19th International Ultmann Chicago Lymphoma Symposium

LIVE Symposium

APRIL 29-30
2022

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MEDICINE & BIOLOGICAL SCIENCES

Toxicities with Chronic Therapies

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Disclosures

- Katherine Thorp, DNP, AGACNP-BC
  - No financial disclosures or conflicts of interest
- Nicole Soriano, PharmD, BCOP
  - No financial disclosures or conflicts of interest

Learning Objectives

1. Identify common toxicities with chronic therapies.
2. Implement current recommended strategies for management and supportive care of checkpoint-inhibitor induced gastrointestinal toxicities.
3. Understand available treatment and supportive care strategies for arthralgias associated with Bruton tyrosine kinase inhibitors.
4. Discuss options for prophylaxis and therapy of opportunistic infections in patients undergoing chemoimmunotherapy.

Checkpoint Inhibitors and Late Diarrhea/Colitis

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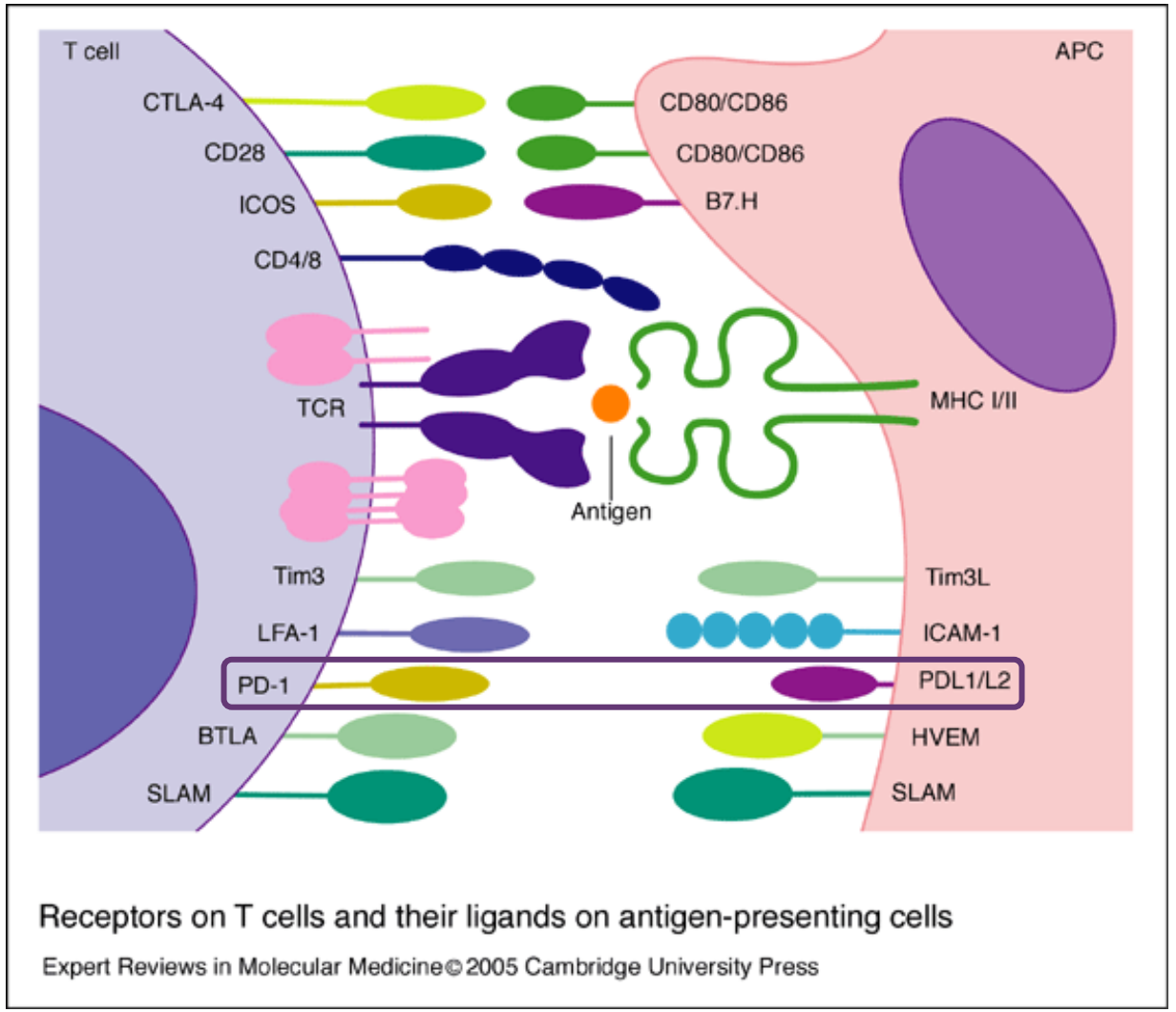
Immune Checkpoint Inhibitors (ICIs): Background

- 1992- Ishida et al. identify programmed cell death protein 1 (PD-1)
- 1996- Leach et al. identify cytotoxic T-lymphocyte antigen-4 (CTLA-4)
- Instrumental to development of ICIs and their current role in cancer therapies
- Function to restrain suppressive T-cell co-stimulatory signals
- 2018- Dr. Tasuku Honjo and Dr. James Allison win the Nobel prize in Physiology or Medicine for their work

