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Characterization of edema adverse events in the CADENZA study of pivekimab sunirine (PVEK) in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN)

Naveen Pemmaraju[1]*, Giovanni Marconi[2], Pau Montesinos[3], Andrew A. Lane[4], Luca Mazzarella[5], David A. Sallman[6], Matthew L. Ulrickson[7], Gary J. Schiller[8], Harry P. Erba[9], Eunice S. Wang[10], Roland B. Walter[11–13], Eric Deconinck[14], Ahmed Aribi[15], Delphine Lebon[16], Valerio Maisano[17], Daniel J. DeAngelo[4], Enrico Derenzini[18,19], Yulei He[20], Rebecca B. Reindel[20], Nisha Kishore[20], Jalaja Potluri[20], Hagop M. Kantarjian[1], Naval G. Daver[1]

[1]Department of Leukemia, University of Texas MD Anderson Cancer Center, Houston, TX, USA; [2]Hematology University of Bologna, Hematology Unit, Ospedale S. Maria delle Croci, Ravenna (RA), Italy; [3]Servicio de Hematología, Hospital U. La Fe, Valencia, Spain; [4]Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, MA, USA; [5]Early Drug Development for Innovative Therapies Division, IRCCS IEO-Istituto Europeo di Oncologia, Milan, Italy; [6]Department of Malignant Hematology, Moffitt Cancer Center, Tampa, FL, USA; [7]Banner MD Anderson Cancer Center, Gilbert, AZ, USA; [8]David Geffen School of Medicine at UCLA, Los Angeles, CA, USA; [9]Department of Medicine, Duke Cancer Institute, Durham, NC, USA; [10]Leukemia Service, Roswell Park Comprehensive Cancer Center, Buffalo, NY, USA; [11]Translational Science and Therapeutics Division, Fred Hutchinson Cancer Center, Seattle, WA, USA; [12]Department of Medicine, Division of Hematology and Oncology, University of Washington, Seattle, WA, USA; [13]Department of Laboratory Medicine and Pathology, University of Washington, Seattle, WA, USA; [14]CHU Besançon, Service d'Hématologie and Université Marie et Louis Pasteur, INSERM UMR RIGHT, Besançon, France; [15]Department of Hematology and Hematopoietic Cell Transplantation, City of Hope National Medical Center, Duarte, CA, USA; [16]Service d'Hématologie Clinique et Thérapie Cellulaire, Centre Hospitalier Universitaire d'Amiens, Amiens, France; [17]Department of Hematology, Institut Paoli-Calmettes, INSERM UMR 1068, CNRS UMR725, CNRS, Aix-Marseille University, Marseille, France; [18]Oncohematology Division, IEO European Institute of Oncology IRCCS, Milan, Italy; [19]Department of Health Sciences, University of Milan, Milan, Italy; [20]AbbVie, Inc, North Chicago, IL, USA.

**Presenting author*

OBJECTIVE

To report in-depth characterization of edema adverse events (AEs) in patients with CD123-positive blastic plasmacytoid dendritic cell neoplasm (BPDCN) treated with pivekimab sunirine (PVEK) in the pivotal CADENZA (NCT03386513) study

CONCLUSIONS

- Edema events were primarily peripheral edema; no grade 4 or 5 edema events were reported in the CADENZA trial
- Edema was manageable with diuretics, and most patients continued PVEK treatment with only 1 (1.2%) patient discontinuing treatment due to edema AE
- Vigilance and early intervention by clinicians kept edema events manageable and enabled patients to continue PVEK treatment to achieve efficacy

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References

1. Pemmaraju N, et al. *Blood*. 2023;141(6):567–578.
2. Pemmaraju N, et al. *HemaSphere*. 2023;7(S3).
3. DECNUPAZ™ (pivekimab sunirine-pvzy) [package insert]. North Chicago, IL, USA. AbbVie Inc. 2026.
4. Kovtun Y, et al. *Blood Adv*. 2018;2(8):848–858.
5. Pemmaraju N, et al. *J Clin Oncol*. 2026;44(10):861–873.

