Real-world treatment patterns and outcomes in patients with extensive-stage small cell lung cancer previously treated with first-line platinum-based chemotherapy

RWD164

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OBJECTIVES

- The primary objective of this analysis was to evaluate the real-world effectiveness outcomes (rwPFS and rwOS) of SOC in France among a cohort of over 900 patients with ES-SCLC who received 2L therapy following 1L PBC (overall 2L index cohort), using the ESME LC EMR-derived database
- The secondary objectives were to describe patient demographic and clinical characteristics, and treatment patterns and sequencing from 1L–4L, among the overall 2L index cohort; identifying potential predictors of rwPFS and rwOS was an exploratory objective

CONCLUSIONS

- This retrospective analysis of real-world patient data in France from a multicenter electronic database showed no clear SOC for patients with ES-SCLC receiving treatment in 2L+ settings; 2L, 3L, and 4L treatments were heterogeneous
- PBC without IO was the most common 2L therapy, followed by lurbinectedin, then topotecan
- As could be expected, platinum rechallenge in 2L was more common among patients with platinum-sensitive disease (chemotherapy-free interval [CTFI] ≥90 days from 1L therapy) than in those with platinum-resistant/refractory disease (CTFI <90 days from 1L therapy), and this patient subgroup had comparatively better rwPFS and rwOS outcomes
  - Patients who received carboplatin + etoposide had numerically better rwPFS and rwOS irrespective of platinum sensitivity
- Overall, outcomes in patients with relapsed ES-SCLC were very poor with SOC 2L therapies, with median rwPFS of 2.6 months and median rwOS of 6.4 months, highlighting the need for novel treatment options in this setting

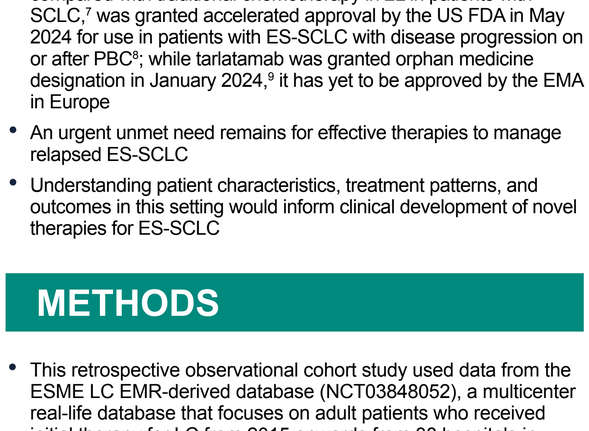
INTRODUCTION

- Patients with ES-SCLC initially respond to systemic 1L SOC PBC ± IO. However, most patients relapse within 6 months, and the prognosis remains poor[1–3]
- Approximately only half of patients with ES-SCLC go on to receive 2L treatment[4]; there is no global SOC from 2L+[1,5,6]
- In Europe, 2L treatments for relapsed ES-SCLC include topotecan, anthracycline-based regimens such as cyclophosphamide + doxorubicin + vincristine (CAV), and lurbinectedin; platinum rechallenge is an option for patients with platinum-sensitive disease[1]
- Tarlatamab, which has demonstrated improved survival outcomes compared with traditional chemotherapy in 2L in patients with SCLC,[7] was granted accelerated approval by the US FDA in May 2024 for use in patients with ES-SCLC with disease progression on or after PBC[8]; while tarlatamab was granted orphan medicine designation in January 2024,[9] it has yet to be approved by the EMA in Europe
- An urgent unmet need remains for effective therapies to manage relapsed ES-SCLC
- Understanding patient characteristics, treatment patterns, and outcomes in this setting would inform clinical development of novel therapies for ES-SCLC

