# ASSESSMENT OF HOSPITALIZATIONS AND CYTOPENIA EVENTS AMONG PATIENTS WITH EXTENSIVE-STAGE SMALL CELL LUNG CANCER (ES-SCLC) RECEIVING CHEMOTHERAPY WITH TRILACICLIB

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## BACKGROUND

- Chemotherapy is the standard treatment for patients with ES-SCLC and it is known to cause myelosuppression, a condition where bone marrow activity is decreased[1,2]
  - Decreases in bone marrow activity can lead to a range of cytopenias, including anemia, neutropenia, and/or thrombocytopenia, which adds a substantial burden to patients and the healthcare system[1,2]
- Trilaciclib, an intravenous therapy, was approved by the Food and Drug Administration to reduce the incidence of chemotherapy-induced myelosuppression (CIM) among adults with ES-SCLC in Feb 2021,[3] and was added to the NCCN Guidelines for Small Cell Lung Cancer and for Hematopoietic Growth Factors[4,5] as a prophylactic option to manage CIM when administrated prior to chemotherapy in patients with ES-SCLC
- Given the relative recency in approval, there is a dearth of real-world evidence assessing outcomes associated with trilaciclib treatment among patients diagnosed with ES-SCLC

## OBJECTIVES

- To evaluate real-world rates of hospitalizations and cytopenia-related outcomes in patients with ES-SCLC treated with chemotherapy and supportive care with trilaciclib, compared to patients who did not receive trilaciclib

## METHODS

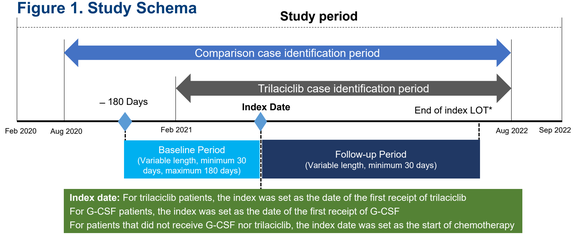
### Data Source

- This retrospective study used data from the 100% Medicare Fee-for-Service and the Inovalon MORE[2] closed claims databases

### Study Population

- Adult patients who met clinician-guided diagnostic criteria for ES-SCLC, as evidenced by the receipt of platinum/etoposide- or topotecan-containing chemotherapy regimens, and were continuously enrolled ≥ 30 days preceding and following chemotherapy initiation were included
- Patients were categorized into 2 study cohorts:
  - Trilaciclib cohort: patients who received trilaciclib at chemotherapy initiation and did not receive prophylactic granulocyte-colony stimulating factor (G-CSF)
  - No trilaciclib cohort: patients who did not receive trilaciclib during chemotherapy
    - No trilaciclib cohort was further categorized into two exploratory sub-groups:
      1) Received prophylactic G-CSF (defined as receiving G-CSF within 3 days of chemotherapy initiation)
      2) Did not receive prophylactic G-CSF

### Figure 1. Study Schema




### Outcomes and Analysis

- All-cause and cytopenia-related hospitalizations (as evidenced by a diagnosis of anemia, neutropenia, febrile neutropenia, or thrombocytopenia) were assessed
  - The rate of hospitalizations per patient per month (PPPM) during the follow-up period, and the proportion of patients hospitalized during the 90-day post-index period were reported
- The proportion of patients experiencing cytopenia during the 90-day post-index period and the PPPM rates of supportive care interventions during follow-up were reported
  - Supportive care interventions included blood transfusions, platelet transfusions, erythropoiesis-stimulating agents (ESAs), ion infusions, IV hydration, G-CSF use and IV antibiotics
- Chi-square tests (for categorial outcomes) and student's t-tests (for continuous variable) were used to assess statistically significant differences between groups
- An exploratory analysis of overall survival was conducted among patients within the Medicare Fee-for-Service database, which houses mortality data validated by CMS, and was assessed using Kaplan Meier analyses. Log-rank tests were used to examine statistically significant differences between cohorts
- Data use agreements prohibit reporting of categorical outcomes of < 11 patients
  - For categorial outcomes containing < 11 patients, relative risk was reported

## RESULTS

### Demographic and Clinical Characteristics

- 132 patients who received trilaciclib (mean age 70.6, male 50.8%) and 11,940 patients who did not receive trilaciclib (age 68.2, male 48.3%) were included for the study (**Table 1**)

### Hospitalization

- Trilaciclib patients had a lower rate of all-cause PPPM hospitalizations during follow-up (0.14±0.25 vs. 0.19±0.27; $p<0.01$; **Figure 2**) and were less likely to be hospitalized within 90 days post-chemotherapy initiation (21.2% vs. 32.1%; $p<0.01$; **Figure 3**), compared to the no trilaciclib patients

