

Durvalumab in the Real-World Management of Extensive-Stage Small Cell Lung Cancer in Alberta: Clinical Outcomes, Treatment Patterns, and a Proof-of-Concept for Outcomes-Based Agreements

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Abstract

Background

To assess the treatment patterns and clinical outcomes in patients with extensive stage small cell lung cancer (ES-SCLC) who received first-line (1L) durvalumab in Canada and determine whether data about a drug's effectiveness could be generated at regular intervals to support outcomes-based agreements (OBAs).

Materials and Methods

This was a retrospective analysis on real-world population level data from the province of Alberta, Canada. Patients diagnosed with ES-SCLC between July 1, 2021, and July 31, 2022, were at least 18 years old at diagnosis, and received durvalumab, were included in this study. Treatment patterns and survival outcomes were collected on a quarterly analysis to replicate the data requirements for an OBA.

Results

The study included 68 patients, with 63 (92.6%) patients who received first-line (1L) durvalumab. With 61 (96.8%) patients discontinuing durvalumab by the data cut-off date, the median 1L treatment duration was 5.5 months. Of the patients receiving 1L durvalumab therapy, the median overall survival (OS) was 11.3 months. The 1-year and 2-year OS rates were 46% and 21%, respectively, and the median time to next treatment or death (TTNT-D) was 8.2 months.

Conclusion

This is the first study to assess the real-world use of durvalumab in ES-SCLC in Canada. Patients with ES-SCLC who received 1L durvalumab plus platinum-etoposide, had similar OS outcomes to those in the CASPIAN trial. Durvalumab has a meaningful role in managing ES-SCLC, and it is feasible to collect and analyze data to operationalize an OBA using existing infrastructure.

Introduction

Lung cancer is the most commonly diagnosed cancer and the leading cause of cancer-related deaths in Canada.¹ Approximately 12% of lung cancer cases in Canada are small-cell lung cancer (SCLC), a high-grade neuroendocrine carcinoma characterized by a rapid proliferative rate, high growth fraction, and propensity to metastasize.^{2,3} Two-thirds of patients with SCLC present with extensive stage disease (ES-SCLC), defined as stage IV disease in which tumor invades beyond the ipsilateral hemithorax and regional lymph nodes, or is unable to be included in a single tolerable radiotherapy field.^{4,5} This diagnosis

is associated with poor prognosis, with a median overall survival (OS) of 8–13 months and 5-year survival rate of only 1–3% prior to the introduction of immunotherapy.^{6,7}

The current standard of care for ES-SCLC is first-line platinum-based chemotherapy (cisplatin or carboplatin) in combination with etoposide and a programmed death-ligand 1 (PD-L1) inhibitor (durvalumab or atezolizumab), with initial response rates up to 78%.^{8,9} This regimen is supported by phase III trials, including CASPIAN and IMpower133, which demonstrated that the addition of durvalumab (CASPIAN) or atezolizumab (IMpower133) to platinum-etoposide significantly and durably improves overall survival compared to chemotherapy alone (median OS 13.0 vs 10.3 months with hazard ratio [HR] 0.73, and median OS 12.3 vs 10.3 months with HR 0.70, respectively).^{10,11,12,13} Patients with extensive-stage disease may also be considered for thoracic radiation therapy in combination with chemotherapy, and prophylactic cranial irradiation or MRI surveillance may be discussed on a case-by-case basis.¹⁴ Despite these advances, treatment remains challenging due to the high rate of recurrence and the development of resistance in nearly all patients.¹⁵

