaño muestral y seguimiento prolongado, para confirmar la supervivencia a largo plazo.

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Introduction

Lung cancer (LC) is the leading cause of cancer-related mortality, responsible for 18.8% of total cancer mortality in 2022. LC is the most commonly diagnosed cancer, ranking first in overall incidence globally. In Spain, 2480675 new cases (13.2% of total) were diagnosed in 2022.¹

Small-cell lung cancer (SCLC) is a highly aggressive neoplasm characterized by rapid tumor growth, early spread, and a high rate of recurrence following primary therapy.² This cancer approximately accounts for 15% of overall LC cases. Most SCLC patients are diagnosed with extensive-stage disease (ES-SCLC), which is associated with a very poor prognosis.^{2,3}

Carboplatin-etoposide chemotherapy (CT) yields high response rates, albeit with a short duration of response. Prior to the introduction of immunotherapy, the median overall survival (OS) ranged from 9 to 10 months, with a 5-year survival rate falling below 5%.^{4,5}

For decades, the standard first-line therapy was classic CT⁶; hence, the emergence of immunotherapy based on immune checkpoint inhibitors (ICIs) represented a paradigm shift. The phase-3 IMPower133 clinical trial demonstrated that the addition of atezolizumab to the carboplatin-etoposide scheme significantly improved progression-free survival (PFS), while showing a controllable safety profile.^{7,8} Based on these findings, the European Medicines Agency (EMA) approved atezolizumab in combination with carboplatin and etoposide as the first-line therapy for extensive-stage small-cell lung cancer, thereby establishing this combination as the new standard of care.⁹

Despite these advancements, the evidence provided in randomized clinical trials presents some limitations, since these studies often include highly selected populations. In routine clinical practice, however, patient profile is more heterogeneous and may include a poor performance status, relevant comorbidities, or active metastases, which are not always considered in pivotal trials.^{10–12} Research based on real-world data (RWD) provides crucial evidence for accurately assessing the effectiveness and safety of these treatments in non-controlled clinical settings.

The purpose of this study was to assess the effectiveness and safety of atezolizumab in combination with carboplatin and etoposide as first-line therapy for extensive-stage small-cell lung cancer administered in routine clinical practice in a third-level hospital. The primary endpoints were PFS and OS. Secondary endpoints included identifying patient baseline characteristics and response to treatment, and evaluating the safety profile of the regimen.

Methods

An analytical, retrospective, observational study was conducted, including the totality of ES-SCLC cases treated with atezolizumab in combination with carboplatin and etoposide in a third-level hospital between March 2022 and May 2024. Patients taking part in clinical trials were excluded. The follow-up period was completed on December 20, 2024.

Variables were extracted from the medical records of the patients, including sex; age; disease; Eastern Cooperative Oncology Group performance status (ECOG); smoking status (current/ former/never smoker); number of cycles received to study completion; best response; date of best response; time to response; date of progression; date of death; reason for treatment discontinuance; grade 3/4 toxicity; type of toxicity; and adverse events that led to treatment discontinuation.

All statistical analyses were performed using the SPSS v26 software package. Qualitative variables were described as absolute frequencies and percentages, whereas quantitative data were expressed as means and standard deviations. Non-parametric data were expressed as median and interquartile range. PFS was calculated from the first day of treatment to disease progression or death from any cause, whereas OS was estimated from treatment initiation to death using the Kaplan–Meier method. Curves were compared using the log-rank test. Statistical significance was established at $p < 0.05$. The log-rank test was used to compare survival among patient subgroups according to their baseline ECOG performance status (0, 1 or 2), diagnosis at metastatic stage, and the number of doses received during the maintenance phase (≤ 2 versus > 3).

Response to treatment was assessed according to the best overall response to treatment and the maximum tumor reduction achieved based on the Response Evaluation Criteria In Solid Tumors (RECIST, version 1.1).¹³ Responses were classified into complete response (CR); partial response (PR); stable disease (SD); progressive disease (PD); and not assessed (NA). Objective response rate (ORR) was defined as the sum of CR and PR. Duration of response was described as the time from first response (CR, PR or SD) to disease progression.