Nishida, T., Iijima, H., & Adachi, S. (2019). Immune checkpoint inhibitor-induced diarrhea/colitis: Endoscopic and pathologic findings. *World journal of gastrointestinal pathophysiology*, *10*(2), 17–28. https://doi.org/10.4291/wjgp.v10.i2.17

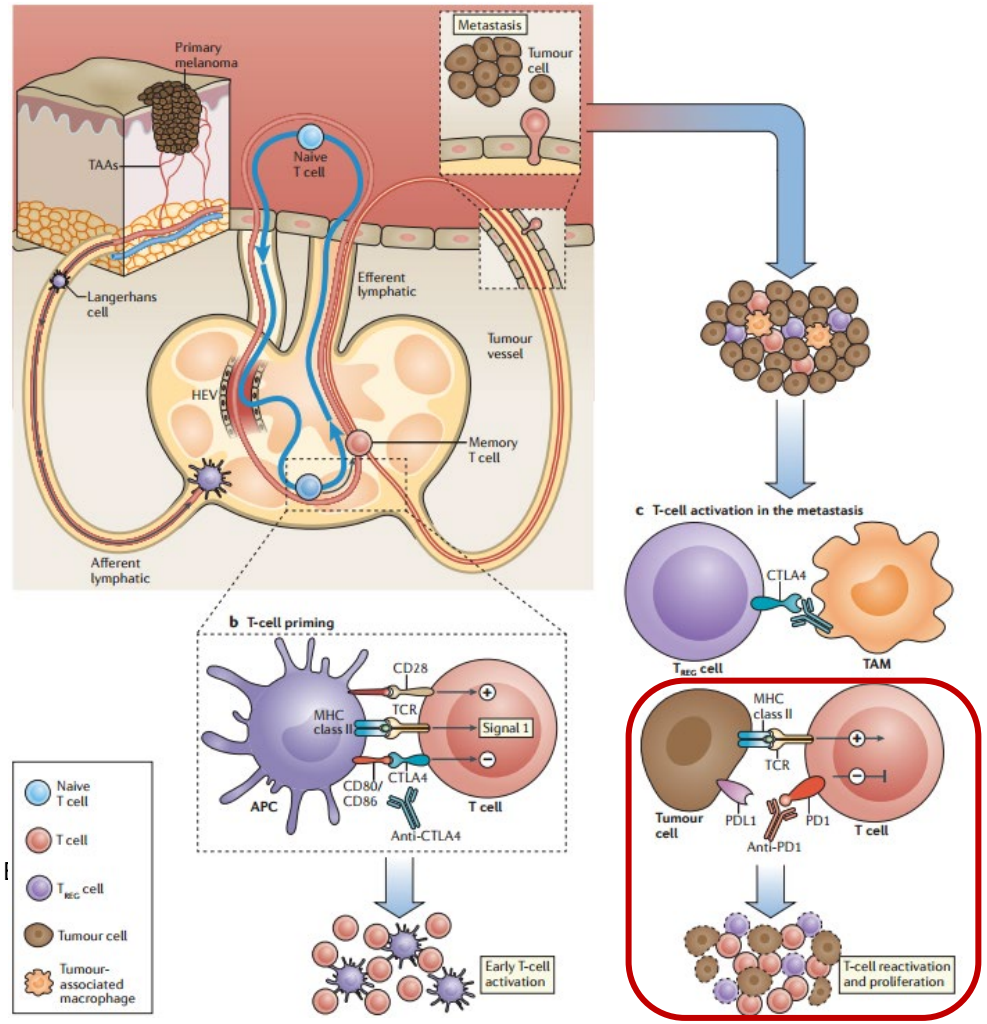
Immunotherapy Targets

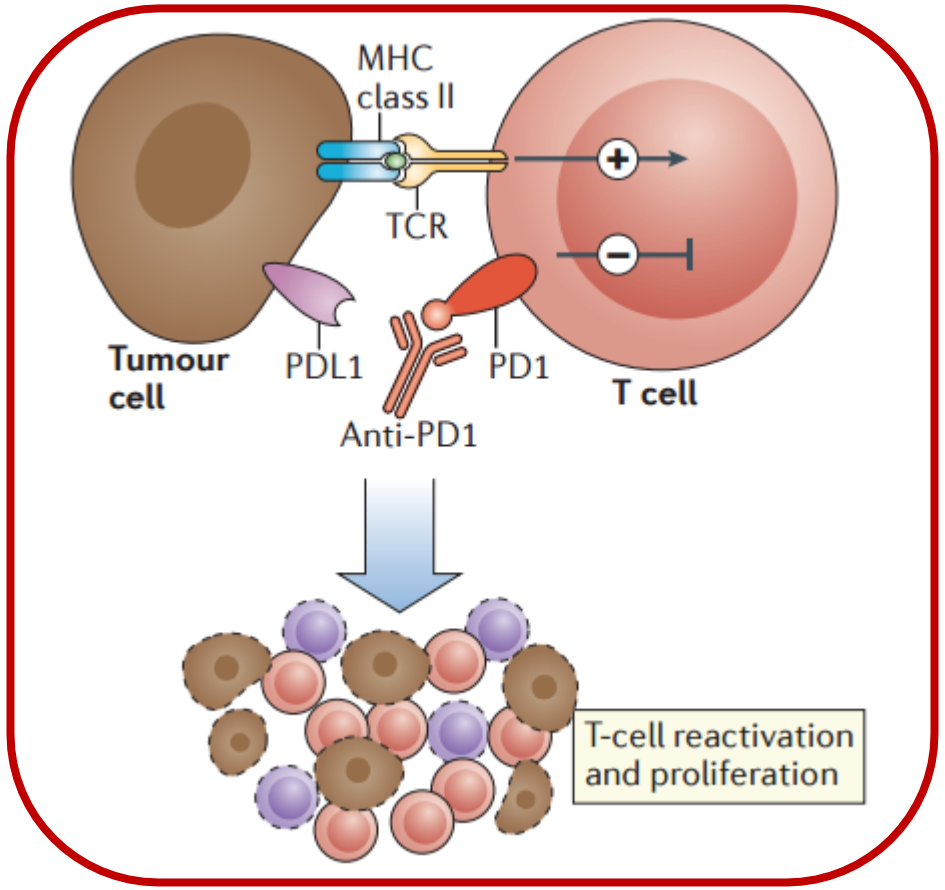