Recent real-world studies have begun to characterize the impact of immuno-oncology agents in ES-SCLC, but Canadian data remain limited. Prior Canadian observational studies, such as those by O'Sullivan et al. and Rittberg et al., demonstrated that most patients received either carboplatin plus etoposide or cisplatin plus etoposide in the first-line setting for ES-SCLC, but overall first-line treatment initiation rates were low (46.5% in Alberta).^{16,17} Median OS ranged from 5.7 to 10.6 months, with patients who received both chemotherapy and radiation having longer OS, while overall 1-year, 2-year, and 5-year survival rates remained poor (26–29%, 7%, and 2.9–3%, respectively). With the adoption of first-line chemoimmunotherapy, real-world evidence of international cohorts has shown a modest improvement in survival outcomes compared to chemotherapy alone which supports the efficacy observed in pivotal trials.^{18,19} However, a recent Canadian study found that only a minority of ES-SCLC patients from British Columbia (23% of all, 35% of platinum-treated) would have been eligible for first-line chemoimmunotherapy due to comorbidities and poor performance status.²⁰ While the American Society of Clinical Oncology (ASCO) and Cancer Care Ontario recommend platinum-etoposide plus a PD-L1 inhibitor as first-line therapy, real-world uptake and effectiveness in Canada are still being defined.²¹

Recognizing the unmet need for effective and innovative therapies for ES-SCLC, we investigated treatment patterns and clinical outcomes in ES-SCLC patients following the introduction of durvalumab in Canada. The objectives of this study were to assess clinical outcomes and treatment patterns in patients with ES-SCLC who received first-line durvalumab.

Further, this was a proof-of-concept study to assess the feasibility of current data infrastructure in Alberta, Canada to support future outcomes-based agreements (OBAs), by replicating the operational aspects of data curation, analyses, and outputs that would be expected for an OBA. An OBA is an agreement between the manufacturer of a novel therapy and a payer, where the manufacturer will issue a refund or rebate to the payer based on the therapy's objective performance in the real-world setting. It is

a strategy that may potentially accelerate patient access and mitigate risk for payers but concerns regarding data limitations and administrative burdens have hindered its acceptance. Recent research has described a feasible process to operationalize an OBA in oncology using real-world administrative health data in Alberta, Canada.²² Additionally, OS and time to next treatment (TTNT) were identified as suitable clinical outcomes for OBAs in oncology. Given this context, our goal was to determine if it was possible to generate data about a drug's effectiveness (i.e., in this case, durvalumab) at regular time intervals to support an OBA.

Materials and Methods

Study Design and Population

This was a retrospective cohort study using real-world, population-level data from Alberta, Canada. Alberta's integrated health network includes 17 cancer centers (2 tertiary, 4 regional, and 11 community centers), serving a population of approximately 4.5 million residents. Patients included in this study were those diagnosed with ES-SCLC between July 1, 2021 and July 31, 2022, the index period, aged 18 years or older at diagnosis, and received durvalumab. Patients initially diagnosed with limited-stage (LS) SCLC that progressed to ES-SCLC during this timeframe were also included. Of note, this index period aligns with the initiation of the durvalumab patient support program administered by AstraZeneca Canada Inc., in July 2021.

Data Sources

The database included Alberta's integrated provincial healthcare system, electronic health records, and lab and pathology results. The Alberta Cancer Registry (ACR) is a population-based registry that collects data on all new cancer cases and deaths in Alberta. The ACR was utilized to identify patients diagnosed with ES-SCLC within the index period and to collect their baseline demographic and clinical characteristics. The Pharmaceutical Information Network (PIN) contains information on the medication profiles of patients, which was then reviewed in order to identify patients diagnosed with ES-SCLC patients who initiated durvalumab. ACR and PIN data were then linked to electronic medical records (EMR) and the Vital Statistics database to obtain data on treatment details and outcomes.

Outcomes and Statistical Analysis

Patient demographic and clinical characteristics and treatment patterns were summarized using descriptive statistics for all patients diagnosed with ES-SCLC. Means, standard deviations (SD), median, and interquartile range (IQR) were reported for continuous variables, while categorical variables were presented with frequencies and percentages. Due to data privacy legislation, data categories with less than 10 counts were suppressed and denoted by "<10".

