Education, Adherence and Symptom Management in Patients with Cervix Cancer Treated with ADC Therapy

Kathleen Lutz, NP
NYU Langone,
Perlmutter Cancer Center
New York, NY

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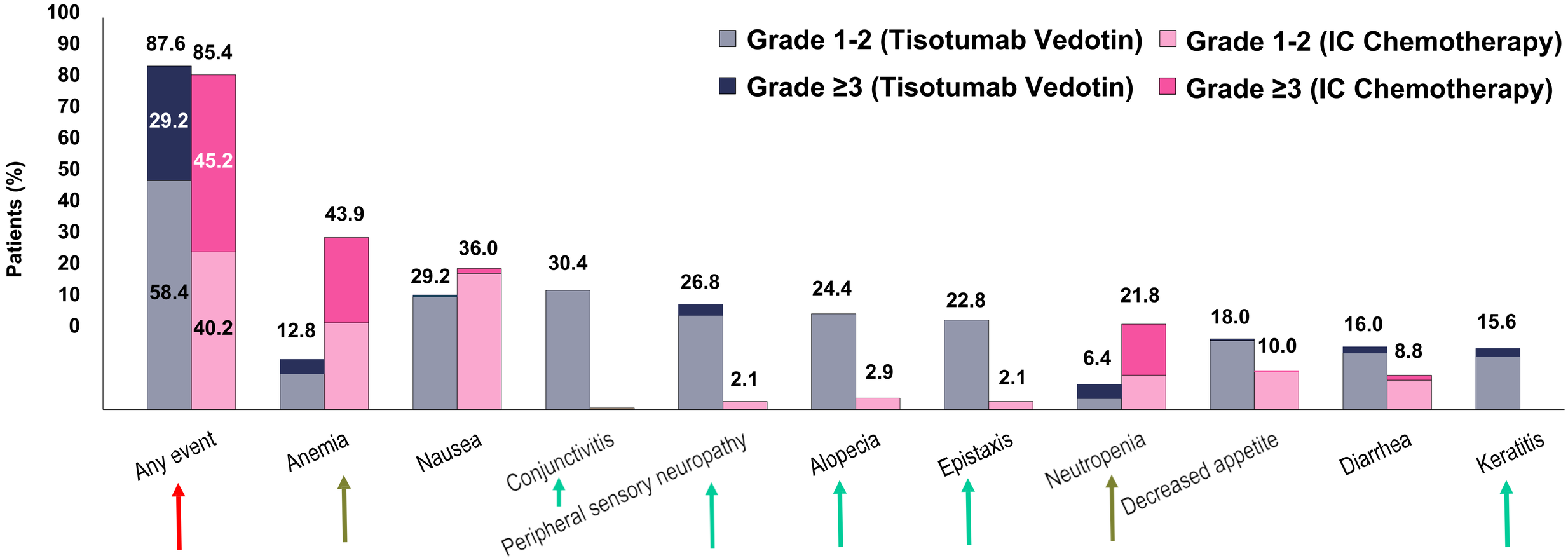
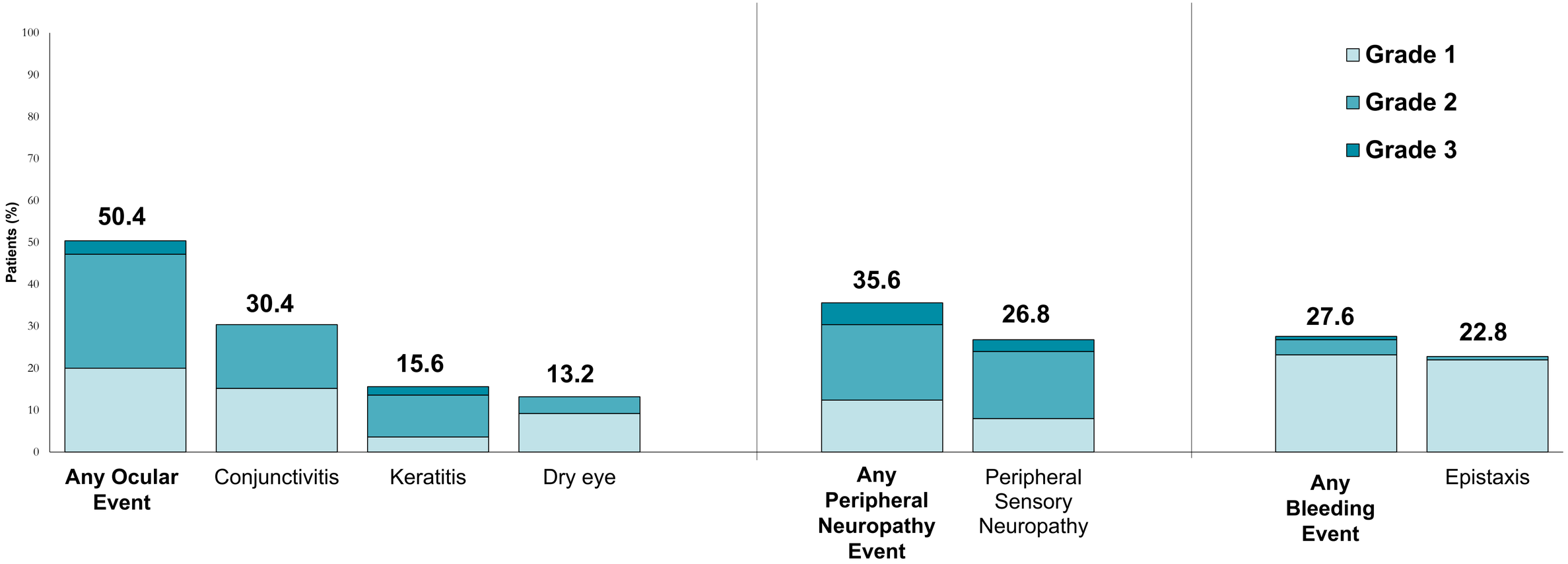
Most Common Treatment-Related Adverse Events[a]



