



Trilaciclib Use and Chemotherapy-Induced Myelosuppression Among Patients with ES-SCLC in US Community Oncology Settings

Jerome Goldschmidt, MD¹, Alisha Monnette, PhD, MPH², Divea Venkatesetty, MPH², Ping Shi, PhD², Lorena Lopez-Gonzalez, PhD³, Huan Huang, PhD³, Paul R Conkling, MD²

¹ Blue Ridge Cancer Centers / US Oncology Research, Blacksburg, VA, USA

² Ontada, Woodlands, TX, USA

³ G1 Therapeutics[®], Inc., Research Triangle Park, NC, USA

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Corresponding author: Jerome Goldschmidt, MD, Blue Ridge Cancer Care, 2600 Research Center Dr., Suite A, Blacksburg, VA 24060, USA,
Email: Jerome.Goldschmidt@USONCOLOGY.COM

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Chemotherapy-induced myelosuppression is a major dose limiting toxicity of chemotherapy for ES-SCLC¹⁻⁴

Myelosuppressive hematologic adverse events (HAEs), resulting from cytotoxic damage to hematopoietic stem and progenitor cells in the bone marrow, are common complications of chemotherapy among patients with cancer^{1,4-6}

Myelosuppression commonly manifests as:

	Traditional Lineage Specific Management Strategies
Neutropenia (fewer neutrophils) ⁷	<ul style="list-style-type: none">▪ G-CSF (supportive care)▪ Chemotherapy dose reduction or delay
Anemia (fewer RBCs) ⁸	<ul style="list-style-type: none">▪ RBC transfusion (supportive care)▪ Chemotherapy dose reduction or delay▪ ESA (supportive care)
Thrombocytopenia (fewer platelets) ⁴	<ul style="list-style-type: none">▪ Platelet transfusion (supportive care)▪ Chemotherapy dose reduction or delay

ESA, erythropoiesis-stimulating agent; ES-SCLC, extensive-stage small cell lung cancer; G-CSF, granulocyte colony stimulating factor; HAE, hematologic adverse event; RBC, red blood cell.

1. Kurtin S. *J Adv Pract Oncol*. 2012;3:209–24. 2. Aapro M, et al; ESMO Guidelines Committee. *Ann Oncol*. 2018;29(suppl 4):iv96–110. 3. Crawford J, et al. *Support Care Cancer*. 2020;28:925–32. 4. Kuter DJ. *Oncology (Williston Park)*. 2015;29:282–94. 5. Barreto JN, et al. *J Pharm Pract*. 2014;27:440–6. 6. Lyman GH. *Clin Cornerstone*. 2006;8 suppl 5:S12–8. 7. Hashiguchi Y, et al. *Anticancer Drugs*. 2015;26:1054–60. 8. Bryer E, Henry D. *Int J Clin Transfus Med*. 2018;21–31.

A previous RWD study assessed the burden of chemotherapy-induced myelosuppression for ES-SCLC patients treated at community oncology practices before trilaciclib FDA approval



- The US Oncology Network includes 1,300 affiliated physicians operating in over 480 sites of care across states, approximately 1.2 million US cancer patients are treated annually in The US Oncology Network.¹ The iKnowMed EHR^a is utilized across all US Oncology Network clinics.
- Non-Network practices are independent community-based oncology clinics that have a partnership with Ontada. Approximately 80 non-Network clinics have adopted the iKnowMed EHR participate in real-world research activities with Ontada
- iKnowMed EHR is utilized by both Network and Non-Network

^a iKnowMed EHR data were supplemented with vital status provided by the US Social Security Administration's Limited Access Death Master File.

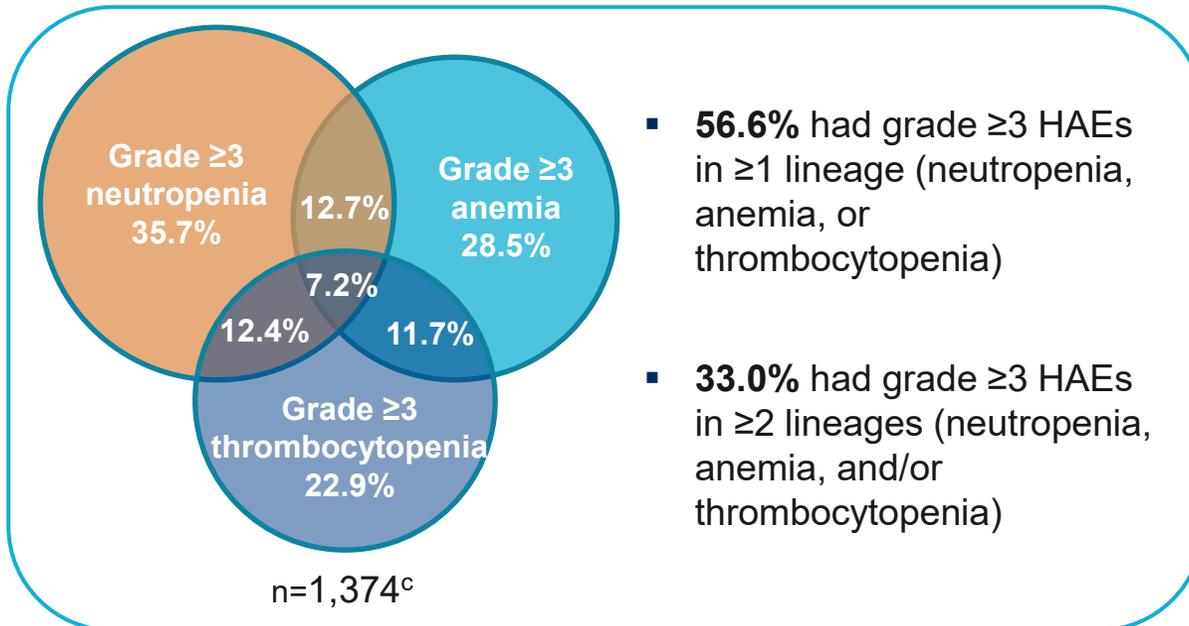
EHR, electronic health record. ES-SCLC, extensive-stage small cell lung cancer ; RWD, real world data.