METHODS

- This retrospective observational cohort study used data from the ESME LC EMR-derived database (NCT03848052), a multicenter real-life database that focuses on adult patients who received initial therapy for LC from 2015 onwards from 38 hospitals in France (18 comprehensive cancer centers [Unicancer Group] spread over 20 sites and 18 public hospitals)
- As of September 2024, 61,139 patients were included in the ESME LC database, of whom 6738 had SCLC (**Figure 1**)
- Patients aged ≥18 years with an ES-SCLC diagnosis on or after January 1, 2019, who had received ≥2 LOTs including 1L PBC (any treatment regimen containing carboplatin or cisplatin), and had ≥6 months of potential follow-up (including patients who died or had an event <6 months prior to data cutoff), were included in the overall 2L index cohort (**Figure 1**)
  - Patients who had a previous LS-SCLC diagnosis and received 1L PBC but progressed to ES-SCLC on treatment or ≤6 months from PBC completion were eligible (in these patients the first metastatic treatment regimen was considered 2L index)
  - Patients were excluded if they received clinical trial study drugs as part of their 1L PBC-containing regimen and/or index LOT (2L)
- Analyses were performed on the overall 2L index cohort and on subgroups of this cohort stratified by index line treatment, CTFI after 1L therapy, and presence of brain metastases at 2L index
- rwPFS and rwOS were assessed from 2L index by Kaplan–Meier method; no formal statistical comparisons were performed
- Multivariable analysis to identify predictors for rwPFS was performed using a Cox proportional hazards model

Figure 1. Patient selection: overall 2L index cohort



[a]Patients with a previous LS-SCLC diagnosis who received 1L PBC and progressed to ES-SCLC on treatment or ≤6 months from completion of treatment were eligible.
[b]Potential follow-up was defined as index date occurring ≥6 months prior to data cutoff, ie, patients dying or having an event within this period were included.

RESULTS

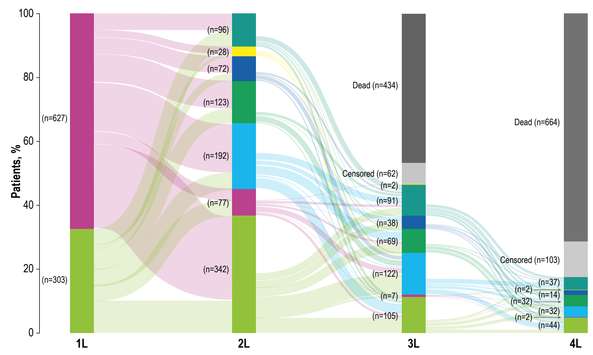
- A total of 930 patients met criteria for inclusion in the overall 2L index cohort (**Figure 1**)
  - Among these patients, 255 (27.4%), 192 (20.6%), 123 (13.2%), and 72 (7.7%) were included in the carboplatin + etoposide, lurbinectedin, topotecan, and CAV subgroups of treatment received at 2L index, respectively (**Table 1**)
  - Among the overall 2L index cohort, 46.7% of patients died (17.6% while receiving 2L treatment and 29.0% following 2L treatment discontinuation), while the remaining patients either went on to receive 3L therapy (46.7%), continued with 2L treatment (3.2%), or discontinued 2L treatment without yet receiving a subsequent LOT (3.4%)
- Patient characteristics were generally similar across the lurbinectedin and topotecan subgroups and were comparable with the overall 2L index cohort (**Table 1**)
  - However, in the carboplatin + etoposide and the CAV subgroups, the proportion of patients with ECOG PS 0–1 (78.7% and 76.3%, respectively) was higher than in the overall 2L index cohort (68.8%)
  - A higher proportion of patients in the carboplatin + etoposide subgroup (89.9%) had a CTFI ≥90 days (platinum-sensitive disease) than in the overall 2L index cohort (53.0%)

Treatment patterns and sequencing

- There was no clear SOC in the 2L, 3L, or 4L settings in the overall 2L index cohort
- The most common treatments in the 2L setting were PBC without IO, lurbinectedin, and topotecan, received by 342 (36.8%), 192 (20.6%), and 123 (13.2%) patients, respectively (**Figure 2A**)
- Platinum rechallenge (PBC with or without IO) in 2L was more common in the CTFI ≥90 days (platinum-sensitive) subgroup (14.2% and 52.1%, respectively) than in the CTFI <90 days (platinum-resistant/refractory) subgroup (1.6% and 19.5%, respectively) (**Figures 2B and 2C**)
- There was no clear SOC in the 3L or 4L settings in the CTFI <90 days or ≥90 days subgroups