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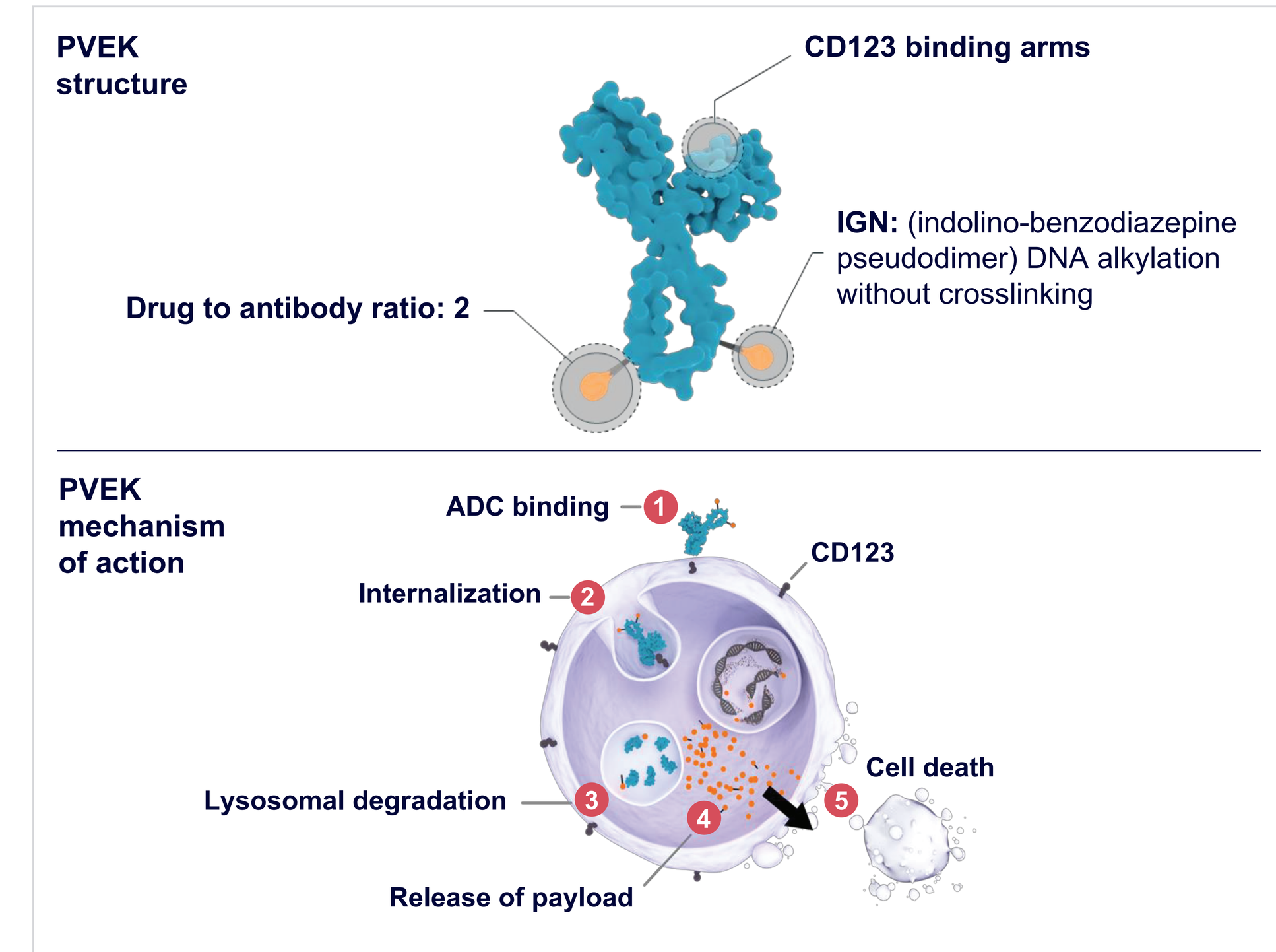
BACKGROUND