1.The US Oncology Network. 2022; <https://www.usoncology.com/our-company>. Accessed June 21, 2022.

Previous study of The US Oncology Network^{1,a} clinics reported more than half of the chemotherapy treated ES-SCLC patients experienced grade ≥ 3 HAEs in at least one lineage

>99% of patients started chemotherapy as first line treatment and 95% received platinum/etoposide-containing regimen with or without IO

Prevalence of grade ≥ 3 HAEs after chemotherapy initiation



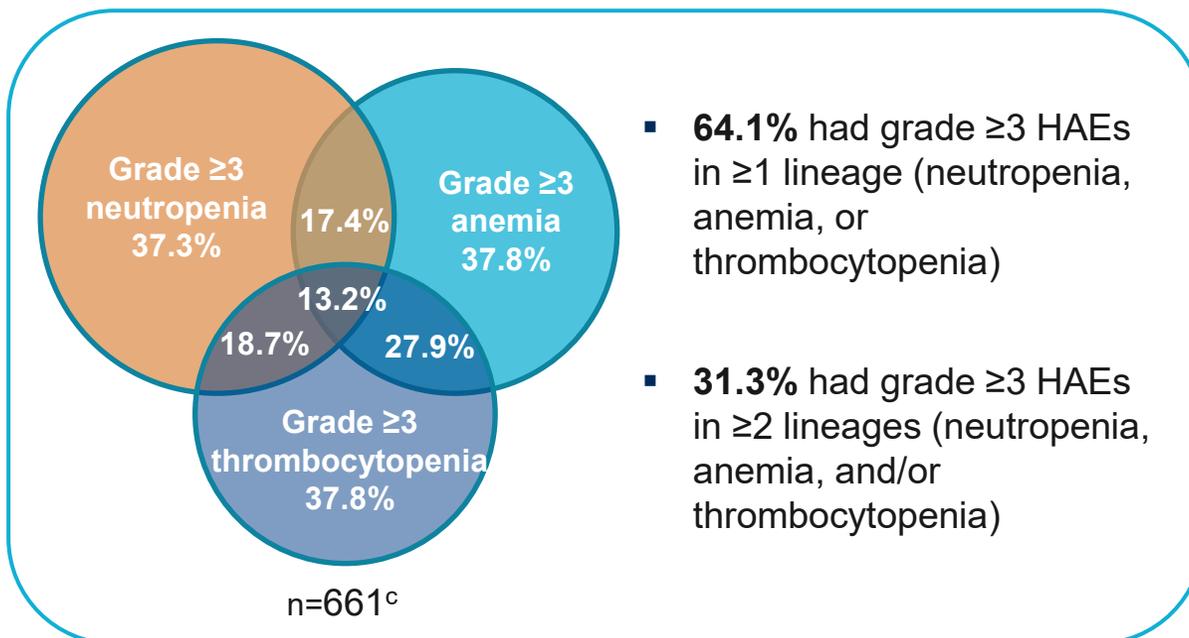
	Network (n=1,574)
Supportive care utilization	
G-CSF	71.5%
IV hydration	59.0%
RBC transfusion eligible ^{d,e}	21.3%
Platelet transfusion eligible ^{e,f}	1.9%
Treatment patterns	
Dose decrease of index treatment	38.1%
Index treatment delay: 14-30 days	83.0%
Index treatment delay: 31-60 days	18.5%

^a Retrospective observational study of patients with ES-SCLC who were treated with chemotherapy using iKnowMed electronic health record structured data from The US Oncology Network. Patients were on average 67.8 years old, 52.4% were female, and 82.2% were White. Average follow-up after chemotherapy initiation was 8.9 months. ^b Before chemotherapy initiation, rates of grade 3 anemia=1.8%, grade 3 neutropenia=4.3%, grade 4 neutropenia=2.1%, grade 3 thrombocytopenia=2.6%, grade 4 thrombocytopenia=1.3%. ^c Percentages were calculated using the number of patients with laboratory value(s) for the corresponding endpoint(s) as the denominator. ^d Eligibility for RBC transfusion based on hemoglobin <8 g/dL. ^e Transfusion administration was not available in the structured EHR data. ^f Eligibility for platelet transfusion based on platelets <10,000/ μ L. ES-SCLC, extensive-stage small cell lung cancer; HAE, hematological adverse event; IO, immunotherapy.