Receptors on T cells and their ligands on antigen-presenting cells

Expert Reviews in Molecular Medicine© 2005 Cambridge University Press

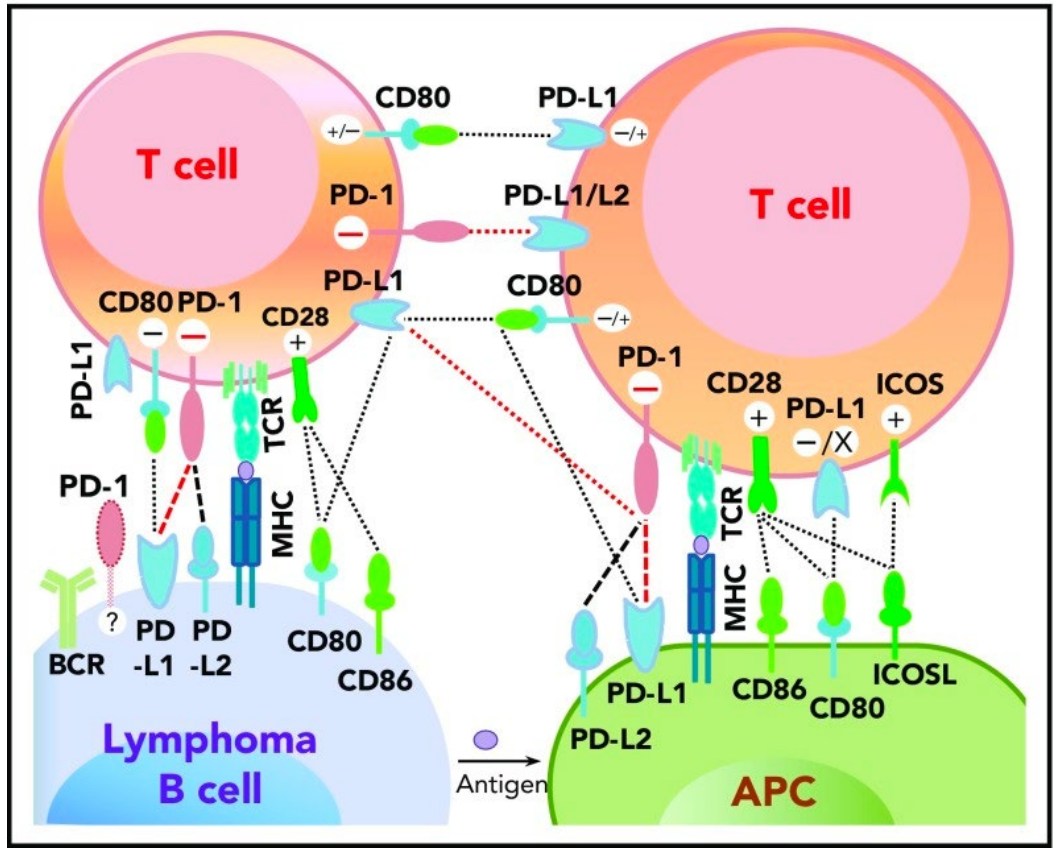
MOA of ICIs: PD-1 and PD-L1





Boutros C, et al. Nat Rev Clin Oncol. 2016;13(8):473-86.

ICIs in Lymphoma



Gatalica, et al. Blood, 2015; 126 (23): 3899.