- BPDCN, a rare and aggressive hematologic malignancy is characterized by CD123 (interleukin-3Rα) overexpression, and primarily involves skin, bone marrow, and lymph nodes[1,2]
- PVEK is the first-in-class and only antibody-drug conjugate approved by the US Food and Drug Administration for adult patients with BDPCN that can be initiated in an outpatient setting[2,3]
- PVEK is comprised of a high-affinity anti-CD123 antibody, a cleavable linker, and an indolinobenzodiazepine pseudodimer payload that alkylates DNA and causes single-strand breaks without crosslinking, demonstrating less toxicity to normal bone marrow progenitors compared with other DNA-targeting payloads[2,4,5]
- In the primary analysis of CADENZA (NCT03386513), patients with frontline BPDCN treated with PVEK achieved high (70%) composite complete response (CR) defined as CR + clinical CR (CRc; CR with minimal skin abnormality); duration of CR + CRc was 9.7 months, and 48% of patients who achieved CR + CRc received stem-cell transplant[3,5]
  - Clinically meaningful responses were also observed in relapsed/refractory patients with BDPCN treated with 1–3 prior systemic therapies[5]
- In CADENZA, PVEK demonstrated an overall tolerable and manageable safety profile, with edema as the most frequently reported AE (59.5%)
- Here, we provide further characterization and details of clinical management of edema AEs reported in the CADENZA trial

PVEK structure and mechanism of action[5]



ADC, antibody-drug conjugate; PVEK, pivekimab sunirine.

METHODS

- Preferred terms for edema AEs included acute pulmonary edema, ascites, face edema, generalized edema, hypervolemia, edema, edema genital, edema peripheral, pericardial effusion, peripheral swelling, pleural effusion, pulmonary edema, swelling face, and weight increased

CADENZA (NCT03386513) patient population[a] (N=84)

Edema analysis objectives

- Incidence[b] rates, prevalence[c], and severity of edema AEs
- Clinical management of edema

All patients received PVEK intravenously (<30-min infusion) on **Day 1 of a 21-day cycle** at the recommended phase 2 dose of **0.045 mg/kg**

[a]Adults (aged ≥18 years) with ECOG PS score of ≤1 and adequate organ function and liver enzyme range were eligible for participation in CADENZA. Exclusion criteria included history of hepatic veno-occlusive disease; grade 4 capillary-leak syndrome, or noncardiac grade 4 edema; and frontline patients with central nervous system disease (patients with relapsed or refractory disease with central nervous system disease could be included if treated and had no evidence of central nervous system disease before first treatment dose). [b]Incidence is defined as the number of patients with ≥1 new event after PVEK dose in the cycle and before the dose of PVEK in the next cycle divided by the number of patients who received PVEK in the respective cycle. [c]Prevalence is defined as the number of patients with a new or ongoing event during the cycle divided by the number of patients who received PVEK in the respective cycle.
AE, adverse event; ECOG PS, Eastern Cooperative Oncology Group performance status; PVEK, pivekimab sunirine.

RESULTS

Baseline demographics and clinical characteristics

Characteristic	Total BDPCN (N=84)
Age, years, median (range)	71.5 (19–85)
Age, years, n (%)	
18–64	24 (28.6)
65–74	33 (39.3)
≥75	27 (32.1)
Sex, n (%)	
Male	69 (82.1)
Female	15 (17.9)
Race,[a] n (%)	
White	69 (82.1)
Black	3 (3.6)
Asian	1 (1.2)
ECOG performance status, n (%)	
0	30 (35.7)
1	51 (60.7)
2	2 (2.4)
3	1 (1.2)
Baseline disease involvement, n (%)	
Skin	65 (77.4)
Bone marrow	40 (47.6)
Peripheral blood	13 (15.5)
Lymph nodes	30 (35.7)
Viscera	3 (3.6)
History of peripheral edema, n (%)	18 (21.4)
Prior treatment for edema,[b] n (%)	
Furosemide	7 (8.3)
Hydrochlorothiazide	1 (1.2)

[a]Race data is missing for 11 patients. [b]One patient received both treatments.
BDPCN, blastic plasmacytoid dendritic cell neoplasm; ECOG, Eastern Cooperative Oncology Group.