Outcomes of interest for this study included OS, time-to-next-treatment or death (TTNT-D), duration of treatment, and reasons for treatment discontinuation for patients treated with durvalumab in the 1L setting. OS was defined as the time from initiation of durvalumab until death from any cause, while TTNT-D was defined as the time from initiation of durvalumab to the initiation of subsequent treatment or death from any cause. For both OS and TTNT-D, patients who did not experience death or next treatment (TTNT-D only) were censored at the earlier of their date of last follow-up or the data cutoff date. The decision to include TTNT-D as an outcome of interest was based on its increasing use as a surrogate endpoint for duration of clinical benefit that also reflects patient tolerance and compliance, in addition to its appropriateness to support an OBA.^{22,23} Survival curves for OS and TTNT-D and corresponding 95% confidence intervals (CI) were estimated using the Kaplan-Meier method, accounting for right-censoring. All study analyses were conducted using R Studio, Version 2023.²⁴

To replicate the circumstances of data requirements for an OBA, a series of retrospective analyses were performed on a quarterly basis until data cut-off on June 25, 2024. Each quarterly analysis involved re-assessment of the refreshed EMR and PIN data for relevant updates on treatment patterns (e.g., receipt of subsequent lines of therapy) and survival outcomes.

Steering Committee for OBA Operationalization

A steering committee comprised of 1 clinician (medical oncologist), 1 administrator (oncology division head) and 1 oncology leader (cancer center director), was established to provide input on a quarterly basis on processes related to the data curation, analyses, and interpretation of outputs, while also offering insights into their relevance for guiding decision-making on clinical care and provincial funding. The industry sponsor was also an observer and silent participant in the steering committee and did not provide any input into funding decisions or how the study findings will be used. Given one of the study's aims was to assess the feasibility of the data infrastructure to support future OBAs, the priority of the steering committee was to advise on aspects of the work that were needed for OBAs to be operationalized. The steering committee met regularly to review each of the reports generated from the aforementioned quarterly analyses and made recommendations on 1) additional data elements that should be collected; 2) extra analyses that should be performed or adjusted; and 3) interpretation of the findings and ways that outcomes can be used by potential stakeholders who are involved in the OBA process.

Results

Patient Baseline Characteristics

A total of 68 patients diagnosed with ES-SCLC were identified, with 63 (92.6%) patients who received first-line (1L) durvalumab (Fig. 1). Among those treated with first-line durvalumab, there was a similar proportion of males (49.2%) and females (50.8%) (Table 1). At the time of diagnosis, 50.0% of patients

were current smokers, and 47 (74.6%) patients had metastatic disease, 80.9% of whom had thoracic lymphatic involvement. At treatment initiation, the median age was 67 (range 55–87) years and more than 65.5% had an ECOG performance status of ≤ 1 . Most patients (81.0%) received treatment at an urban cancer center. 61 (96.8%) patients discontinued durvalumab during the study period and 2 (3.2%) patients continued receiving durvalumab at the time of data cut-off.

Table 1
Baseline demographic and clinical characteristics of patients
with extensive-stage small-cell lung cancer who initiated first-
line durvalumab

Characteristic	N = 63
Age at treatment initiation, years	
Mean $\pm$ SD	68 $\pm$ 7
Median (IQR)	67 (63, 73)
Sex	
Female	32 (50.8%)
Male	31 (49.2%)
Weight at initial diagnosis, kg	
Mean $\pm$ SD	76 $\pm$ 21
Median (IQR)	71 (62, 89)
<60 kg	13 (21.7%)
$\geq$ 60 kg	47 (78.3%)
Missing	3
Smoking status at initial diagnosis	
Current Smoker	31 (50.0%)
Former Smoker	31 (50.0%)
Missing	1
Centre type	
Urban	51 (81.0%)
Sub-Urban	12 (19.0%)
Stage at initial diagnosis	
Extensive Stage	Suppressed
Limited Stage	< 10
ECOG PS at initial diagnosis	
0	< 10
1	38 (65.5%)
2	13 (22.4%)