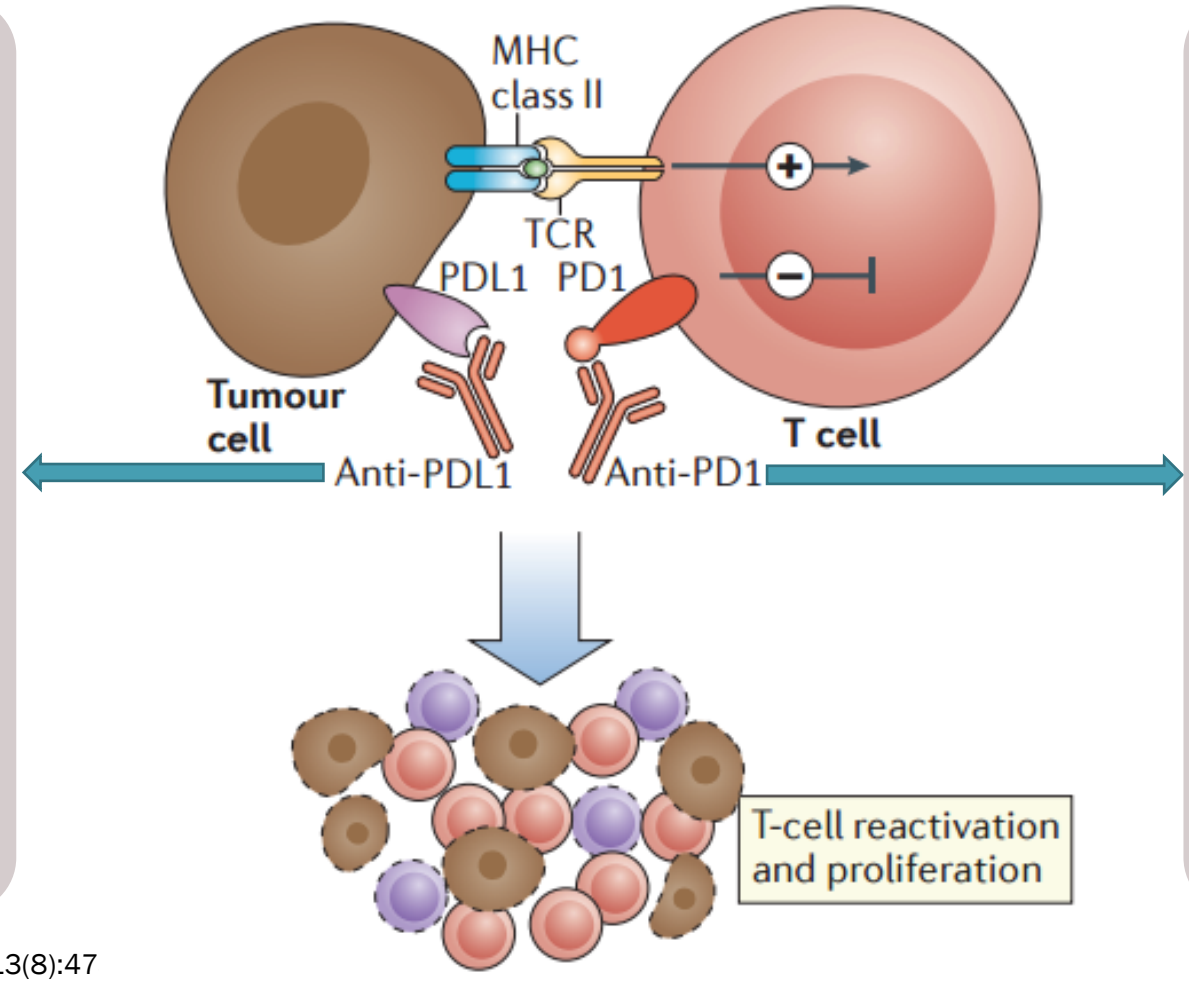
Xu-Monette, et al. Blood. 2018; 131(1): 68–83.

- Overexpression of PD-L1 found in:
  - Classical Hodgkin lymphoma
  - Diffuse large B cell lymphoma
  - T/NK cell lymphoma
  - Lymphomatoid granulomatosis
- High activity also seen in:
  - Follicular lymphoma
  - Primary mediastinal large B cell lymphoma (PMBCL)
  - CLL w/ Richter's
  - Marginal zone lymphoma

Available PD-1 and PD-L1 Agents

PD-L1 Inhibitors

- Atezolizumab
- Avelumab
- Durvalumab



PD-1 Inhibitors

- Pembrolizumab
- Nivolumab
- Cemiplimab
- Dostarlimab

Boutros C, et al. Nat Rev Clin Oncol. 2016;13(8):47

Approved ICIs in Lymphoma

1. Nivolumab

- Approved in classical Hodgkin lymphoma
- Dose: 240mg q 2 weeks or 480mg q 4 weeks
- Toxicities: fatigue (57%), rash (35%), myalgia (32%), headache (23%), ***diarrhea (37%)***, nausea (23%)
- Caution in autoimmune disorders

2. Pembrolizumab

- Approved in relapsed classical Hodgkin lymphoma and PMBCL > 2 lines of therapy
- Dose: 200mg q 3 weeks or 400mg q 6 weeks
- Toxicities: fatigue (28%), rash (24%), arthralgia (18%), cough (17%), ***diarrhea (26%)***, nausea (21%), pruritus (17%)
- Caution in autoimmune disorders