Similar rates of myelosuppression after chemotherapy initiation were reported in patients with ES-SCLC treated in Non-Network clinics^{1,a}

>99% of patients started chemotherapy as first line treatment and 96% received platinum/etoposide-containing regimen with or without IO

Prevalence of grade ≥3 HAEs after chemotherapy initiation



	Non-Network (n=959)
Supportive care utilization	
G-CSF	69.6%
IV hydration	49.5%
RBC transfusion eligible ^{d,e}	24.2%
Platelet transfusion eligible ^{e,f}	3.2%
Treatment patterns	
Dose decrease of index treatment	49.2%
Index treatment delay: 14-30 days	82.2%
Index treatment delay: 31-60 days	17.3%

^a Retrospective observational study of patients with ES-SCLC who were treated with chemotherapy using iKnowMed electronic health record structured data from Non-Network clinics. Patients were on average 67.4 years old, 51.0% were female, and 81.0% were White. Average follow-up after chemotherapy initiation was 9.5 months. ^b Before chemotherapy initiation, rates of grade 3 anemia=3.3%, grade 3 neutropenia=4.9%, grade 4 neutropenia=7.5%, grade 3 thrombocytopenia=2.7%, grade 4 thrombocytopenia=2.2%. ^c Percentages were calculated using the number of patients with laboratory value(s) for the corresponding endpoint(s) as the denominator. ^d Eligibility for RBC transfusion based on hemoglobin <8 g/dL. ^e Transfusion administration was not available in the structured EHR data. ^f Eligibility for platelet transfusion based on platelets <10,000/μL. ES-SCLC, extensive-stage small cell lung cancer; HAE, hematological adverse event; IO, immunotherapy.

Another RWD study suggested a trend toward increasing healthcare utilization among SCLC patients with grade ≥ 3 HAEs in more than 1 cell lineage

Myelosuppressive AE category ^{1,a}	Patients, n	Patients with each type of supportive treatment or visit within 12 months after chemotherapy initiation, %				
		G-CSF	RBC transfusion	Platelet transfusion	IP visits ^b	ED visits
No grade ≥ 3 myelosuppressive AEs	132	25	11	0	60.6	26.5
Grade ≥ 3 AE in one lineage only	90	54	37	7	63.3	45.6
Neutropenia only	46	59	11	2	54.3	45.7
Anemia only	33	45	76	12	72.7	42.4
Thrombocytopenia only	11	64	27	9	72.7	54.5
Grade ≥ 3 AEs in two lineages	61	66	77	20	85.2	49.2
Neutropenia and anemia	41	68	80	15	85.4	46.3
Neutropenia and thrombocytopenia	10	70	40	20	80	50
Anemia and thrombocytopenia	10	50	100	40	90	60
Grade ≥ 3 AEs in all three lineages (neutropenia, anemia, and thrombocytopenia)	55	67	85	49	85.5	56.4
Total population	338	47	42	13	69.8	41.7

Retrospective cohort analysis of 338 patients with SCLC who were treated with chemotherapy within an integrated health system (40 oncology clinics associated with community hospitals across 7 states in the US) from January 2016 to December 2019. AE, adverse event; ED, emergency department; ESA, erythropoiesis-stimulating agent; G-CSF, granulocyte colony-stimulating factor; IP, inpatient; RBC, red blood cell ; RWD, real world data; SCLC, small cell lung cancer.

^a Grade 1/2 myelosuppressive AEs were not included in the analysis. Patients reported as having no grade ≥ 3 AEs or grade ≥ 3 AEs in a particular lineage (e.g., neutropenia only) may also have had lower-grade AEs affecting other blood cell lineages. ^b Includes IP and ED to IP visits. ED to IP includes patients who were treated in the ED and then admitted to the same or a different hospital for IP services.

Traditional supportive care treatments in ES-SCLC are suboptimal^{1,2}

- Limitations with traditional treatment strategies for myelosuppression: ^{1,2}
 - Specific to single lineage
 - Administered after the start of chemotherapy when damage to red blood cells, neutrophils, or platelets is underway
 - May be associated with side effects (e.g., bone pain associated with G-CSF)
- Multilineage myelosuppression may lead to greater health care resource utilization of both supportive care interventions, inpatient admissions, and ER visits³
- Unmet need remains for treatment that can minimize side effects by providing multilineage protection from myelosuppression¹ in patients with ES-SCLC

Study objectives



To evaluate real-world outcomes (myelosuppression, supportive care utilization and treatment patterns) in patients with ES-SCLC treated with trilaciclib in the community oncology setting