Figure 2. Treatment patterns and sequencing

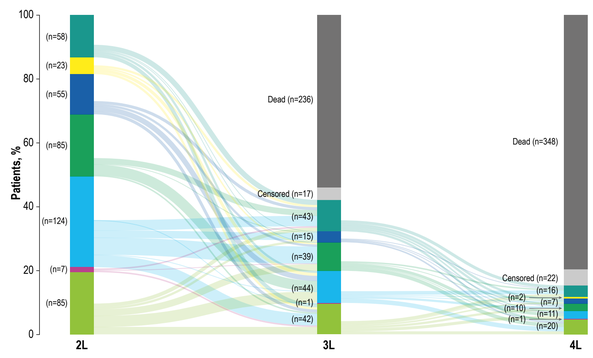
A. Overall 2L index cohort (N=930)



Treatment category, n (%)	1L (N=930)	2L (N=930)	3L (n=434)	4L (n=163)
PBC with IO	627 (67.4)	77 (8.3)	7 (1.6)	2 (1.2)
PBC without IO	303 (32.6)	342 (36.8)	105 (24.2)	44 (27.0)
Lurbinectedin	0	192 (20.6)	122 (28.1)	32 (19.6)
Topotecan	0	123 (13.2)	69 (15.9)	32 (19.6)
CAV	0	72 (7.7)	38 (8.8)	14 (8.6)
IO alone	0	28 (3.0)	2 (0.5)	2 (1.2)
Other regimen[a]	0	96 (10.3)	91 (21.0)	37 (22.7)

Between 2L and 3L treatment, 62 patients were censored and 434 patients died. Between 3L and 4L treatment, a further 41 patients were censored and a further 230 patients died.

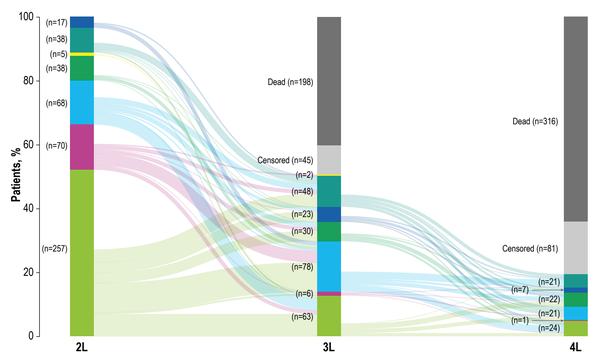
B. CTFI[b] <90 days subgroup (n=437)



Treatment category, n (%)	CTFI <90 days (n=437) 2L (n=437)	3L (n=184)	4L (n=67)
PBC with IO	7 (1.6)	1 (0.5)	1 (1.5)
PBC without IO	85 (19.5)	42 (22.8)	20 (29.9)
Lurbinectedin	124 (28.4)	44 (23.9)	11 (16.4)
Topotecan	85 (19.5)	39 (21.2)	10 (14.9)
CAV	55 (12.6)	15 (8.2)	7 (10.4)
IO alone	23 (5.3)	0	2 (3.0)
Other regimen[a]	58 (13.3)	43 (23.4)	16 (23.9)

Between 2L and 3L treatment, 17 patients were censored and 236 patients died. Between 3L and 4L treatment, a further 5 patients were censored and a further 112 patients died.

C. CTFI[b] ≥90 days subgroup (n=493)



Treatment category, n (%)	CTFI ≥90 days (n=493) 2L (n=493)	3L (n=250)	4L (n=96)
PBC with IO	70 (14.2)	6 (2.4)	1 (1.0)
PBC without IO	257 (52.1)	63 (25.2)	24 (25.0)
Lurbinectedin	68 (13.8)	78 (31.2)	21 (21.9)
Topotecan	38 (7.7)	30 (12.0)	22 (22.9)
CAV	17 (3.4)	23 (9.2)	7 (7.3)
IO alone	5 (1.0)	2 (0.8)	0
Other regimen[a]	38 (7.7)	48 (19.2)	21 (21.9)

Between 2L and 3L treatment, 45 patients were censored and 198 patients died. Between 3L and 4L treatment, a further 36 patients were censored and a further 118 patients died.