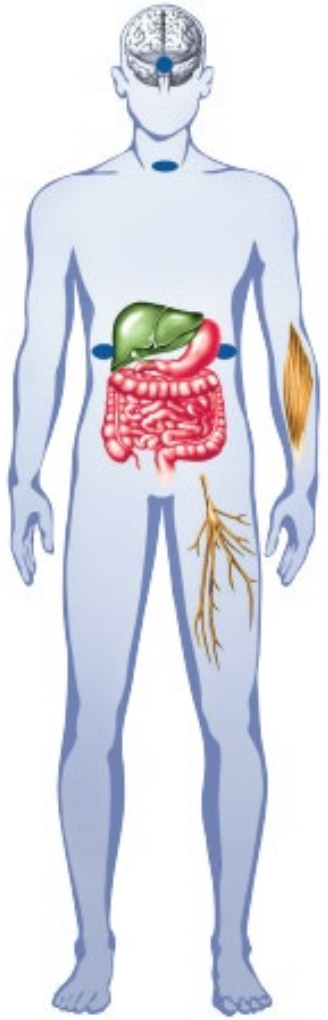
Xu-Monette, et al. Blood. 2018; 131(1): 68–83.

ICIs: Adverse Effects

Endocrine- hypopituitarism, adrenal insufficiency, and thyroid dysfunction

Liver- increase AST/ALT

Gastrointestinal- diarrhea, abdominal pain, bowel perforation, ileus



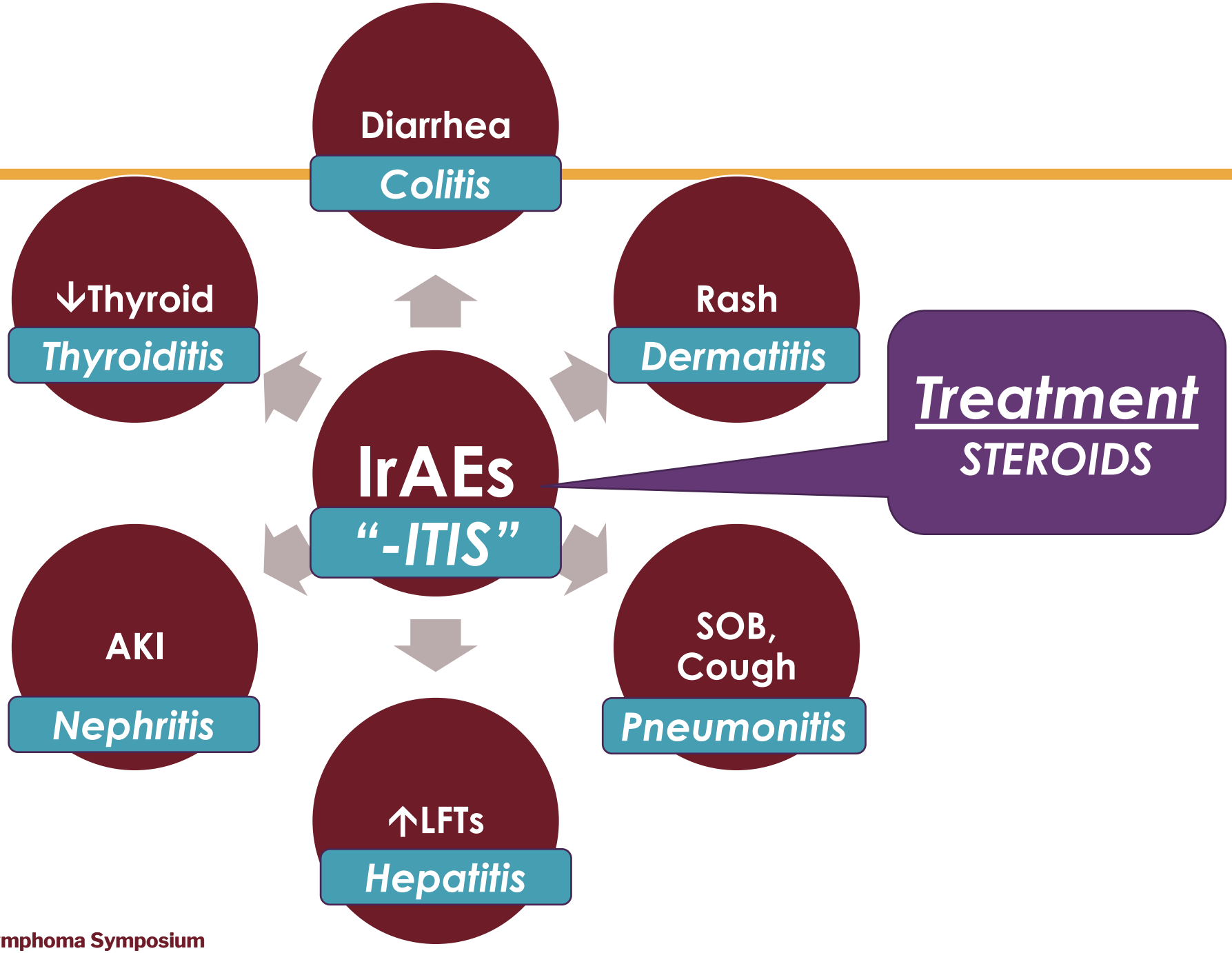
Immune-Related Adverse Effects = IrAEs

Neurologic- fatigue, weakness, sensory alterations, paresthesia

Skin- rash, pruritus

Infusion-related reactions *(rare)*
Autoimmune-related hemolytic anemia

IrAEs


Diarrhea
Colitis
↓Thyroid
Thyroiditis
Rash
Dermatitis
IrAEs
"-ITIS"
Treatment
STEROIDS
AKI
Nephritis
SOB,
Cough
Pneumonitis
↑LFTs
Hepatitis

General IrAE Management

- American Society of Clinical Oncology (ASCO) Guidelines
- Grading of toxicities based off of Common Terminology Criteria for Adverse Events (CTCAE)

GRADE	MANAGEMENT
1	Usually observation; hold for pneumonitis, nephritis
2	Intervention needed – hold ICI, initiate symptom management + steroids
3	Patient admit for management, hold ICI
4	Patient admit for management, permanently discontinue ICI

- Exception: endocrinopathies can usually be managed with hormone replacement and do not require discontinuation

J Clin Oncol. 2018 Jun 10;36(17):1714-1768

Common Terminology Criteria for Adverse Events (CTCAE), 2017

General IrAE Management

- **STEROIDS, STEROIDS, STEROIDS**
  - Prednisone or methylprednisolone 1-2 mg/kg/day (or equivalent)
  - PROLONGED TAPER required over 4-6 weeks
    - In case of flare of symptoms during taper, increase dose of steroids back to high doses
- Refractory – may require infliximab or other immunosuppressive therapy
- Other symptom management – based off of site of IrAE
  - i.e. NSAIDs for myositis, eye drops for uveitis/iritis

J Clin Oncol. 2018 Jun 10;36(17):1714-1768

Patient Case A.B.

- 87-year-old female