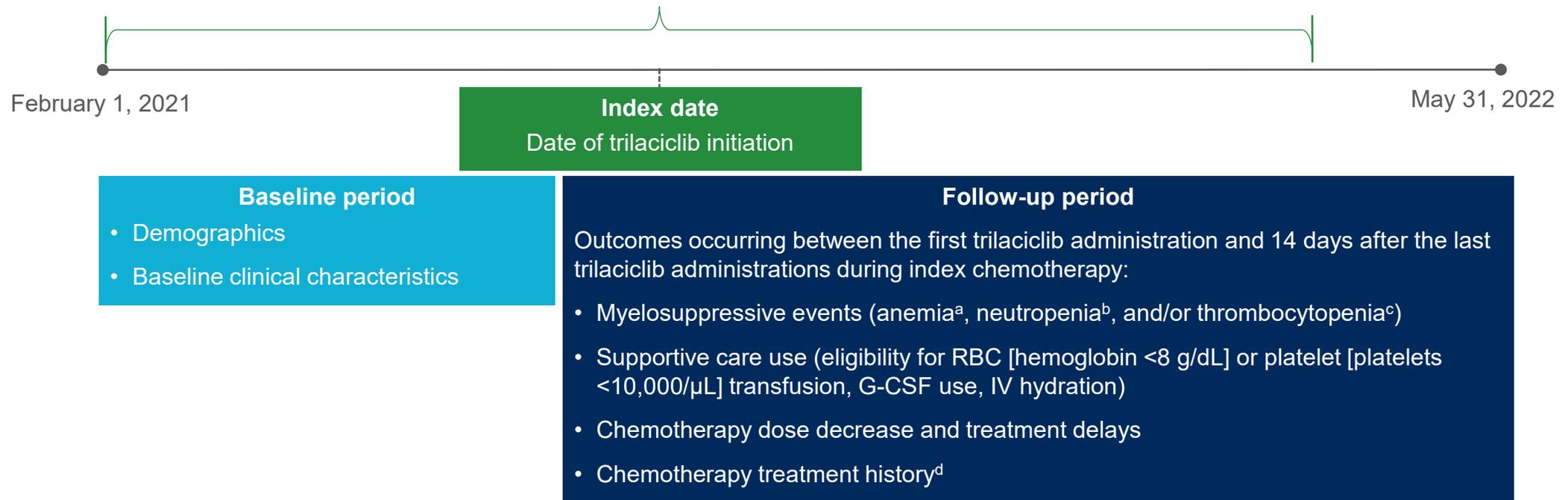
- A first-in-class intervention that provides multilineage bone marrow protection (myeloprotection) among patients with ES-SCLC receiving a platinum/etoposide- or topotecan-containing chemotherapy regimen
- Received FDA approval in February 2021 to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-or topotecan-containing chemotherapy regimen for ES-SCLC¹
- In March 2021, the NCCN Guidelines added trilaciclib as a prophylactic option to manage chemotherapy-induced myelosuppression when administered prior to chemotherapy in patients with ES-SCLC to Guidelines for Small Cell Lung Cancer² and for Hematopoietic Growth Factors³

ES-SCLC, extensive-stage small cell lung cancer; NCCN, National Comprehensive Cancer Network.

1. Cosela® (trilaciclib) for injection [package insert]. Durham, NC: G1 Therapeutics, Inc; 2021. Please see Important Safety Information, full Prescribing Information, and Patient Information for Cosela at <https://www.g1therapeutics.com/cosela/pi/> 2. NCCN. SCLC. NCCN clinical practice guidelines in oncology. Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. 3. NCCN. Hematopoietic growth factors. NCCN clinical practice guidelines in oncology. Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf.

Retrospective observational study design

Adult ES-SCLC patients who initiated trilaciclib during chemotherapy between February 1, 2021–April 30, 2022 were identified
(Patients without evidence of chemotherapy treatment or in clinical trials were excluded)



^a Anemia defined as hemoglobin <8 g/dL (grade 3). ^b Neutropenia defined as ANC of 500–1000/μL (grade 3) or ANC <500/μL (grade 4). ^c Thrombocytopenia defined as platelets of 25,000–50,000/μL (grade) or platelets <25,000/μL (grade 4) ^d chemotherapy treatment sequences captured from date of first trilaciclib administration to last visit date with vital signs, death, or end of the study period.

ANC, absolute neutrophil count; chemotherapy-induced myelosuppression; EHR, electronic medical record; ES-SCLC, extensive-stage small cell lung cancer; G-CSF, granulocyte colony stimulating factor; RBC, red blood cells.

Network results: Patient characteristics and trilaciclib use

68% of patients started trilaciclib during first line chemotherapy and 94% received platinum/etoposide-containing regimen with or without IO

Demographic and clinical characteristics	(n=31)
Age at index treatment initiation, years, mean (SD) [median]	67.1 (7.3) [66]
< 65, n (%)	12 (38.7)
≥ 65, n (%)	19 (61.3)
Female sex, n (%)	15 (48.4)
Follow up duration from initiation of index treatment, months, mean (SD) [median]	4.8 (3.0) [4.0]
Index chemotherapy during use of trilaciclib, n (%)	
Platinum/etoposide-containing regimen with or without IO	29 (93.5)
Topotecan-containing regimen	0 (0.0)
Start of trilaciclib by, n (%)	
LOT 1 ^a	21 (67.7)
LOT 1 and Cycle 1	19 (61.3)
LOT 2 ^b	10 (32.3)
Index chemotherapy cycles during use of trilaciclib, mean (SD) [median]	3.1 (1.1) [3]
Administrations of trilaciclib during index chemotherapy, mean (SD) [median]	8.6 (3.8) [9]