[a]Includes treatment as part of a clinical trial, cyclophosphamide/etoposide/lomustine, paclitaxel ± topotecan, other non-PBC regimens, or other regimens. [b]CTFI is defined as the time from last platinum dose received in 1L to first disease progression (regardless of any maintenance treatment).

Table 1. Baseline sociodemographic and clinical characteristics

	Overall 2L index cohort (N=930)	Subgroups of treatment received at 2L index: Carboplatin + etoposide (n=255)	Lurbinectedin (n=192)	Topotecan (n=123)	CAV (n=72)
Age at 2L index, median (range), years	66.0 (27–88)	66.0 (41–87)	66.0 (36–85)	66.0 (27–87)	64.0 (39–85)
Male, n (%)	578 (62.2)	152 (59.6)	119 (62.0)	76 (61.8)	53 (73.6)
ES-SCLC at initial diagnosis, n (%)	865 (93.0)	240 (94.1)	185 (96.4)	117 (95.1)	70 (97.2)
ECOG PS 0–1 at 2L index,[a] n (%)	276 (68.8)	85 (78.7)	56 (69.1)	34 (56.7)	29 (76.3)
Data not available, n (%)	529 (56.9)	147 (57.6)	111 (57.8)	63 (51.2)	34 (47.2)
CTFI from 1L therapy, n (%)					
<90 days	437 (47.0)	26 (10.2)	124 (64.6)	85 (69.1)	55 (76.4)
≥90 days	493 (53.0)	229 (89.8)	68 (35.4)	38 (30.9)	17 (23.6)
Brain metastasis at 2L index, n (%)					
Yes	522 (56.1)	148 (58.0)	105 (54.7)	72 (58.5)	39 (54.2)
No	408 (43.9)	107 (42.0)	87 (45.3)	51 (41.5)	33 (45.8)
Prior 1L IO, n (%)	627 (67.4)	186 (72.9)	147 (76.6)	80 (65.0)	50 (69.4)

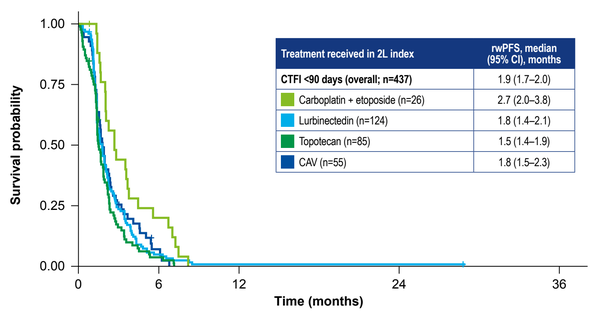
[a]The number of patients with data available for ECOG PS was used as the denominator when calculating the percentage. ECOG PS data were available for 401 (overall 2L index cohort), 108 (carboplatin + etoposide), 81 (lurbinectedin), 60 (topotecan), and 38 (CAV) patients.

Effectiveness outcomes

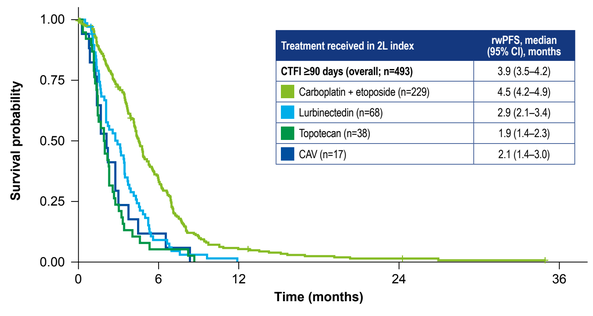
- From the start of 2L therapy, among the overall 2L index cohort, median rwPFS was 2.6 months (95% CI, 2.3–2.8) and median rwOS was 6.4 months (95% CI, 6.1–7.0)
- From the start of 2L therapy, among the carboplatin + etoposide, lurbinectedin, topotecan, and CAV subgroups of treatments received at 2L index:
  - Median (95% CI) rwPFS was 4.3 (4.0–4.8), 2.1 (1.7–2.2), 1.7 (1.4–1.9), and 1.9 (1.5–2.3) months, respectively
  - Median (95% CI) rwOS was 9.2 (8.2–10.7), 6.1 (5.0–6.5), 3.2 (2.3–4.1), and 4.5 (2.8–5.4) months, respectively
- rwPFS and rwOS from the start of 2L therapy were numerically better among patients with platinum-sensitive disease (CTFI ≥90 days) than those with platinum-resistant/refractory disease (CTFI <90 days; **Figure 3A–D**)
  - rwPFS and rwOS were numerically longer with carboplatin + etoposide than with other 2L treatments in both CTFI subgroups
- rwPFS and rwOS from the start of 2L therapy were similar between patients with and without brain metastases, with median rwPFS of 2.8 (95% CI, 2.4–3.0) and 2.4 (95% CI, 2.2–2.8) months, respectively, and median rwOS of 6.2 (95% CI, 5.7–6.8) and 6.9 (95% CI, 6.3–7.8) months, respectively