Characteristic	N = 63
3	< 10
Missing	5
Any metastasis at initial diagnosis	
Yes	47 (74.6%)
Site of metastasis at initial diagnosis* (n = 47)	
Thoracic lymphatic	38 (80.9%)
Bone	11 (23.4%)
Liver	19 (40.4%)
Lung	12 (25.5%)
Abdominal lymphatic	< 10
Adrenal	< 10
Brain	< 10

SD, standard deviation; IQR, interquartile range; ECOG PS, Eastern Cooperative Oncology Group Performance Status

*Patients may have multiple sites of metastatic disease

Treatment Patterns and Outcomes

The majority of patients (57.1%) received radiation therapy at some point throughout the course of the disease, with the brain (52.8%) and thorax (47.2%) being the most common sites irradiated (Table 2). In the 1L setting, 46 (73.0%) patients received carboplatin, etoposide, and durvalumab, while the remaining patients (27.0%) received cisplatin, etoposide, and durvalumab. Of the 61 patients who discontinued 1L treatment, median duration of 1L treatment was 5.5 (range 3.3–8.5) months with the most common reason for 1L treatment discontinuation being disease progression (59.0%). 29 (47.5%) patients initiated the 2L treatment regimen; the majority (55.2%) received carboplatin and etoposide (Table 2). Additionally, 20 patients (31.7%) received two or more lines of platinum-based therapy.

The median OS of patients receiving 1L durvalumab therapy was 11.3 months (95% CI: 8.8 – 14.6) (Fig. 2A). 1-year and 2-year OS rates were 46% (95% CI: 35%-60%) and 21% (95% CI: 13%-33%), respectively. Median TTNT-D was 8.2 months (95% CI: 6.1 – 9.3) (Fig. 2B). 1-year and 2-year TTNT-D rates were 24% (95% CI: 15%-37%) and 8% (95% CI: 3%-18%), respectively. Median follow-up time from treatment initiation was 11.3 (range 0.4–33.0) months.

Table 2
Treatment patterns of patients with extensive-stage small-cell lung cancer who initiated first-line durvalumab

Characteristic	N = 63
Any radiation therapy received	36 (57.1%)
Site/type of radiation (n = 36)	
Brain	19 (52.8%)
Thoracic	17 (47.2%)
Skeletal	< 10
Prophylactic cranial irradiation	< 10
Time from ES diagnosis to 1L treatment, mo	
Mean ± SD	1.6 ± 1.4
Median (IQR)	1.4 (1.1, 1.6)
Missing	12
1L regimen	
Durvalumab + carboplatin + etoposide	46 (73.0%)
Durvalumab + cisplatin + etoposide	17 (27.0%)
1L treatment duration, mo (n = 61)	
Mean ± SD	6.5 ± 4.9
Median (IQR)	5.5 (3.3, 8.5)
1L dose reduction	< 10
Reason for 1L treatment discontinuation (n = 61)	
Progression	36 (59.0%)
Toxicity/death	Suppressed
Other	< 10
2L treatment received (n = 61)	29 (46.0%)
Time to 2L treatment, mo (n = 29)	
Mean ± SD	1.5 ± 2.6
Median (IQR)	0.4 (0.2, 1.1)
2L regimen (n = 29)	

Characteristic	N = 63
Carboplatin + etoposide	16 (55.2%)
Cyclophosphamide + doxorubicin + vincristine	< 10
Irinotecan + carboplatin	< 10
Irinotecan	< 10
Topotecan	< 10
Cisplatin + etoposide	< 10
Durvalumab + carboplatin + etoposide	< 10
Etoposide	< 10
2 + lines of platinum-based therapy	20 (31.7%)
Follow-up time from 1L initiation, mo	
Mean ± SD	13.4 ± 8.9
Median (IQR)	11.3 (5.6, 19.1)

ES, extensive stage; 1L, first line; SD, standard deviation; IQR, interquartile range

Data Feasibility for an OBA

Quarterly reports were successfully generated throughout the entire study period. For each report, clinical outcomes such as OS and TTNT-D were ascertained, analyzed, and described. Attrition due to death and treatment discontinuation were also summarized. The steering committee was satisfied that the quarterly reports offered a comprehensive, longitudinal assessment of outcomes for ES-SCLC patients treated with first-line durvalumab. The committee agreed that presenting similar information for a novel drug in this format could be useful for clinical and funding-related decision making.