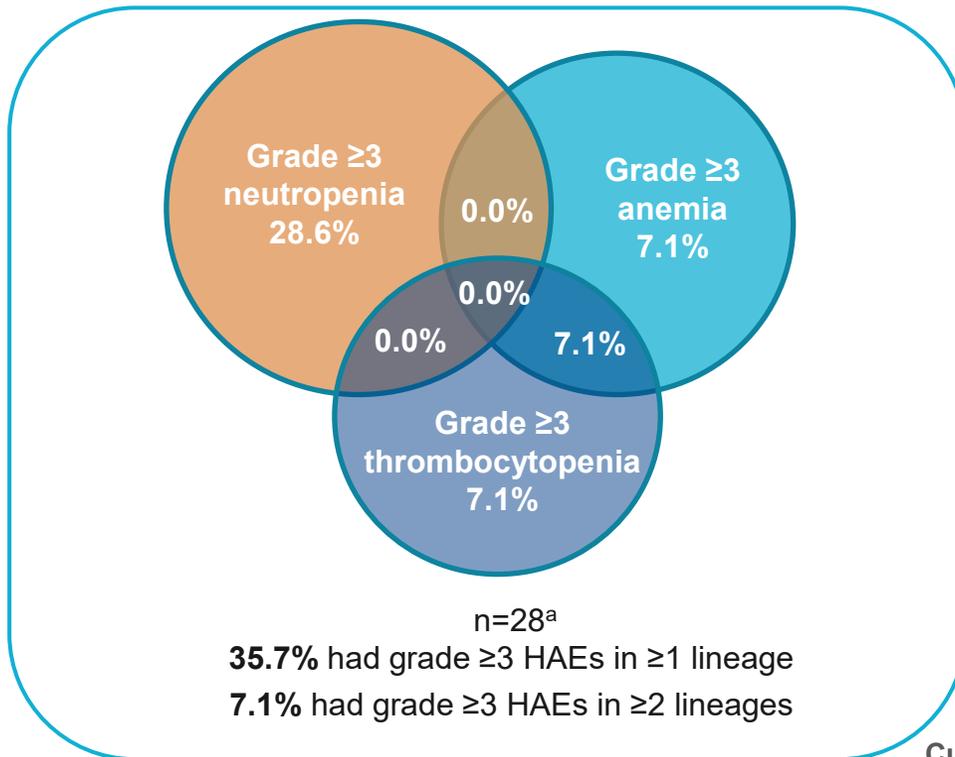
^a 19 patients started trilaciclib at cycle 1, 1 started at cycle 2, and 1 started at cycle 3 or greater. ^b 6 patients started trilaciclib at cycle 1, 1 started at cycle 2, and 3 started at cycle 3 or greater.

ES-SCLC, extensive-stage small cell lung cancer; n, number of patients; IO, immunotherapy; LOT, line of therapy; SCLC, small cell lung cancer; SD, standard deviation.

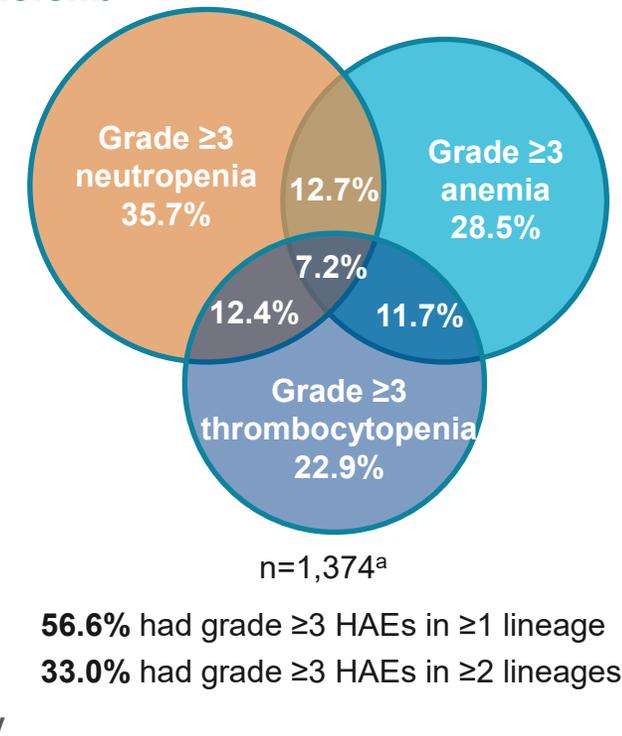
Network results: Prevalence of myelosuppression after trilaciclib use during index chemotherapy

After trilaciclib initiation, 35.7% had grade ≥3 HAEs in at least 1 lineage, 7.1% of patients had grade ≥3 HAEs in 2 lineages, and no patients had grade ≥3 HAE in all 3 lineages

Prevalence of grade ≥3 HAEs after trilaciclib initiation



Previous RWD study among patients who did not receive trilaciclib



Current study ← Previous study

^a Percentages were calculated using the number of patients with laboratory value(s) for the corresponding endpoint(s) as the denominator.
HAE, hematological adverse event; n, number of patients; RWD, real world data.

Network results: Supportive care utilization after trilaciclib use during index chemotherapy

10% of patients used G-CSF after trilaciclib initiation, 32% used IV hydration, and 3.2% were eligible for RBC transfusion; no patients were eligible for platelet transfusion

	Network (n=31)	Previous RWD study among patients who did not receive trilaciclib (n=1,574)
Supportive care utilization after trilaciclib initiation		
G-CSF	9.7%	71.5%
IV hydration	32.3%	59.0%
RBC transfusion eligible ^{a,b}	3.2%	21.3%
Platelet transfusion eligible ^{b,c}	0%	1.9%
Treatment patterns after trilaciclib initiation		
Chemotherapy dose decrease ^d	12.9%	38.1%
Chemotherapy treatment delay: 14-30 days ^d	86.7%	83.0%
Chemotherapy treatment delay: 31-60 days ^d	6.7%	18.5%

Current study ← → Previous study

^a Eligibility for RBC transfusion based on hemoglobin <8 g/dL. ^b Transfusion administration was not available in the structured EHR data. ^c Eligibility for platelet transfusion based on platelets <10,000/ μ L. ^d Treatment patterns data available for 30 patients. ES-SCLC, extensive-stage small cell lung cancer; G-CSF, granulocyte colony stimulating factor; IV, intravenous; n, number of patients; RBC, red blood cell; RWD, real world data.