AEs were classified according to the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE v5.0).¹⁴

Reasons for treatment discontinuance were expressed as follows:

- PD: identified as a 20% increase in the sum of diameters of target lesions compared to the baseline sum on study or the appearance of new metastatic malignant lesions (not recorded at diagnosis).
- Patient clinical deterioration not caused by progressive disease or drug toxicity.
- Treatment discontinuance for treatment-associated toxicity.
- Treatment discontinuance by patient decision.

Patients received treatment in accordance with its indication, as specified in the Summary of Product Characteristics document, i.e. as a first-line scheme for extensive disease. The dosage regimen involved more than four 21-day cycles of atezolizumab (fixed dose of 1200 mg via intravenous infusion on Day 1 of each cycle); carboplatin (area under the curve of 5 mg/ml min, intravenously on Day 1 of each cycle) and etoposide (100 mg/m² of body surface intravenously from Day 1 to Day 3 of each cycle), followed by maintenance treatment with atezolizumab (1200 mg intravenously every 3 weeks).

Table 1
 Characteristics of the population.

Baseline Characteristics	
Total of patients	48
Age (mean; SD)	66.4; 6.5
Male sex (n, %)	27 (56.3)
ECOG (n, %)	
0	13 (27.1)
1	28 (58.3)
2	7 (14.6)
Metastases at diagnosis (n, %)	43 (89.6)
Brain metastases (n, %)	14 (29.2)
Smoking status (n, %)	
Former smoker	26 (54.2)
Current smoker	21 (43.8)
Never smoker	1 (2.1)
Line of overall therapy (n, %)	
1 L	45 (93.8)
2 L	2 (4.2)
3 L	1 (2.1)

ST: Standard Deviation.

Results

A total of 48 patients were included in the study. Table 1 summarizes patient demographics and baseline clinical characteristics prior to starting the atezolizumab + carboplatin + etoposide scheme.

A median of 4 (range 2–6) cycles of atezolizumab + carboplatin + etoposide were administered, with a median of three atezolizumab maintenance regimes per patient (range 0–33). The median duration of total treatment was 4.4 months (range 0.8–26.8). Five patients (10.4%) received the treatment for more than 12 months.

A total of 41 patients (85.4%) experienced disease progression or died, and 7 (14.6%) were censored from PFS analysis. In most cases, treatment was discontinued due to DP ($n = 30$; 62.5%), whereas clinical deterioration and treatment-associated toxicity led to treatment discontinuation in 8 (16.7%) and 2 (4.2%) cases, respectively. Only in one case, treatment was discontinued by patient decision (2.1%).

Upon study completion, 22.9% ($n = 11$) of patients had survived, of whom 14.6% ($n = 7$) were still receiving treatment.

Responses to treatment are described in Table 2. The median duration of follow-up was 7.6 months (range 1.5–28.4). The median PFS and OS were 5.8 months (95%CI: 4.8–6.7 months) and 7.1 months (95%CI: 3.6–10.7 months), respectively. A total of 41 patients (85.4%) developed progressive disease or died from any cause, whereas 37 patients (77.1%) did not survive. Survival curves are shown in Figs. 1 and 2.

ECOG performance status also influenced clinical outcomes. Patients with ECOG 0 exhibited a longer PFS, as compared to ECOG 1 and 2 cases (7.3 months versus 5.1 and 3.7 months, respectively; $p = 0.004$ y $p = 0.005$). No significant differences were observed between ECOG 1 and 2. OS was higher among ECOG 0 cases, as compared to ECOG 1 and 2

patients (18.6 months versus 6.7 and 5 months, respectively; $p < 0.001$ and $p = 0.003$), without differences between ECOG 1 and 2 ($p = 0.057$).

Survival was also assessed as a function of the number of maintenance atezolizumab doses received. The patients who received ≤ 2 doses ($n = 22$, 45.8%) exhibited an OS of 4.5 months, which is significantly lower than in patients who received > 2 doses ($n = 26$, 54.2%; 17.1 months; $p < 0.001$). Likewise, PFS was also higher in this group (3.6 vs. 7.2 months; $p < 0.001$). Survival data are provided in Table 3.