Discussion

We conducted a population-based cohort study of ES-SCLC patients treated with 1L durvalumab in Alberta, Canada. To our knowledge, this is the first real-world study to evaluate the use of durvalumab in ES-SCLC in a Canadian setting, thus helping address an existing knowledge gap in the treatment of this disease. We found that, of 68 patients diagnosed with ES-SCLC between July 2021 and July 2022, 63 patients received 1L durvalumab. With nearly all patients discontinuing 1L durvalumab by the data cut-off date, median 1L treatment duration was 5.5 (range 0.1–26.6) months. Median OS was 11.3 months (95% CI: 8.8–14.6 months) while median TTNT-D was 8.2 months (95% CI: 6.1–9.3 months).

At baseline, the characteristics of our cohort were comparable to those of the durvalumab plus platinum-etoposide arm from the CASPIAN clinical trial with respect to age distribution, smoking status, and rate of liver metastasis.¹³ The proportion of patients treated with cisplatin versus carboplatin was also similar between our study and CASPIAN.^{11,12} Additionally, our median OS of 11.3 months (95% CI: 8.8 – 14.6 months) was similar to the median OS of 12.9 months (95% CI: 11.3–14.7 months) in the durvalumab plus platinum-etoposide arm of the CASPIAN trial.²⁵ This difference was also reflected in the 2-year OS rates of 21% (95% CI: 13%-33%) versus 23% (95% CI: 18%-28%). This degree of similarity in OS outcomes supports the clinical benefit of 1L durvalumab in ES-SCLC in the real-world, although discrepancies may be explained by the specific inclusion and exclusion criteria for participants in CASPIAN. It was reported that only 14.7% of participants met the eligibility criteria for CASPIAN, with participants excluded if they had a performance status of 2 or greater, or if they presented with brain metastases at diagnosis.²⁶ In contrast, our study included all ES-SCLC patients treated with 1L durvalumab, regardless of performance status and extent of metastasis, and was by design more representative of the real-world clinical setting.

A recent cohort study published by Misawa et al. evaluated ES-SCLC patients who received 1L durvalumab plus platinum-etoposide at a Japanese institution.²⁷ Among the 40 patients included, median age was 68 years and 63% had a performance status of ≤ 1 . With a median follow-up time of 13.0 months (95% CI: 8.0-22.2 months), median OS was 25.4 months (95% CI: 4.6–46.2 months). A possible reason for the longer median OS in Misawa et al. is that significantly more patients (77.8%) received subsequent treatment following 1L discontinuation, compared to the present cohort (46.0%). Additionally, we note that the smaller sample size and short follow-up time in the Misawa et al. study may have contributed to the high uncertainty and influenced the accuracy of OS estimates. In another real-world analysis, Qu et al. studied PD-L1 inhibitor use for the 1L treatment of ES-SCLC at two Chinese centers.²⁸ The 109 patients who received durvalumab plus platinum-etoposide had a median age of 63 years (range 43–72 years). 87.2% had a performance status of ≤ 1 . The median OS was also longer than the present study at 19.0 months. This discrepancy may have been driven by younger age, better performance status, and a higher rate of subsequent line therapy, including 27.5% who received immune checkpoint inhibitors after durvalumab discontinuation.