Non-Network results: Patient characteristics and trilaciclib use

65% of patients started trilaciclib during first line chemotherapy, 86% received platinum/etoposide-containing regimen with or without IO, and **11% received topotecan-containing regimen**

Demographic and clinical characteristics	(n=35)
Age at index treatment initiation, years, mean (SD) [median]	67.7 (7.9) [64.4]
< 65, n (%)	18 (51.4)
≥ 65, n (%)	17 (48.6)
Female sex, n (%)	19 (54.3)
Follow up duration from initiation of index treatment, months, mean (SD) [median]	4.0 (2.9) [2.9]
Index chemotherapy during use of trilaciclib, n (%)	
Platinum/etoposide-containing regimen with or without IO	30 (85.7)
Topotecan-containing regimen	4 (11.4)
Start of trilaciclib by, n (%)	
LOT 1 ^a	23 (65.7)
LOT 1 and Cycle 1	18 (51.4)
LOT 2 or later ^b	12 (34.3)
Index chemotherapy cycles during use of trilaciclib, mean (SD) [median]	3.8 (1.9) [4]
Administrations of trilaciclib during index chemotherapy, mean (SD) [median]	10.5 (6.7) [10]

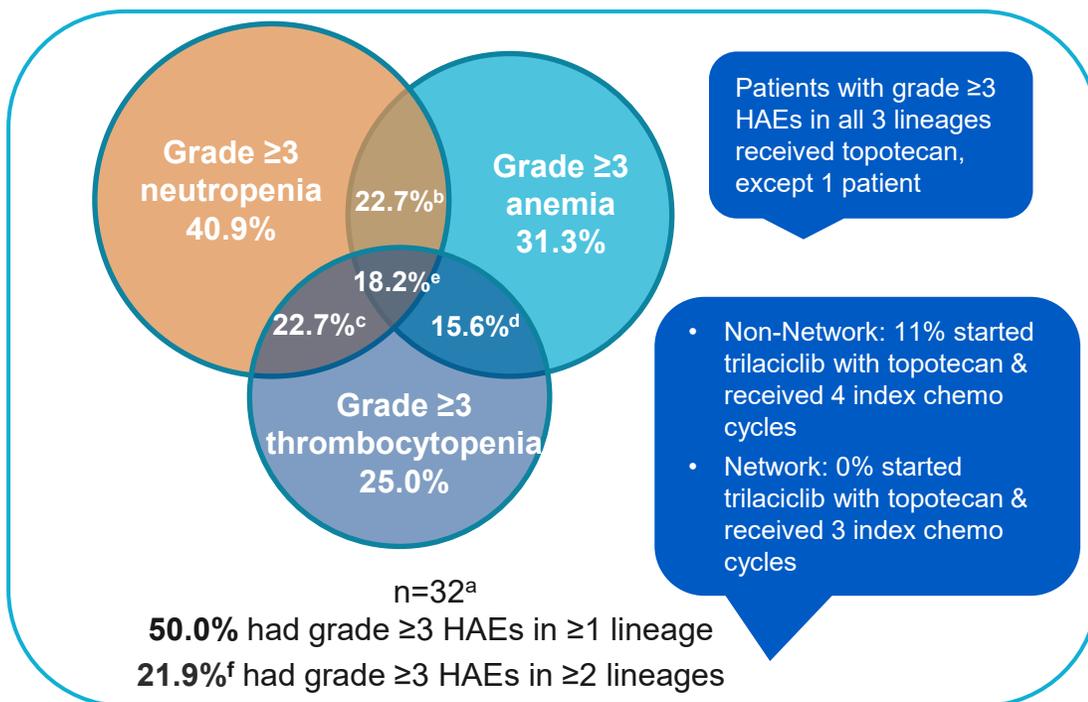
^a 18 patients started trilaciclib at cycle 1, 3 started at cycle 2, and 2 started at cycle 3 or greater. ^b 7 patients started trilaciclib at cycle 1, 2 started at cycle 2, and 3 started at cycle 3 or greater.

ES-SCLC, extensive-stage small cell lung cancer; n, number of patients; IO, immunotherapy; LOT, line of therapy; SCLC, small cell lung cancer; SD, standard deviation.

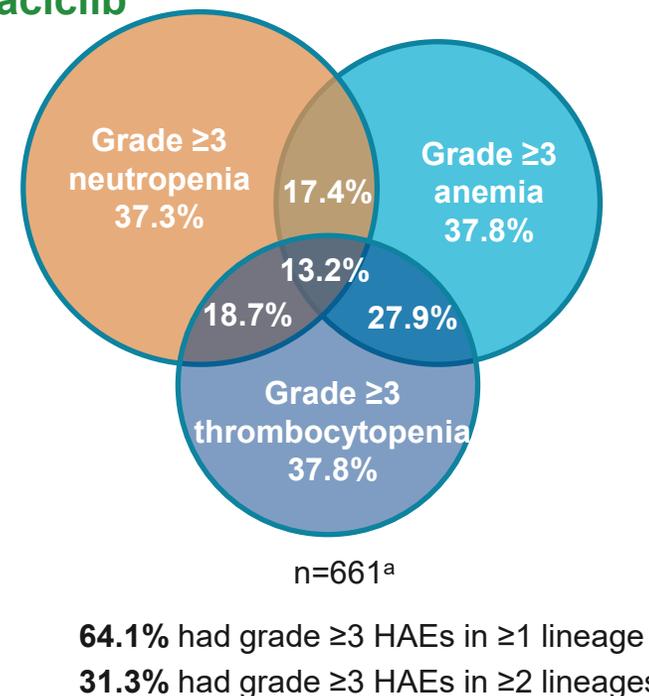
Non-Network results: Prevalence of myelosuppression after trilaciclib use during index chemotherapy