CI: confidence interval; OS: overall survival; PFS: progression-free survival. PFS and OS as estimated using the Kaplan–Meier method or SPSS v26 software, expressed as median values with their 95% confidence intervals.

Table 4 summarizes treatment-associated adverse events (AEs). Among the 48 patients, 29 (60.4%) developed grade 3–4 AEs; 27 (67.5%) experienced grade-3 AEs; and 13 (32.5%) developed grade-4 AEs. Most frequently, AEs occurred during induction cycles with the CT-atezolizumab combination, whereas only 4 patients (13.8%) developed AEs during maintenance therapy with atezolizumab.

The most common grade 3–4 AEs included neutropenia (60.0%), anemia (12.5%), and thrombocytopenia (10.0%).

Treatment was discontinued due to toxicity in two cases (4.2%): one for recurrent grade-3/4 episodes of thrombocytopenia, and another case due to grade 4 anemia.

Of the 48 patients, 3 (6.25%) experienced immune-mediated grade 3–4 AEs, including immune-mediated diabetes mellitus, immune-mediated mucositis, and immune-mediated pancreatitis.

Discussion

In our study, the atezolizumab-carboplatin-etoposide combination therapy demonstrated reasonable effectiveness and a satisfactory safety profile, although with some differences with respect to the pivotal trial. The phase III IMpower133¹⁵ clinical trial reported a PFS of 5.2 months (95%CI:4.4–5.6 months) and an OS of 12.3 months (95%CI: 10.8–15.8 months).

As compared to the IMpower133 study population,¹⁵ the median age in our study was slightly higher (66.1 years versus 64 years), with a lower percentage of male participants (56.3% versus 65%). ECOG performance status score 1 was the most frequent in the two studies (58.3% versus 64%). However, a higher proportion of our patients exhibited characteristics associated with poorer clinical outcomes, such as an ECOG ≥ 2 (14.6% versus none) and a higher prevalence of brain metastases (29.2% versus 9%). The IMpower133 trial only included treated and stable brain metastases, whereas our study also included untreated metastases, which could have contributed to a poorer baseline profile. These differences were expected, since this is a real-world study, and clinical trials generally include more selected and homogeneous populations of patients. In our study, no significant association was observed between the presence of brain metastases at diagnosis and PFS or OS. However, OS tended to improve in cases free of brain metastases at diagnosis (9.2 months versus 5.3 months, $p = 0.06$).

In contrast, significant differences were observed in PFS and OS according to patient performance status. Patients with ECOG 1 or 2 demonstrated a significantly poorer PFS, as compared to those with ECOG 0 ($p < 0.05$). Likewise, OS was poorer among patients with ECOG 1 and 2, as compared to ECOG 0 ($p < 0.005$). Further studies are needed to explore the role of immunotherapy in ES-SCLC with poor prognosis to confirm the effectiveness of this scheme in these patients.

As compared to the 2021 IMpower133 update,¹⁵ the median PFS obtained in our study was slightly higher than that reported in the IMpower133 study (5.8 months versus 5.2 months). In contrast, OS in our study was substantially poorer (7.1 months versus

Table 2
 Response to treatment.

Response to treatment	n (%)
Total of patients	48
Type of response	
Complete response	4 (8.3)
Partial response	24 (50.0)
Stable disease	8 (16.7)
Progressive disease	5 (10.4)
Not assessable	7 (14.6)
Objective response rate	58.3%
Median time to best response (range, months)	3.0 (0.8–11.8)
Median time to first response (range, months)	3.0 (0.8–3.9)
Median duration of response (range, months)	3.6 (0.2–24.0)
Patients still responsive upon study completion	7 (14.6)