Figure 3. Real-world PFS and OS among the CTFI subgroups by 2L treatment received

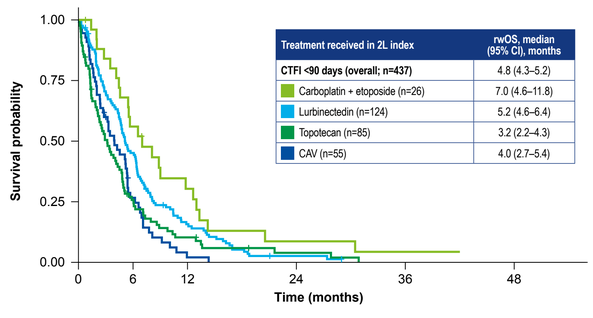
A. rwPFS in CTFI[a] <90 days subgroup (n=437)



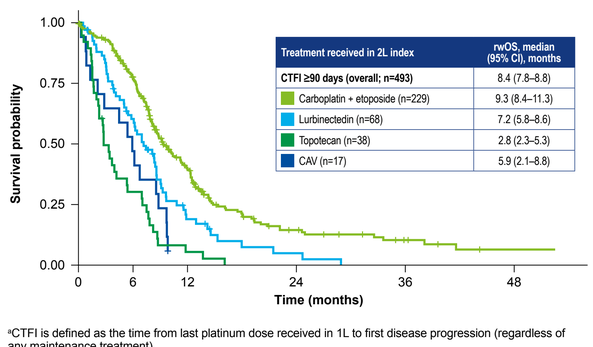
B. rwPFS in CTFI[a] ≥90 days subgroup (n=493)



C. rwOS in CTFI[a] <90 days subgroup (n=437)



D. rwOS in CTFI[a] ≥90 days subgroup (n=493)



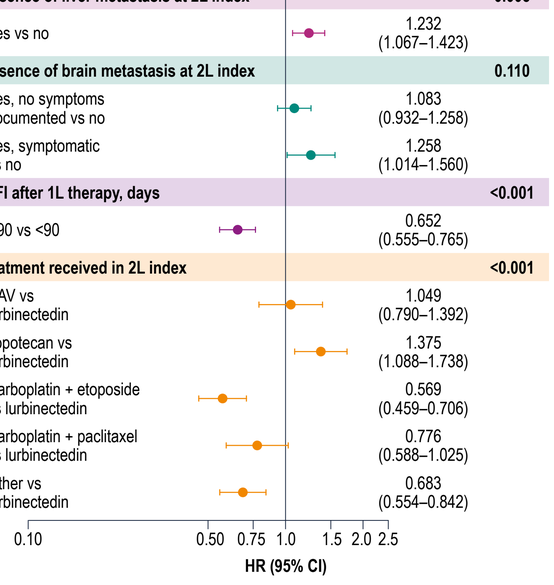
[a]CTFI is defined as the time from last platinum dose received in 1L to first disease progression (regardless of any maintenance treatment).