After trilaciclib initiation, 50.0% had grade ≥3 HAEs in at least 1 lineage, 21.9% of patients had grade ≥3 HAEs in 2 lineages, and 18.2% had grade ≥3 HAE in all 3 lineages

Prevalence of grade ≥3 HAEs after trilaciclib initiation



Previous RWD study among patients who did not receive trilaciclib



Current study ← → Previous study

^a Percentages were calculated using the number of patients with laboratory value(s) for the corresponding endpoint(s) as the denominator. ^b 5 patients had grade ≥3 neutropenia and grade ≥3 anemia out of 22 patients who had ANC and hemoglobin value, ^c 5 patients had grade ≥3 neutropenia and grade ≥3 thrombocytopenia out of 22 patients who had ANC and platelet value, ^d 5 patients had grade ≥3 anemia and grade ≥3 thrombocytopenia out of 32 patients who had platelet and hemoglobin value, ^e 4 patients had grade ≥3 events in all 3 lineages out of 22 patients who had ANC, hemoglobin, and platelet, ^f 7 patients had grade ≥3 event in at least 2 lineages out of 32 **15** patients who had platelet, hemoglobin, or ANC available. HAE, hematological adverse event; n, number of patients; RWD, real world data.

Non-Network results: Supportive care utilization after trilaciclib use during index chemotherapy

29% of patients used G-CSF after trilaciclib initiation, 37% used IV hydration, and 29% were eligible for RBC transfusion; no patients were eligible for platelet transfusion

	Non-Network (n=35)	Previous RWD study among patients who did not receive trilaciclib (n=959)
Supportive care utilization after trilaciclib initiation		
G-CSF	28.6%	69.6%
IV hydration	37.1%	49.5%
RBC transfusion eligible ^{a,b}	28.6%	24.2%
Platelet transfusion eligible ^{b,c}	0.0%	3.2%
Treatment patterns after trilaciclib initiation		
Chemotherapy dose decrease ^d	9.7%	49.2%
Chemotherapy treatment delay: 14-30 days ^d	87.1%	82.2%
Chemotherapy treatment delay: 31-60 days ^d	9.7%	17.3%

Current study ← → Previous study

^a hemoglobin <8 g/dL. ^b Transfusion administration was not available in the structured EHR data. ^c platelets <10,000/μL. ^d Treatment patterns data available for 31 patients.

ES-SCLC, extensive-stage small cell lung cancer; G-CSF, granulocyte colony stimulating factor; IV, intravenous; n, number of patients; RBC, red blood cell; RWD, real world data.

Use of trilaciclib has the potential to reduce the burden of myelosuppression among patients with ES-SCLC



In both Network and Non-Network clinics, approximately **two-thirds of patients started trilaciclib with first line chemotherapy** and the other third started trilaciclib with second line or later chemotherapy

Patients in the Non-Network clinics appeared to have higher hematological toxicity before starting trilaciclib



Early real-world data in this study suggest that the use of trilaciclib in patients with ES-SCLC treated in the community oncology setting may:

Reduce the prevalence of myelosuppression

Reduce the proportion of patients requiring supportive care utilization

Reduce chemotherapy dose decreases and treatment delays

Findings from real-world study were consistent with what were observed in trilaciclib clinical trials



Chemotherapy induced myelosuppression and associated consequences can be reduced when **trilaciclib is prophylactically used as recommended by NCCN SCLC and Hematopoietic Growth Factors Guidelines[®]**

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- Barreto JN, et al. *J Pharm Pract*. 2014;27:440–6.
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The background features a light blue and white color palette. On the left, there are several overlapping, semi-transparent white circles of varying sizes. On the right, there is a close-up, high-angle view of a globe covered in water droplets, with a blue color gradient. The word "Appendix" is written in a dark blue, sans-serif font, preceded by a vertical orange bar.

Appendix

Definitions of neutropenia, anemia, and thrombocytopenia¹

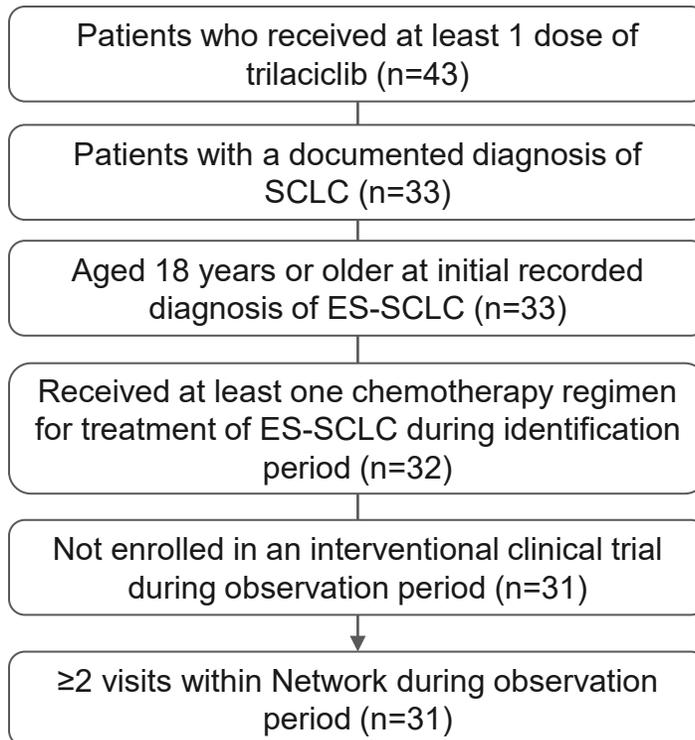
Grade	Neutropenia	Anemia	Thrombocytopenia
Grade 1	ANC 1500 to 2500 cells/ μ L	Hb 10.0 to < 13.0 g/dL	Platelets 75,000 to 150,000/ μ L
Grade 2	ANC 1000 to < 1500 cells/ μ L	Hb 8.0 to < 10.0 g/dL	Platelets 50,000 to < 75,000/ μ L
Grade 3	ANC 500 to < 1000 cells/ μ L	Hb < 8.0 g/dL	Platelets 25,000 to < 50,000/ μ L
Grade 4	ANC < 500 cells/ μ L	–	Platelets < 25,000/ μ L