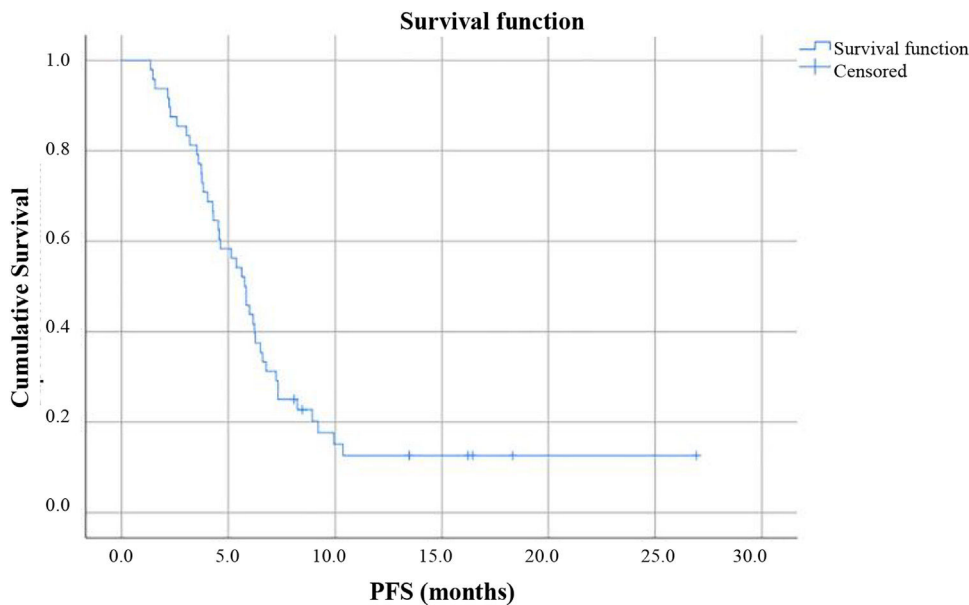


Figure 1. Progression-free survival ($n = 48$). Kaplan–Meier estimates.

12.3 months). This striking difference could be explained by differences in the baseline characteristics of patients, along with a poorer performance status and higher prevalence of brain metastases in our study population. Additionally, the limited follow-up period, added to the small sample size hinder the comparability of results. ORR was comparable between both studies (58.0% versus 60.2%), which suggests that treatment preserves efficacy even in a more heterogeneous and real-world setting.

The mean treatment duration documented in the last IMpower133 update¹⁵ was similar to that in our site (4.7 months versus 4.4 months, respectively). Conversely, the median follow-up duration was substantially lower in our study (7.6 months versus 22.9 months). Inconsistencies in survival rates are likely to be associated with our small sample size rather than the duration of follow-up.

The PFS documented in other real-world studies is comparable, although with significant inconsistencies in OS results. In Corea, a single-center retrospective study revealed a poorer PFS (4.6 versus 5.8 months) but a longer OS (12.0 versus 7.1 months). This study included patients with brain metastases (25%) while excluding patients with ECOG ≥ 2 .¹⁶ A case-control multicentric study on ES-SCLC involving a mean follow-up period of 11.9 months yielded a slightly higher PFS (6.7 versus 5.8 months) and a significantly higher OS, as compared to our results (15.5 versus 7.1 months). That study also included patients with ECOG ≥ 2 (10.6% versus 14.6% in our population) and brain metastases (25% versus 29.2% in our population).¹⁷ A retrospective multicentric study conducted in Turkey involving a follow-up period of 11.9 months reported a slightly improved PFS, as compared to that in our study (6.8 versus 5.8 months) and a