- PMH: HTL, HLD, DVT (on apixaban)
- Diagnosis: classical Hodgkin Lymphoma
- Treatment History:
  - Sequential administration of Brentuximab Vedotin + AVD -->PR
  - Not a candidate for HSCT
  - Pembrolizumab monotherapy
    - Initially 200mg q3 weeks
    - Transitioned to 400mg q6 weeks
  - PET-CT following dose #5 with significant reduction in disease burden

Patient Case IrAE

- A.B. reports new symptoms at follow up visit prior to dose #8 of Pembrolizumab monotherapy
- Symptoms include:
  - Mild abdominal discomfort
  - Diarrhea x1 week
    - 2-4 bowel movements per day
  - 2 episodes of rectal bleeding
    - Blood is bright red and large in quantity
    - 1 episode a week prior to visit was unreported
    - 1 episode morning of visit

Clinical Management

- Vital signs
  - BP 142/64, HR 66, Sp02 98% RA, RR WNL
- CBC
- Assess for infection
- Management location
- Discontinue Anticoagulation
- Consider CT imaging
- Hold therapy
- GI referral for urgent colonoscopy/sigmoidoscopy
  - Gold standard for diagnosis
- Slow steroid taper
  - Consider addition of PPI

Nishida, T., Iijima, H., & Adachi, S. (2019). Immune checkpoint inhibitor-induced diarrhea/colitis: Endoscopic and pathologic findings. *World journal of gastrointestinal pathophysiology*, *10*(2), 17–28. https://doi.org/10.4291/wjgp.v10.i2.
Tang, L., Wang, J., Lin, N., Zhou, Y., He, W., Liu, J., & Ma, X. (2021). Immune Checkpoint Inhibitor-Associated Colitis: From Mechanism to Management. *Frontiers in immunology*, *12*, 800879. https://doi.org/10.3389/fimmu.2021.800879

Grading ICI Associated Colitis

Grade 1
Increase <4 stools/day

- Loperamide or atropine x 2-3 days
- Increased hydration
- Consider holding immunotherapy

Grade 2
Increase 4-6 stools/day

- Hold immunotherapy
- Initiate prednisone 1 mg/kg/day
- Consider CT imaging
- If no response in 2-3 days can add infliximab or vedolizumab