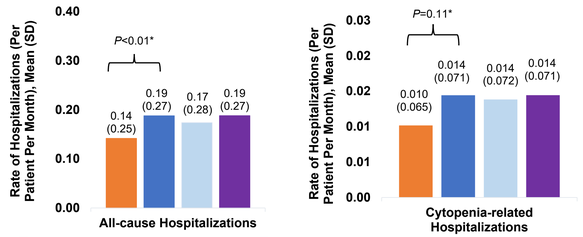
### Cytopenia-related Outcomes

- Compared to the no trilaciclib patients, trilaciclib patients had a statistically significantly lower risk of febrile neutropenia (relative risk 15.5%, $p=0.03$) and numerically lower risk of anemia, neutropenia and thrombocytopenia in the 90-day post-index period (**Table 2**)

### Survival Outcomes

- Patients receiving trilaciclib had a numerically higher survival at 6 months (84.1%) compared to the no trilaciclib group (72.3%), although the difference was not statistically significant ($p=0.12$)
- Trilaciclib patients had a survival hazard ratio of 0.63 (95% CI: 0.35-1.14, $p=0.13$) compared to the no trilaciclib group (**Figure 4**)

### Figure 2. Rate of Hospitalizations Following Chemotherapy




*P-value compares Trilaciclib cohort vs. the No Trilaciclib cohort
**The No Trilaciclib with Prophylactic G-CSF cohort and No Trilaciclib and No Prophylactic G-CSF cohorts are sub-groups of the No Trilaciclib cohort

### Table 1. Patient Characteristics

| | Trilaciclib with No Prophylactic G-CSF N = 132 | | No Trilaciclib N =11,940 | | No Trilaciclib with Prophylactic G-CSF[a] N = 184[a] | | No Trilaciclib and No Prophylactic G-CSF[a] N = 11,756[a] | | *P*-value[b] |
|---|---|---|---|---|---|---|---|---|---|
| **Age (Mean, SD)** | 70.6 | 8.0 | 68.2 | 9.1 | 66.6 | 10.4 | 68.2 | 10.4 | **<0.01** |
| **Age (N, %)** | | | | | | | | | **0.01** |
| 18-64 | 27 | 20.5% | 3,715 | 31.1% | 79 | 42.9% | 3,636 | 30.9% | |
| 65+ | 105 | 79.5% | 8,225 | 68.9% | 105 | 57.1% | 8,120 | 69.1% | |
| **Sex (N, %)** | | | | | | | | | 0.57 |
| Male | 67 | 50.8% | 5,766 | 48.3% | 81 | 44.0% | 5,685 | 48.4% | |
| Female | 65 | 49.2% | 6,174 | 51.7% | 103 | 56.0% | 6,071 | 51.6% | |
| **Elixhauser Comorbidity Index (Mean, SD)** | 29.7 | 9.9 | 28.6 | 10.4 | 28.6 | 10.6 | 28.6 | 10.4 | 0.17 |
| **Race/Ethnicity (N, %)** | | | | | | | | | 0.37 |
| Non-Hispanic White | 94 | 71.2% | 8,603 | 72.1% | 113 | 61.4% | 8,490 | 72.2% | |
| Hispanic or Latino or African American | 12 | 9.1% | 928 | 7.8% | 24 | 13.0% | 904 | 7.7% | |
| Other/Unknown | 26 | 19.7% | 2,409 | 20.2% | 47 | 25.5% | 2,362 | 20.1% | |
| **Payer (N, %)** | | | | | | | | | **0.02** |
| Commercial | 17 | 12.9% | 2,029 | 17.0% | 34 | 18.5% | 1,995 | 17.0% | |
| Medicare Fee-for-Service | 100 | 75.8% | 7,514 | 62.9% | 80 | 43.5% | 7,434 | 63.2% | |
| Managed Medicaid or Medicare Advantage | 15 | 11.4% | 2,397 | 20.1% | 70 | 38.0% | 2,327 | 19.8% | |
| **Index Year (N, %)** | | | | | | | | | **<0.01** |
| 2020 | 0 | 0.0% | 3,319 | 27.8% | 46 | 25.0% | 3,273 | 27.8% | |
| 2021 | 34 | 25.8% | 5,991 | 50.2% | 99 | 53.8% | 5,892 | 50.1% | |
| 2022 | 98 | 74.2% | 2,630 | 22.0% | 39 | 21.2% | 2,591 | 22.0% | |
| **Duration of Follow-up (Months)** | | | | | | | | | |
| Mean, SD | 4.1 | 2.1 | 8.2 | 5.7 | 8.1 | 5.4 | 8.2 | 5.7 | **<0.01** |
| Median | 3.6 | | 6.7 | | 6.7 | | 6.7 | | |

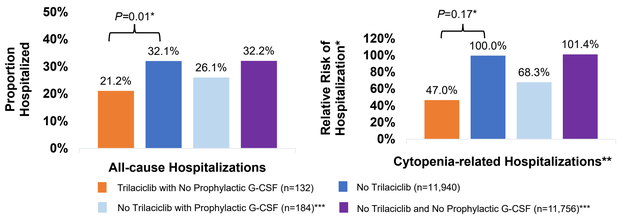
[a]The No Trilaciclib with Prophylactic G-CSF cohort and No Trilaciclib and No Prophylactic G-CSF cohorts are sub-groups of the No Trilaciclib cohort
[b]P-value compares the Trilaciclib cohort with the No Trilaciclib cohort