- Grade 5 TRAEs occurred in 2 (0.8%) and 1 (0.4%) patients in the tisotumab vedotin and IC chemotherapy arms, respectively[b]
- Median relative dose intensity was 96.1% and 90.0% in the tisotumab vedotin and IC chemotherapy arms, respectively

[a]TRAEs listed are those occurring in ≥15% of patients on either arm; [b]Grade 5 TRAEs included acute kidney injury (n=1) and Stevens-Johnson syndrome (n=1) in the tisotumab vedotin arm and pancytopenia (n=1) in the IC chemotherapy arm.

AESIs in ≥5% of Patients in the Tisotumab Vedotin Arm



- Overall, the incidence of any grade TRAEs was similar across both arms (tisotumab vedotin: 87.6% versus chemotherapy: 85.4%)
  - 58.4% of TRAEs experienced by patients on the tisotumab vedotin arm were Grades 1-2
- Treatment-related AESIs for tisotumab vedotin were consistent with the previous known safety profile, including ocular, peripheral neuropathy, and bleeding events[1]
  - There were no Grade 4-5 AESIs

AESI, adverse event of special interest

1. Coleman RL. Lancet Oncol. 2021:609-619.

TV: FDA Approval with Black Box Warning

Black Box Warnings:

- Ocular toxicity
- Causes changes in corneal epithelium and conjunctiva resulting in vision changes, including severe vision loss, and corneal ulceration
- Conduct ophthalmic examination at baseline, prior to each dose, and as clinically indicated
- Adhere to premedication and required eye care before, during, and after infusion
- Withhold until improvement and resume, reduce the dose, or permanently discontinue, based on severity

Patient Adherence

- **Access to eye care providers** - set up patients with ophthalmologist
- **Access to eye drops** - make sure they can fill the scripts and bring to clinic prior to initiating treatment
- **Care during infusion** - instruct infusion staff how to manage eye care (eye drops/ice pack before during and after infusion)

Eye Drops/Eye Care Plan

Steroid Eye Drops

- Provide protection against erythema, edema and pruitus
- 10 minutes prior to infusion and the 2x per day on day of treatment, then 3x per day for 3 days post treatment

Vasoconstrictor Eye Drops

- Reduces blood flow in the eyes
- Right before infusion

Lubricating Eye Drops

- Helps reduce and relieve dryness/discomfort
- Use throughout the duration of treatment and for 30 days after your last dose

Ice packs

- Apply to both eyes after administration of vasoconstrictor eye drops, change often during infusion and keep cold pack on for 20 minutes after infusion

Symptom Management: Tisotumab Vedotin

Eye toxicity: Exam, drops, ice packs, self assessments

Peripheral Neuropathy: Assess baseline prior to starting, trial of regional cooling of hands/feet, trial of Gabapentin or Duloxetine