The availability of real-world data in Alberta to support an OBA has previously been addressed.²² The present study served to confirm the feasibility of collecting, analyzing, and reporting real-world data. With available administrative data and targeted EMR review, we were able to conduct the study that conforms with previously presented oncology OBA processes for OS and TTNT.^{22,29} Our index period of 13 months allowed for a sufficient number of patients to start on therapy, and subsequent patient monitoring and data collection occurred over an extended period of 20 months. Altogether, this study took place within the estimated timeframe of 2.5-3 years. Furthermore, each quarterly analysis included real-time data collection, necessary data cleaning, and semi-automated reporting structures using statistical software such as R. Data privacy legislation within the province of Alberta was adhered to throughout. Importantly, the steering committee perceived the curated data to be robust and clinically informative without

significant need for data cleaning. Data missingness was also negligible, underscoring the data and administrative feasibility of an OBA. To this end, insights from this current exercise may help to inform manufacturers, payers, health technology assessment agencies, and other stakeholders involved in new therapies and OBAs in oncology.

Strengths and Limitations

This study has several notable strengths. First, we employed provincial data sources that allowed analysis of patient and treatment characteristics that are representative of the population with ES-SCLC in Alberta. Our data sources together demonstrated a high degree of completeness for the variables of interest. Importantly, the present study is the first to assess the real-world use of 1L durvalumab in ES-SCLC in Canada, and its findings may be generalizable to other provinces.

Our study also has limitations inherent to its design. Owing to the study scope, data on adverse events and certain patient demographics, such as ethnicity, were not available for assessment. While TTNT-D accounted for patient tolerance, future real-world studies better characterizing the safety profile of durvalumab are warranted. Although many of our data elements are routinely recorded in the EMR in the clinical environment, there exists the potential for variability in how information was recorded by different clinicians.

Conclusion

In patients with ES-SCLC receiving 1L durvalumab plus platinum-etoposide in a real-world Canadian setting, we found that OS outcomes were similar to those observed in the CASPIAN trial. Durvalumab continues to play a meaningful role in the management of ES-SCLC in clinical practice. We additionally found it feasible to collect, analyze, and report real-world data required to operationalize an OBA in oncology, using existing infrastructure in Alberta, Canada.

Declarations

Ethics approval and consent to participate

This study was approved by the Health Research Ethics Board of Alberta (HREBA-CC-23-0125). The HREBA-CC provides ethical review and oversight for all cancer and cancer-related research involving humans (adult and pediatric), their information and/or samples. It ensures that at a minimum the study will be conducted in accordance with:

- ICH GCP Guidelines
- Part C Division 5 of the Food and Drugs Act and applicable Regulations of Health Canada, and
- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

This was a retrospective study that conducted secondary analysis of previously collected health data, with no direct patient contact. As such, the Institutional Review Board considered this study to be minimal risk and thus the requirement for informed consent was waived following review board approval.

Availability of data and materials

Individual-level data are not publicly available due to Canadian data privacy laws governing personal health information.

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Competing interests

P.Q.D. and W.Y.C. received research funding from AstraZeneca. Authors R.Q., Y.K., I.Q., F.Y., and A.S., are employees of AstraZeneca.

Author contributions

All authors contributed equally.