- Overall, 84 patients with CD123-positive BPDCN were enrolled (33 frontline; 51 relapsed/refractory); median (range) number of treatment cycles was 3.5 (1–34)
- Of enrolled patients, median age (range) was 71.5 (19–85) years; 69 (82.1%) were male; 69 (82.1%) were White; 18 (21.4%) had a history of peripheral edema at baseline

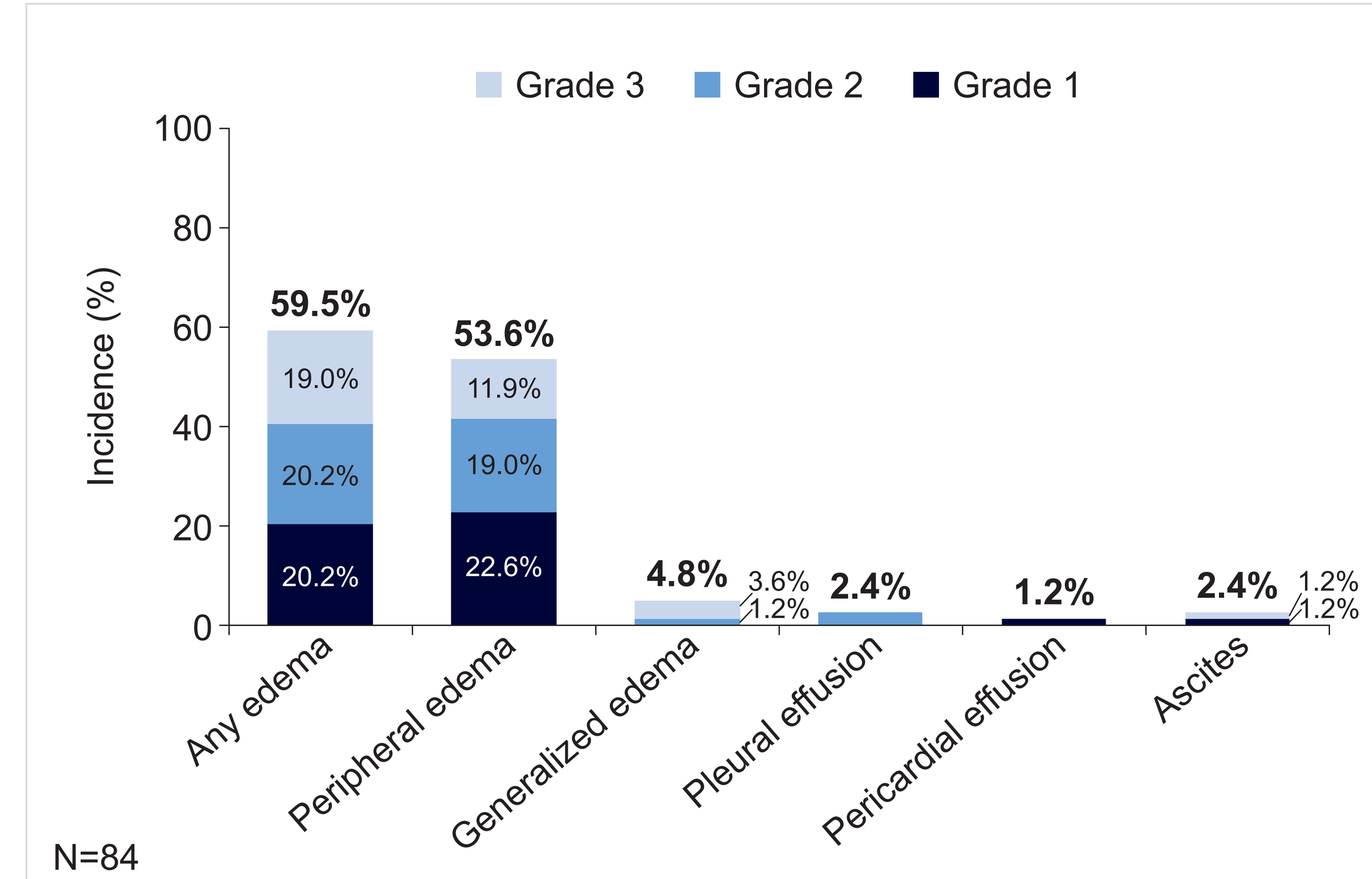
Summary of edema AEs

	Total BDPCN (N=84)
Any edema AE, n (%)	50 (59.5)
Serious[a]	7 (8.3)
Leading to death	0
Time to onset, days, median (range)	53.0 (0–157)
Edema AEs in patients with clinical risk factors at baseline	
History of peripheral edema, n/N (%)	10/18 (55.6)
Chronic kidney disease, n/N (%)	5/7 (71.4)
Diastolic dysfunction, n/N (%)	0/2