Predictors of rwPFS

- An exploratory multivariable analysis showed that ECOG PS at 2L index, CTFI from 1L therapy, and type of 2L treatment received were significant prognostic factors associated with rwPFS following 2L treatment (P<0.001; **Figure 4**)
- Lurbinectedin (the reference treatment) was associated with improved rwPFS outcomes compared with topotecan or CAV, even after accounting for major prognostic factors such as ECOG PS, platinum sensitivity, and presence of brain metastases
  - Conversely, carboplatin-based regimens demonstrated a favorable prognostic impact compared with lurbinectedin, even after adjustment for the same variables

Figure 4. Multivariable analysis of predictors for rwPFS in the overall 2L index cohort

Potential prognostic factor	HR (95% CI)	P value
Sex		**0.325**
Male vs female	1.072 (0.933–1.232)	
Age at ES-SCLC diagnosis, years		**0.431**
65−75 vs <65	0.982 (0.849–1.137)	
≥75 vs <65	0.867 (0.697–1.079)	
Smoking status		**0.475**
Former smoker vs non smoker	1.338 (0.880–2.035)	
Smoker vs non smoker	1.292 (0.848–1.969)	
Stage at initial diagnosis		**0.577**
ES-SCLC vs LS-SCLC	1.079 (0.825–1.411)	
Number of metastatic locations at ES-SCLC diagnosis		**0.109**
<3 vs ≥3	0.863 (0.720–1.034)	
ECOG PS at 2L index		**<0.001**
0 vs ≥3	0.233 (0.152–0.357)	
1 vs ≥3	0.335 (0.230–0.488)	
2 vs ≥3	0.427 (0.284–0.642)	
Presence of liver metastasis at 2L index		**0.005**
Yes vs no	1.232 (1.067–1.423)	
Presence of brain metastasis at 2L index		**0.110**
Yes, no symptoms documented vs no	1.083 (0.932–1.258)	
Yes, symptomatic vs no	1.258 (1.014–1.560)	
CTFI after 1L therapy, days		**<0.001**
≥90 vs <90	0.652 (0.555–0.765)	
Treatment received in 2L index		**<0.001**
CAV vs lurbinectedin	1.049 (0.790–1.392)	
Topotecan vs lurbinectedin	1.375 (1.088–1.738)	
Carboplatin + etoposide vs lurbinectedin	0.569 (0.459–0.706)	
Carboplatin + paclitaxel vs lurbinectedin	0.776 (0.588–1.025)	
Other vs lurbinectedin	0.683 (0.554–0.842)	



DISCUSSION AND STUDY LIMITATIONS

- In the overall 2L index cohort, patient attrition due to censoring or death across later LOTs was substantial, with only 46.7% and 17.5% of patients going on to receive 3L and 4L therapy, respectively
- This study was subject to limitations related to the methodology (screening platform and centralization of data) for maintaining the ESME LC data platform, including the limitation of patient data from 38 hospitals (which may not reflect all patients treated for SCLC in France), unavailability of some patient data (eg, ECOG PS, smoking status), and variations in data cutoff and follow-up between patients
- While the multivariable analysis predicted better rwPFS in 2L for carboplatin + etoposide than for lurbinectedin, the retrospective nature of the study, as well as notable variables such as toxicity in 1L that were not taken into account in the analysis, should be considered when interpreting these results

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DISCLOSURES

Dr Gobbini has served on speaker bureaus for MSD, Bristol Myers Squibb, Regeneron, Sanofi, and Janssen, and is the spouse of an AstraZeneca employee.

The ESME LC database receives financial support from several pharmaceutical companies. Unicancer manages the database independently (ie, data collection and analysis) and is the sole data controller for data processing.

ABBREVIATIONS

1L, first-line; **2L(+)**, second-line (and beyond); **3L**, third-line; **4L**, fourth-line; **CAV**, cyclophosphamide + doxorubicin + vincristine; **CI**, confidence interval; **CTFI**, chemotherapy-free interval; **ECOG PS**, Eastern Cooperative Oncology Group performance status; **EMA**, European Medicines Agency; **EMR**, electronic medical record; **ESME**, Epidemiological Strategy and Medical Economics; **FDA**, Food and Drug Administration; **HR**, hazard ratio; **IO**, immunotherapy; **LC**, lung cancer; **LOT**, line of therapy; **(rw)OS**, (real-world) overall survival; **PBC**, platinum-based chemotherapy; **(rw)PFS**, (real-world) progression-free survival; **(LS/ES-)SCLC**, (limited-stage/extensive-stage) small cell lung cancer; **SOC**, standard-of-care; **US**, United States.

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