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Figures

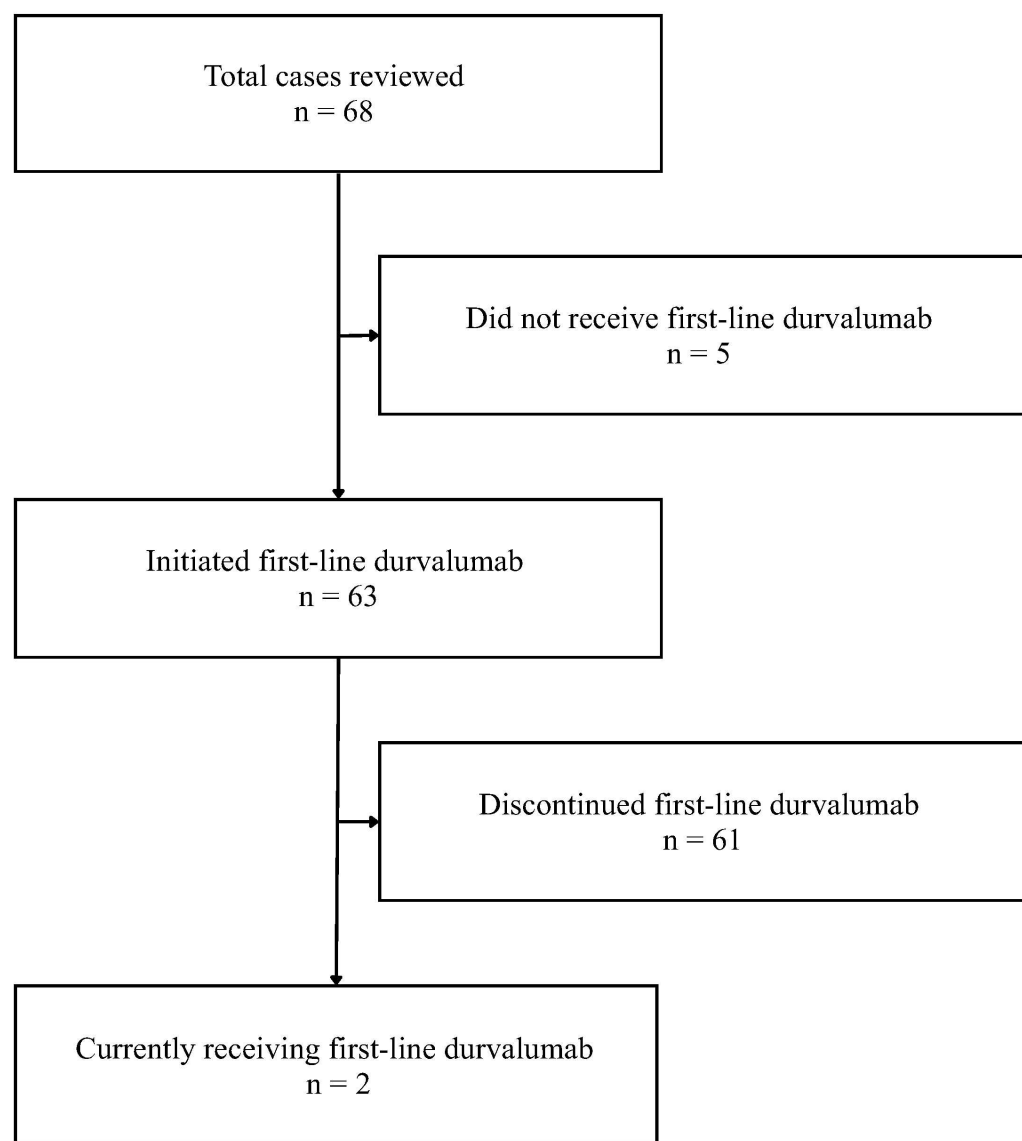
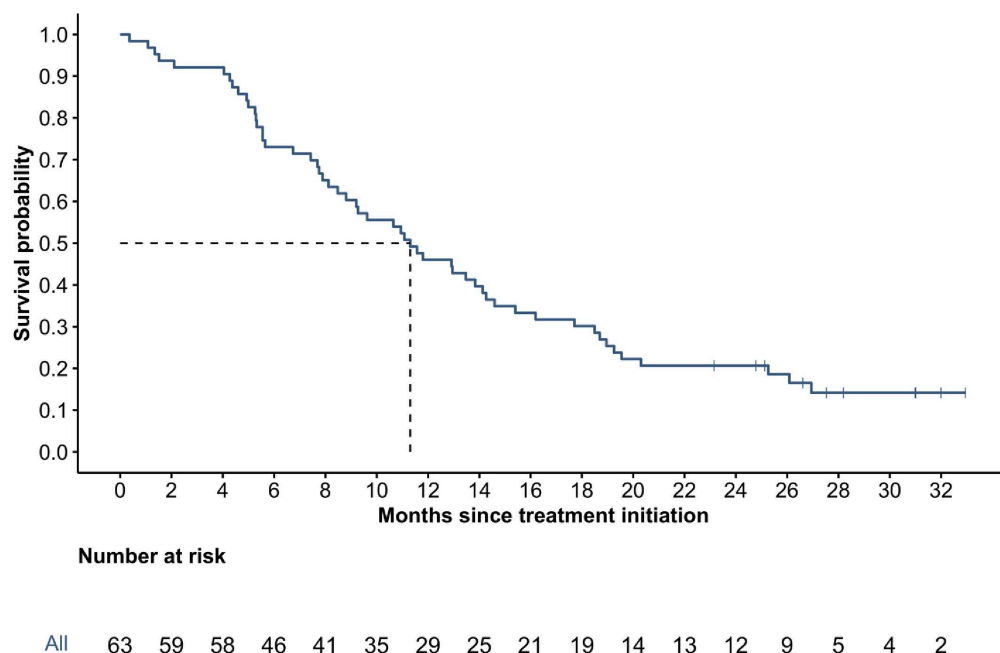