[a]Defined as any AE occurring at any dose that results in any of the following: death, is life-threatening, requires inpatient hospitalization, requires prolongation of existing hospitalization, a persistent or significant disability of incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly or birth defects, or important medical events which may jeopardize the patient and may require medical or surgical intervention to prevent 1 of the outcomes listed.
AE, adverse event; BDPCN, blastic plasmacytoid dendritic cell neoplasm.

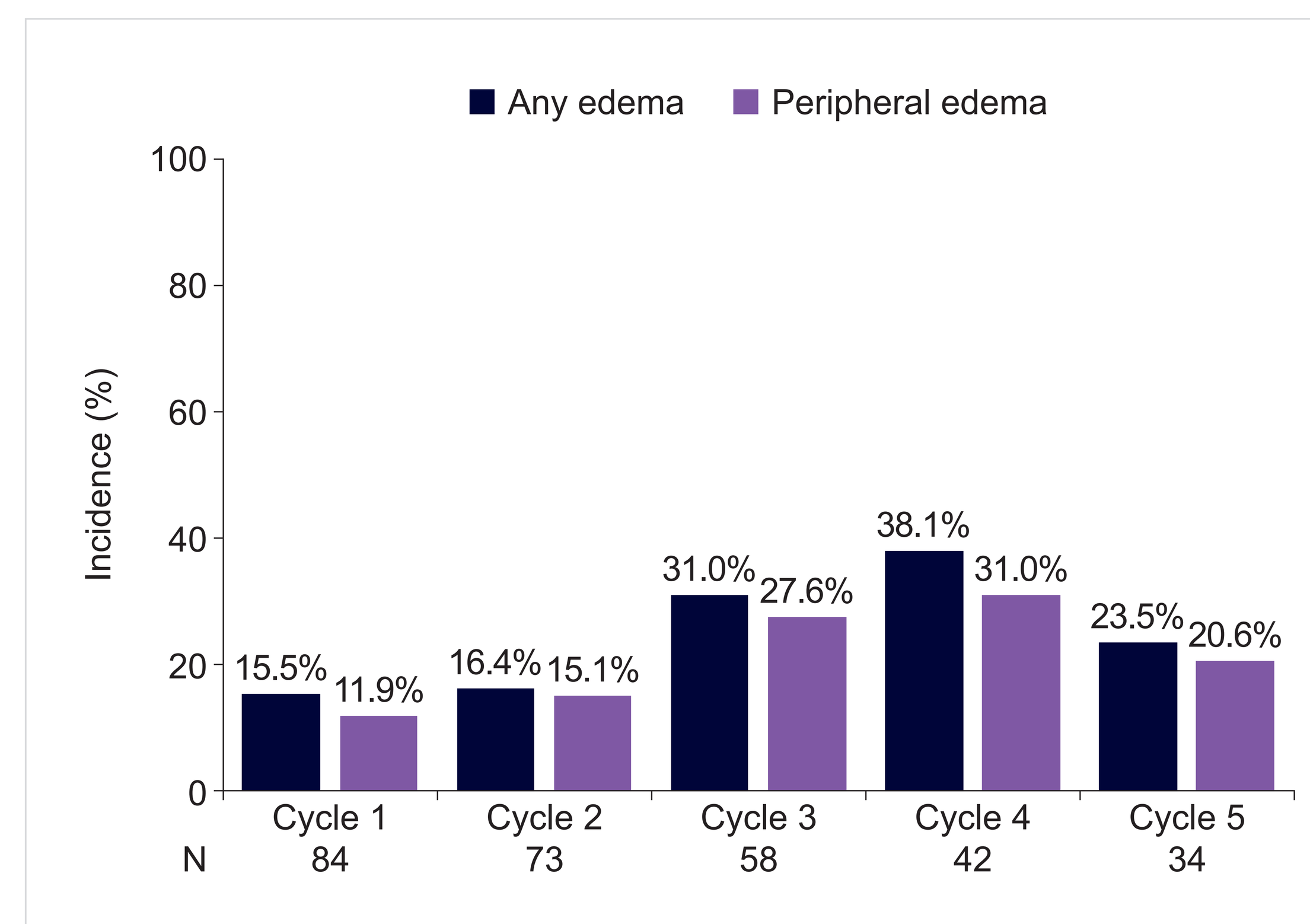
- Median (range) time to onset of edema AEs was 53.0 (0–157.0) days
- Of patients with a history of peripheral edema (n=18), 10 (55.6%) experienced edema AEs following PVEK treatment
- Of patients previously treated for edema (n=7), 2 (28.6%) experienced edema AEs after receiving PVEK treatment