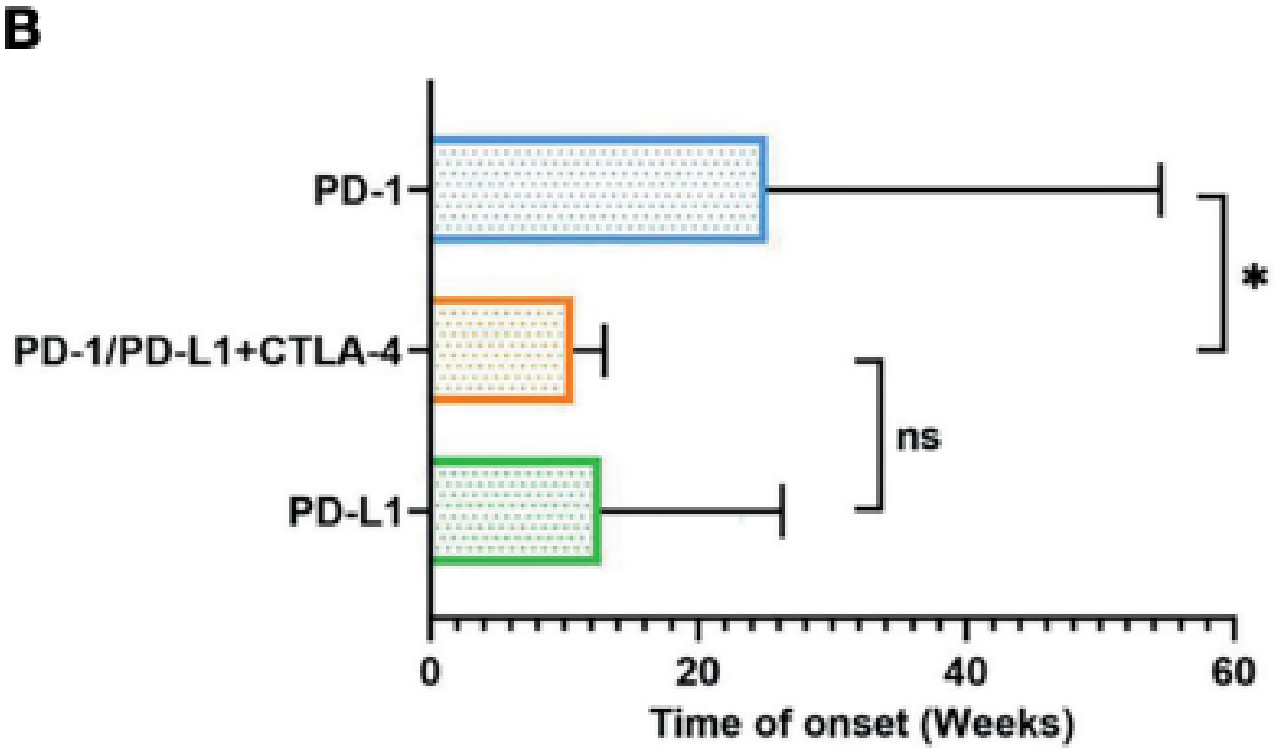
Grade 3-4
Increase >6 stools/day

- IV methylprednisolone 1-2 mg/kg/day
- G3: Hold treatment; consider resuming after resolution
- G4: Discontinue immunotherapy
- Consider inpatient care

NCCN Guidelines for Patients Immunotherapy Side Effects: Immune Checkpoint Inhibitors, 2020

Timing/Onset ICI Diarrhea/Colitis

- Symptoms typically develop within 6-8 weeks after starting therapy



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- NCCN Guidelines for Patients Immunotherapy Side Effects: Immune Checkpoint Inhibitors, 2020

Audience Response Question (MOC)

- G.H. presents with 4 reported stools within the last 24 hours and no other GI symptoms. What grade of ICI diarrhea/colitis does G.H. have and how should it be managed?
  A. Grade 2, continue ICI, administer loperamide
  B. Grade 2, hold ICI, administer steroids
  C. Grade 3, hold ICI, administer steroids
  D. Grade 3, permanently discontinue ICI, admit to hospital

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BTK Inhibitors and Musculoskeletal Adverse Effects

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What is BTK?

- BTK = Bruton Tyrosine Kinase
  - Named for Lt Colonel Ogden C. ***Bruton***
    - Chief of Peds, Walter Reed Army Medical Center in 1950's
    - Discovered first host immunodeficiency, in 1951:

X-linked agammaglobulinemia

Lack of mature B cells and associated immunoglobulins

Pediatrics. 1998 Jul;102(1 Pt 2):213-5.

Cell. 1993;72(2):279–90.

BTK Function

- BTK = non-receptor-linked protein tyrosine kinase
  - B cell development
    - Autophosphorylation leads to upregulation of transcription
  - B cell signaling