### Table 2. Cytopenia and Supportive Care Interventions Following Chemotherapy

| | Trilaciclib with No Prophylactic G-CSF N = 132 | | No Trilaciclib N =11,940 | | No Trilaciclib with Prophylactic G-CSF N = 184[a] | | No Trilaciclib and No Prophylactic G-CSF N = 11,756[a] | | *P*-value[b] |
|---|---|---|---|---|---|---|---|---|---|
| **Number and proportion of patients experiencing cytopenia within 90 days following chemotherapy** | | | | | | | | | |
| Anemia (N,%) | 57 | 43.2% | 6,095 | 51.1% | 102 | 55.4% | 5,993 | 51.0% | 0.07 |
| Neutropenia (N,%) | 12 | 9.1% | 1,652 | 13.8% | 28 | 15.2% | 1,624 | 13.8% | 0.12 |
| Thrombocytopenia (Relative Risk)* | 65.7% | | Reference | | 141.4% | | 99.4% | | 0.20 |
| Febrile neutropenia (Relative Risk)* | 15.5% | | Reference | | 77.8% | | 100.3% | | **0.03** |
| **Rates of supportive care interventions per patient per month (Mean, SD)** | | | | | | | | | |
| Blood Transfusion | 0.07 | 0.20 | 0.10 | 0.26 | 0.14 | 0.36 | 0.10 | 0.26 | **<0.01** |
| Platelet Transfusion | 0.00 | 0.03 | 0.01 | 0.08 | 0.01 | 0.13 | 0.01 | 0.08 | 0.22 |
| Erythropoiesis-Stimulating Agents | 0.07 | 0.33 | 0.05 | 0.33 | 0.15 | 0.60 | 0.05 | 0.32 | 0.87 |
| Iron Infusions | 0.00 | 0.04 | 0.01 | 0.12 | 0.01 | 0.08 | 0.01 | 0.12 | 0.64 |
| G-CSF | 0.05 | 0.26 | 0.02 | 0.21 | 1.03 | 1.34 | 0.00 | 0.05 | **<0.01** |
| IV Antibiotics | 0.10 | 0.22 | 0.06 | 0.24 | 0.08 | 0.26 | 0.06 | 0.24 | **0.04** |
| IV Hydration | 0.46 | 1.12 | 0.35 | 0.81 | 0.43 | 0.78 | 0.34 | 0.81 | 0.33 |

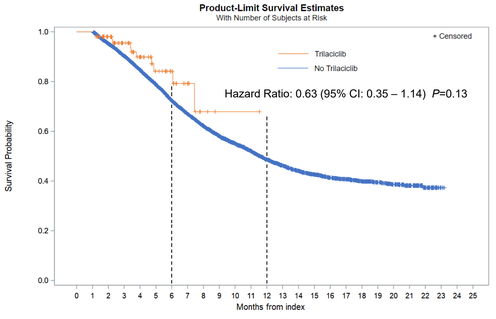
*Due to low sample sizes for select outcomes (N <11), relative risk was reported instead of number and proportion of patients with these outcomes
[a]The No trilaciclib with Prophylactic G-CSF cohort and No trilaciclib and No Prophylactic G-CSF cohorts are sub-groups of the No Trilaciclib cohort
[b]P-value compares the Trilaciclib cohort with the No Trilaciclib cohort

### Figure 3. Hospitalizations within 90 days Following Chemotherapy




*P-value compares Trilaciclib cohort vs. the No Trilaciclib cohort
**Because <11 patients presented a cytopenia-related hospitalization, relative risk was reported. The reference group is the No Trilaciclib cohort
***The No Trilaciclib with Prophylactic G-CSF cohort and No Trilaciclib and No Prophylactic G-CSF cohorts are sub-groups of the No Trilaciclib cohort

### Figure 4. Kaplan Meier Plot of Survival




## LIMITATIONS

- Myelosuppression was defined using ICD-10-CM diagnosis codes and did not incorporate lab data, which may have led to under-reporting of myelosuppression
- There may be systematic differences between the study cohorts on variables that cannot be measured in claims, which may account for differences found in study outcomes
- Analyses incorporating a longer follow-up period is recommended to confirm findings on survival

## CONCLUSIONS

- This real-world study demonstrated that trilaciclib administered prior to chemotherapy was associated with lower rates of hospitalizations and cytopenia events, along with an early trend toward improved survival
- Trilaciclib may be an effective intervention to prevent adverse events associated with treatment for ES-SCLC
- A follow-up study may further examine the difference in hospitalizations among trilaciclib patients versus patients who did not receive trilaciclib but did receive prophylactic G-CSF

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**DISCLOSURES**
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