Overall, 50 (59.5%) patients had any adverse event of edema; peripheral edema was most common



- Grade 3 peripheral edema occurred in 10 (11.9%) patients
- No grade 4 or 5 events of any edema were reported
- Generalized edema occurred in 4 (4.8%) patients, with 3 (3.6%) experiencing grade 3 events
- Pleural effusion, pericardial effusion, and ascites were reported in 2 (2.4%), 1 (1.2%), and 2 (2.4%) patients, respectively; all were grade 1 or 2, except for 1 (1.2%) patient with grade 3 ascites

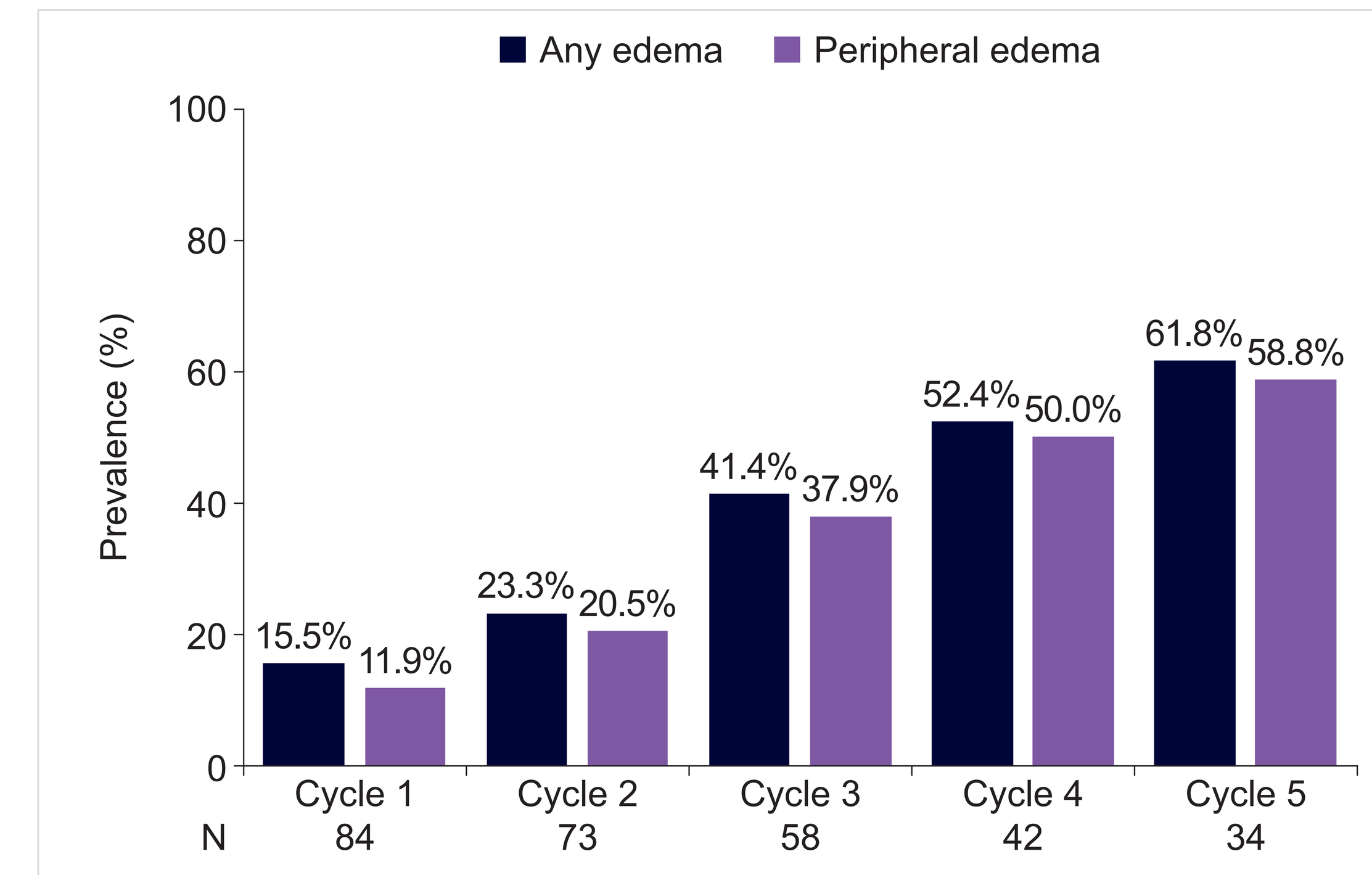
Highest incidence of edema was reported during cycle 4 (38.1%) and was most frequently peripheral edema