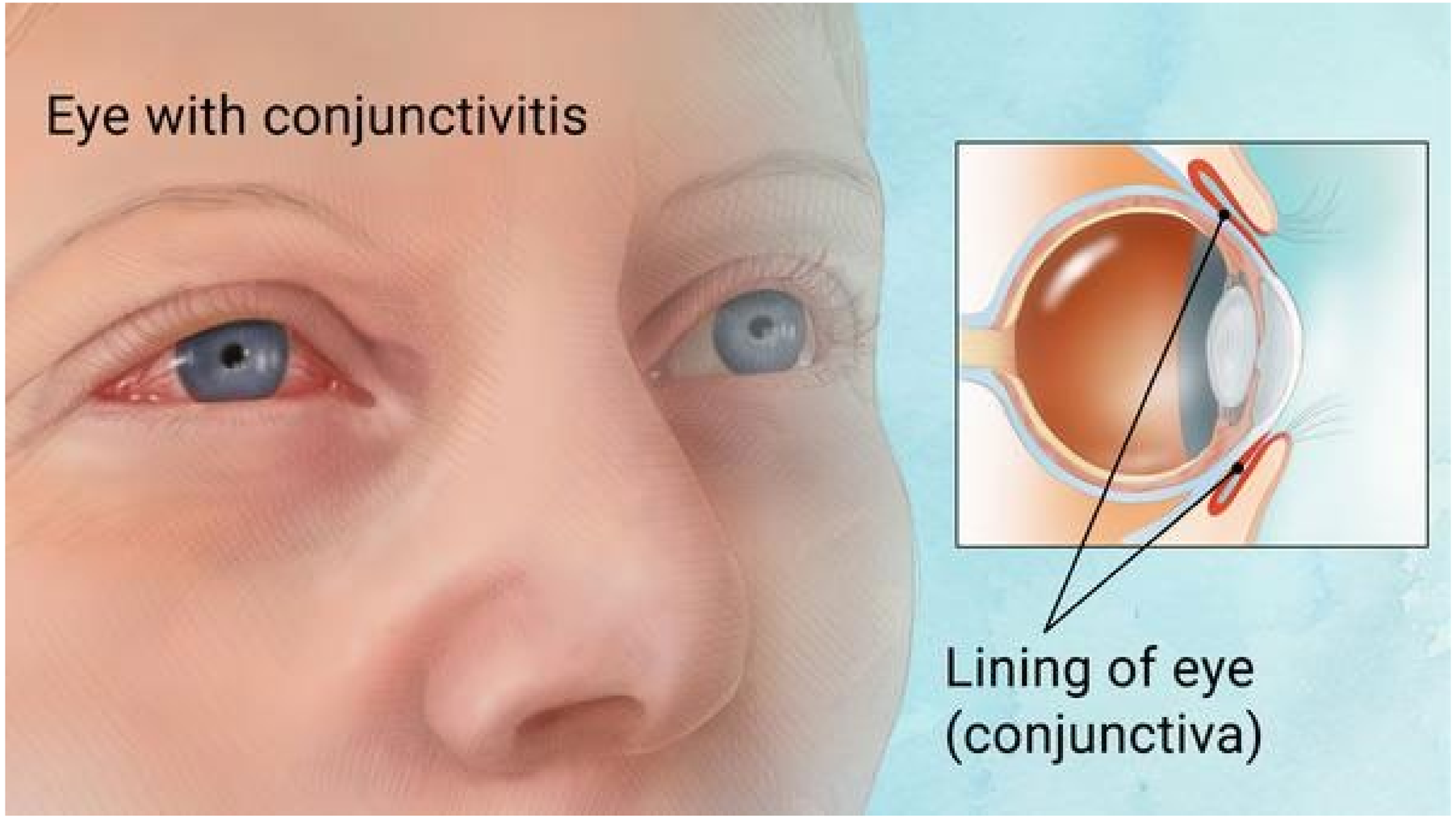
Bleeding: Monitor source and amount of bleeding, monitor CBC

Nausea: Antinausea medication such as ondansetron or olanzapine, ginger candy, teas