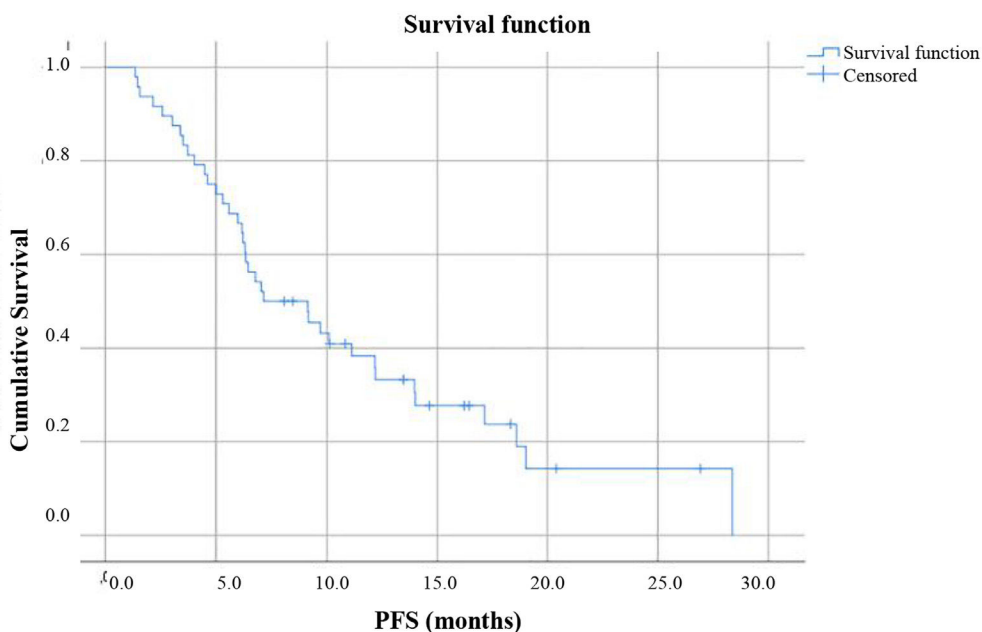


Figure 2. Overall survival ($n = 48$). Kaplan–Meier estimates.

Table 3
Stratified progression-free survival and overall survival.

Parameter	n PATIENTS	PFS			p	OS			p
		n Events	Median (months)	95%CI		n Events	Median (months)	95%CI	
Total	48	41	5.8	4.8–6.7		37	7.1	3.6–10.7	
Brain metastases									
No	34	29	6.0	5.5–6.5	0.203	26	9.2	5.1–13.2	0.06
Yes	14	12	4.0	3.2–4.8		11	5.3	2.5–8.1	
Extensive-stage disease									
No	5	3	7.3	4.1–10.5	0.155	3	18.6	NA	0.349
Yes	43	38	5.6	4.1–7.2		34	7.0	3.5–10.5	

more prolonged OS (11.9 versus 7.1 months). The study included patients with ECOG ≥ 2 (7.5%), although the presence of brain metastasis was not documented.¹⁸ The higher proportion of patients with ECOG ≥ 2 and brain metastases in our study with respect to other real-world studies probably contributed to our poorer OS outcomes. These findings suggest that, although PFS remains relatively consistent across studies, OS is determined by the patient baseline profile and the limited size of the sample, which may influence the precision of long-term overall survival estimates.

In terms of safety, 64.5% of patients developed grade 3–4 hematological toxicity. The majority of grade 3–4 AEs occurred during the induction phase with CT-atezolizumab, whereas only a small percentage (13.8%) of patients experienced grade 3–4 AEs during the maintenance phase with atezolizumab. These findings suggest that the scheme is safe and well-tolerated, especially during the maintenance phase.

Although dose adjustment or supportive therapies were not recorded, the concentration of grade 3–4 AEs during the induction phase suggests that toxicity could have determined the continuation or intensity of treatment. Treatment was discontinued in two patients due to toxicity (4.2%), both during the induction phase. This fact, added to the poorer baseline characteristics of our study population, could have indirectly contributed to the survival outcomes observed.

Subtle differences were noted in treatment safety between our study and the IMpower133 study.¹⁵ Grade 3–4 neutropenia was more frequent in our population (41.6% versus 22.7%), whereas the incidence of anemia and thrombocytopenia was slightly lower (10.4% versus 14.1% and 8.3% versus 10.1%, respectively). Grade 3–4 immunomediated AEs were less common (6.3% versus 39.9%). In our study, treatment was discontinued owing to treatment toxicity in two patients (4.2%) as compared to 11.1% reported in the IMpower133 study. These differences could be related to the small sample included in our study and its retrospective design. In the pivotal study, the most common immunomediated AEs included hypothyroidism and rash; however, data on these AEs are not available in our study, since only grade 3–4 AEs were documented. However,

other less common AEs were recorded, including immunomediated mucositis and pancreatitis.