ANC, absolute neutrophil count; Hb, hemoglobin; ICD-9-CM, International Classification of Diseases, 9th Revision, Clinical Modification; ICD-10, International Classification of Diseases, 10th Revision.

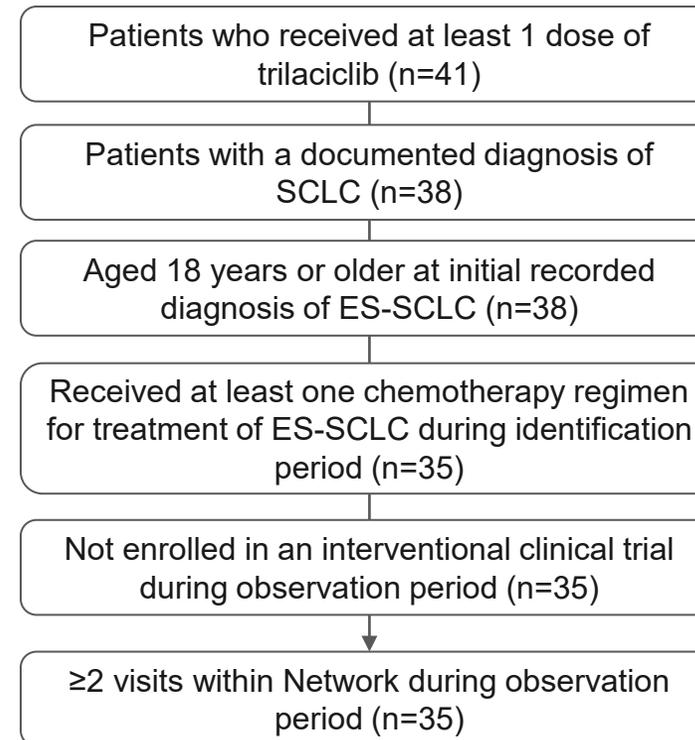
1. National Cancer Institute (US). Common terminology criteria for adverse events (CTCAE). 2010. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_4.03.xlsx. Accessed February 24, 2022.

Patient flow diagrams

Network



Non-Network



Demographics and clinical characteristics

	Network Trilaciclib (n=31)	Non-Network Trilaciclib (n=35)
Age, years, mean	66.8	67.5
< 65	13 (41.9)	18 (51.4)
≥ 65	18 (58.1)	17 (48.6)
Male sex, n (%)	16 (51.6)	16 (45.7)
ECOG PS, n (%)		
0	2 (6.5)	1 (2.9)
1	10 (32.3)	9 (25.7)
2	5 (16.1)	1 (2.9)
≥ 3	0	0
Not documented	14 (45.2)	24 (68.6)
Index LOT , n (%)		
LOT 1	21 (67.7)	23 (65.7)
LOT 2 or later	10 (32.3)	12 (34.3)
Myelosuppression prior to index, ^a n (%)		
Grade 3 anemia	1 (4.2)	3 (9.7)
Grade 3 neutropenia	2 (8.7)	1 (4.8)
Grade 4 neutropenia	0	4 (19.0)
Grade 3 thrombocytopenia	0	5 (15.6)
Grade 4 thrombocytopenia	1 (4.2)	2 (6.3)

Previous RWD study among patients who did not receive trilaciclib

	Network ¹ Chemo-treated (n=1,574)	Non-Network ² Chemo-treated (n=959)
	67.8	67.4
	611 (38.8)	378 (39.4)
	963 (61.2)	581 (60.6)
	750 (47.6)	470 (49.0)
	113 (7.2)	81 (8.5)
	761 (48.3)	355 (37.0)
	331 (21.0)	174 (18.1)
	36 (2.3)	12 (1.3)
	333 (21.2)	337 (35.1)
	1,566 (99.5)	955 (99.6)
	8 (0.5)	4 (0.4)
	83 (6.9)	15 (2.9)
	40 (3.5)	15 (3.6)
	19 (1.7)	23 (5.6)
	32 (2.7)	12 (2.3)
	15 (1.2)	9 (1.7)

Current study ← → Previous study

ECOG PS, Eastern Cooperative Oncology Group performance status; ES-SCLC, extensive-stage small cell lung cancer; LOT, line of therapy

^a denominator was the number of patients with available lab value of interest

1. Goldschmidt J, et al. Real-world burden of myelosuppression among patients with ES-SCLC treated in the community oncology setting [poster]. AMCP Nexus, Oct 18-21, 2021.
2. Ontada/The US Oncology Network. Real-world burden of myelosuppression among patients with small cell lung cancer treated in the community oncology setting. Final Report. 2022.