Incidence of edema was assessed within the first 5 cycles in patients who received ≥1 treatment cycle.

- Edema AEs were primarily low grade; 11 (13.1%) patients experienced grade 3 edema (2 each in cycles 1, 2, 3, and 5, and 3 in cycle 4)

New or ongoing edema adverse events were most prevalent during cycles 4 (52.4%) and 5 (61.8%)



Prevalence of edema was assessed within the first 5 cycles in patients who received ≥1 treatment cycle.

Edema AEs were manageable

	Patients with edema (N=50)
Any edema AE leading to, n (%)	
Dose reduction	3 (6.0)
Dose delay	5 (10.0)
Discontinuation	1 (2.0)
Diuretic administration for edema management, n (%)	35 (70.0)
Furosemide	32 (64.0)
Torsemide	7 (14.0)
Bumetanide	4 (8.0)
Spironolactone	5 (10.0)
Potassium canrenoate	4 (8.0)
Metolazone	1 (2.0)
Time to diuretic receipt, days, median (range)	2.0 (1–426)
Patients with ≥1 resolution of edema event, n (%)	
With concomitant diuretic	24 (48.0)
Without concomitant diuretic	16 (32.0)
Time to resolution[a], days, median (range)	
With concomitant diuretic[b]	23.0 (1–156)
Without concomitant diuretic[b]	12.5 (2–87)

[a]Of the longest edema event per patient; time to resolution was calculated as event end date – event onset date + 1 if the event resolved and a complete end date was recorded. [b]Within 7 days of edema onset.
AE, adverse event.

- Discontinuation of PVEK due to edema AEs occured in 1 (2.0%) patient
- Edema events were manageable; 40 (80.0%) patients had ≥1 edema AE that resolved
- Of patients with edema, 32 (64.0%) received furosemide as management; median time to resolution was 23.0 days in patients with concomitant diuretic within 7 days of onset vs 12.5 days in patients without concomitant diuretics
- Combination diuretic regimens, defined as treatment with 2 different diuretics ≤1 day apart, were administered to 6 (12.0%) patients with edema; of these, three patients had a grade 2 event and three patients had a grade 3 event