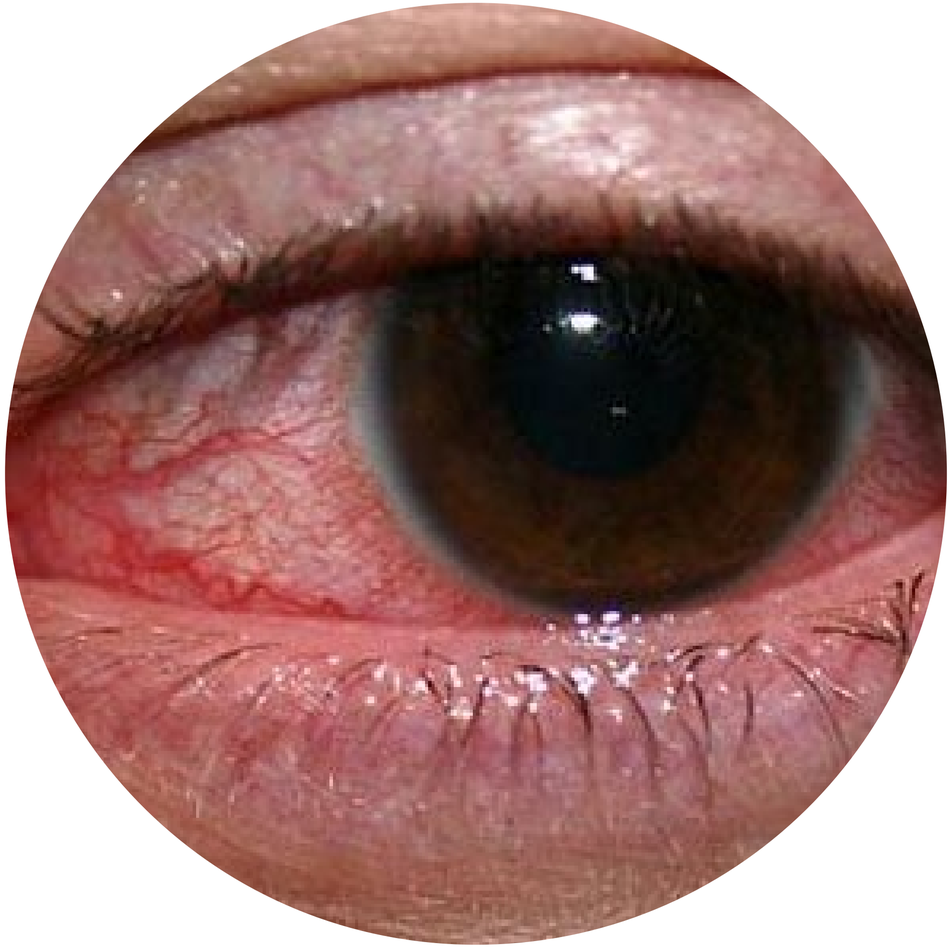
Anorexia: Smaller meals often, avoid spicy/fried food

Fatigue: Rest periods as needed, daily exercise routine, improve sleep at night

Tisotumab Vedotin: Eye Toxicity



Keratitis



- Symptoms of keratitis include:
- Red eyes
- Pain and irritation in the affected eye
- Vision changes, such as blurriness or inability to see
- Sensitivity to light
- Inability to open your eye
- Eye discharge
- Excessive tearing

HER2 Targeted ADC- Trastuzumab Deruxtecan

- Another ADC with potential benefit in the treatment of GYN cancers (NCCN listed but not FDA approved)
- Was reviewed in the Phase 2 Destiny-PanTumor02 Study
- **Increased risk of ILD Pneumonitis**
- Other AE may include Nausea/Vomiting/Diarrhea/Loss of Appetite/Alopecia

Phase 2 DESTINY-PanTumor02 Study

Adverse event	Cervical cancer (n = 40)	Endometrial cancer (n = 40)	Ovarian cancer (n = 40)	Biliary tract cancer (n = 41)	Pancreatic cancer (n = 25)	Bladder cancer (n = 41)	Other tumors (n = 40)
Drug-related AE, %	90.0	90.0	85.0	80.5	60.0	92.7	85.0
Grade ≥3	47.5	35.0	52.5	39.0	28.0	41.5	37.5
Leading to discontinuation	7.5	7.5	2.5	12.2	4.0	9.8	15.0
Associated with death	0	5.0	0	0	0	2.4	2.5
Most common drug-related AEs (>10% of total patients), No. (%)							
Nausea	65.0	72.5	55.0	46.3	28.0	51.2	57.5
Diarrhea	37.5	40.0	20.0	19.5	12.0	31.7	15.0
Vomiting	25.0	40.0	17.5	22.0	12.0	14.6	37.5
Decreased appetite	17.5	20.0	20.0	17.1	8.0	19.5	17.5
Alopecia	20.0	22.5	12.5	22.0	8.0	12.2	17.5