As in any research, this study has some strengths and limitations. One of its main strengths is that the population of this study is more representative of the real-world cancer population, including patients with different ECOG scores showing some clinical characteristics that are generally excluded from clinical trials. The RWD obtained in this study provide a more realistic insight into the effectiveness and tolerability of the atezolizumab + carboplatin + etoposide scheme in routine clinical practice, thereby supporting its applicability in diverse clinical settings.

A limitation of this study is that it is a single-center study including a small sample size (48 patients). Additionally, the availability of some data –especially AE-related data– is limited by the retrospective design of the study, whereby data were extracted from the medical records of patients. Differences were observed in clinical practice with respect to pivotal trials. Unlike in previous studies, some of our patients received more than four cycles of CT. Finally, the short follow-up period could have influenced results. Larger, prospective clinical trials involving longer follow-up periods are needed to verify the clinical benefits of the schemes.

According to the results of our study, the combination therapy of atezolizumab + etoposide + carboplatin is feasible and safe as first-line therapy for extensive small-cell lung cancer in routine clinical practice. These findings underline the importance of considering the heterogeneous characteristics of real-life patients when assessing the tolerability and applicability of anti-cancer therapies.

As compared to the IMpower133 study, the atezolizumab + etoposide + carboplatin scheme was associated with improved PFS, but with a poorer OS, probably due to the limited follow-up period and small number of study patients included.

Large, prospective, multicentric studies involving a longer follow-up period are necessary to confirm the duration of response, toxicity and effects of this regimen on long-term survival.

Contribution to the scientific literature

Patients with extensive-stage small-cell lung cancer have a poor prognosis even after the incorporation of immunotherapy into the standard of care. Although clinical trials demonstrate that overall survival rates have improved with the addition of atezolizumab, the available real-world evidence is still limited.

This study provides data on the effectiveness and safety of atezolizumab in combination with carboplatin and etoposide in routine clinical practice. The results obtained contribute to assessing the applicability of the treatment outside the controlled setting of a clinical trial. Additionally, our findings provide guidance for therapeutic decision-making in comparable settings, thereby helping identify population subgroups with a poorer prognosis.

Real-world evidence is useful for optimizing patient selection and follow-up. This evidence outlines the need for further real-world

Table 4
Adverse events associated with the medication scheme.

Grade 3–4 AE	Total of patients (percentage)
Neutropenia	20 (41.6)
Anemia	5 (10.4)
Thrombocytopenia	4 (8.3)
Neutropenic fever	2 (4.2)
Asthenia	1 (2.1)
Hypomagnesemia	1 (2.1)
Grade 3–4 immune-related AE	
Immune-mediated diabetes mellitus	1 (2.1)
Immune-mediated mucositis	1 (2.1)
Immune-mediated pancreatitis	1 (2.1)

AE: adverse event.

evidence that complements the results of clinical trials and supports therapeutic decision-making in this scenario.

Conflict of interest

The authors confirm that there are no known conflicts of interest associated with this publication.

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CRedit authorship contribution statement

María Belén Aznar de la Riera: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Carmen María Valencia Soto:** Writing – review & editing, Visualization, Validation, Supervision, Software, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Adela García-Avello Fernández-Cueto:** Writing – review & editing, Visualization, Validation, Supervision, Software, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **María Victoria Villacañas Palomares:** Writing – review & editing, Validation, Supervision, Methodology. **Nerea Muñoz Unceta:** Writing – review & editing, Validation, Supervision, Methodology, Conceptualization. **Víctor Fernández Martínez:** Writing – review & editing, Validation, Supervision. **Sara Barbadillo Villanueva:** Writing – review & editing, Validation, Supervision. **María Rioja Carrera:** Writing – review & editing, Validation, Supervision. **Marta Valero Dominguez:** Writing – review & editing, Validation, Supervision. **Virginia Martínez Callejo:** Writing – review & editing, Validation, Supervision, Project administration.

Ethical considerations

This study was conducted in compliance with the tenets of the Declaration of Helsinki and was approved by the local Ethics Committee for Research with Medicinal Products of Cantabria (CEIm) (code 2024.426, date of approval January 17, 2025). Pursuant to the Spanish Organic Data Protection Law 3/2018 and Regulation 2016/679 of the European Parliament and European Council of April 27, 2016, patients were identified using a numerical code.

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