Figure 1

Flow chart of patients diagnosed with extensive stage small cell lung cancer and who received durvalumab in Alberta, Canada between July 1, 2021 and July 31, 2022.

A Overall Survival



B Time to Next Treatment or Death

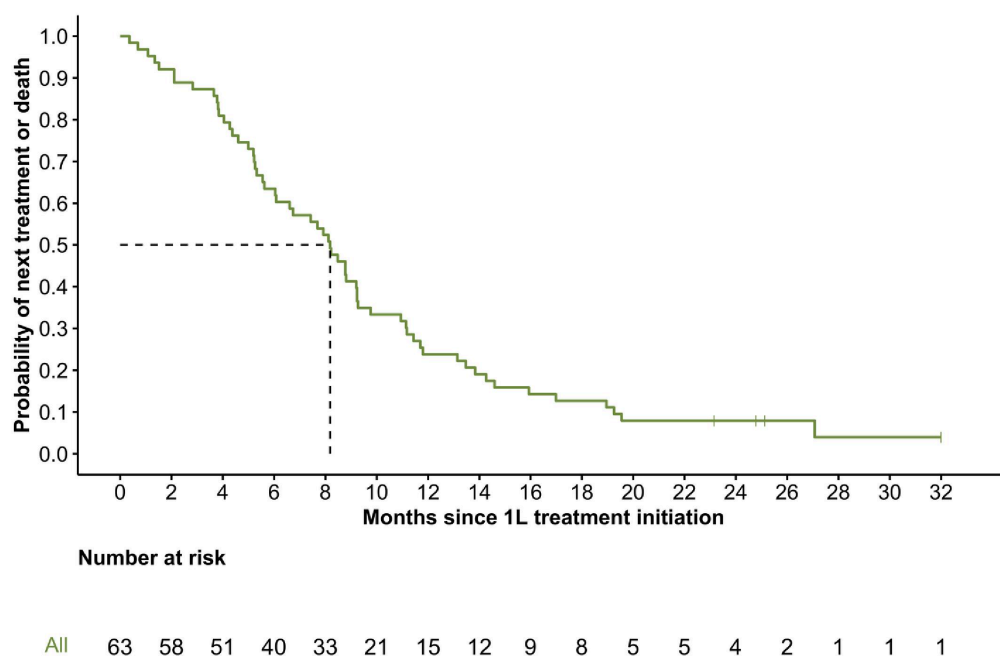


Figure 2

Kaplan-Meier curves for overall survival (A) and time to next treatment or death (B) since first-line treatment initiation for patients with ES-SCLC who received first-line durvalumab.