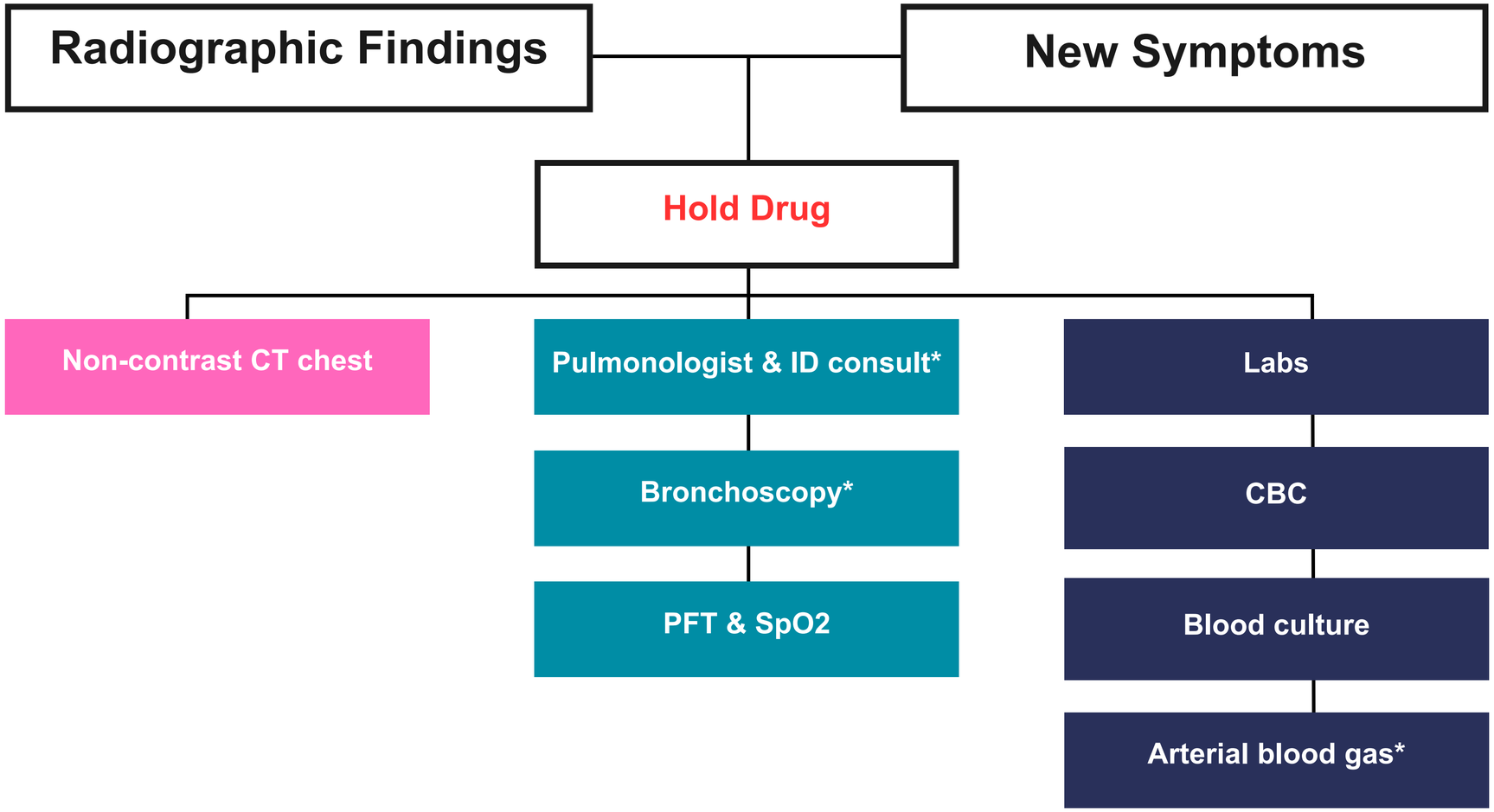
Drug-related AEs led to discontinuation in 8.6% of patients and to dose reduction in 20.2% of patients

T-DXd is not approved by the FDA for these indications.

Incidence of ILD Pneumonitis

- A review of 14 studies totaling 1193 patients receiving the drug for a variety of advanced solid malignancies
- The overall incidence of all-grade ILD/pneumonitis was 11.4 percent, and the majority of cases (79 percent) were grade 1 or 2
- Grade 5 (fatal) toxicity occurred in 13 of the 122 cases (10.7 percent)

Work-up



* = *if indicated*

Take Aways

- Easy to miss, can progress rapidly
- Risk for ILD increased with exposure to immunotherapies?
- Any suspicion on imaging warrants further workup
- Hold treatment until resolves to grade 0

ADCs Are Here To Stay

Close Monitoring

And

Proactive Management of Adverse Events

CAN EQUAL

SUCCESS FOR OUR PATIENTS