Loss of function

→ **X-linked agammaglobulinemia**

Overexpression

→ ***MALIGNANCY***

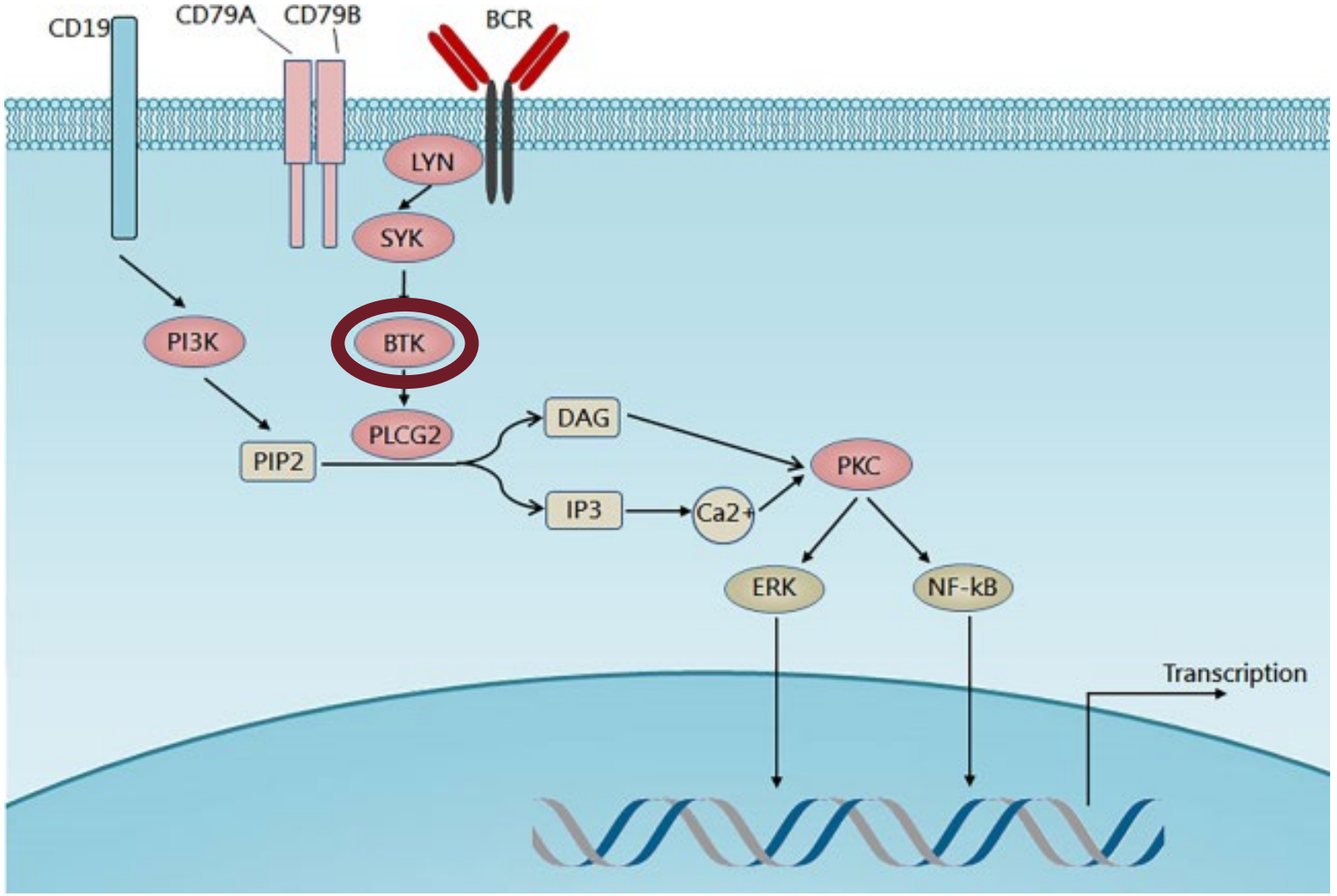
Blood. 2011 Jun 9;117(23):6287-96.

Oncogene. 2017 Apr;36(15):2045-2053.

J Hematol Oncol. 2021 Mar 6;14(1):40.

What is a BTKi?

- BTKi = BTK inhibitor
  - Covalently binds to BTK, inhibiting function
- 1st Gen
  - Ibrutinib
- 2nd Gen
  - Acalabrutinib
  - Zanubrutinib



Modified from: J Hematol Oncol. 2021 Mar 6;14(1):40.

BTKi Place in Therapy

CLL/SLL

Marginal Zone Lymphoma

Mantle Cell Lymphoma

Waldenstrom's Macroglobulinemia

Future:

Hairy Cell Leukemia, Richter's?

BTKi Characteristics

	Ibrutinib	Acalabrutinib	Zanubrutinib
Dose	420-560mg PO daily	100mg PO twice daily	160mg PO twice daily
Renal/ Hepatic D ose Adjust	Reduce in mild-moderate hep impairment, avoid in severe hepatic impairment	Avoid in severe hepatic impairment	Reduce dose in severe hepatic impairment
DDIs	CYP3A4, CYP2D6	**Antacids** CYP3A4, P glyc	CYP3A4

BTKi: Select Non-Heme Adverse Effects

Ibrutinib

- Afib
- Diarrhea
- Hypertension
- Rash
- Arthralgias

Acalabrutinib

- Headaches
- Diarrhea

Zanubrutinib

- Hypertension
- Rash

Am J Hematol. 2019 Dec; 94(12): 1353–1363.

J Clin Oncol. 2021 Nov 1;39(31): 3441-3452.

Future Oncol. 2020 Apr;16(10):517-523.

Patient Case C.D.

- 64-year-old female
- PMH: RA
- Diagnosis: Chronic Lymphocytic Leukemia
- Oncologic History:
  - 2014-2016: Observation
  - 2016: Rituximab + Bendamustine x4 cycles with good response
  - Fall 2016-January 2021: Observation
  - February 2021: Ibrutinib 420mg daily
    - Discontinued due to side effect profile
  - August 2021- Present: Acalabrutinib 100mg BID

Patient Case C.D.

- Ibrutinib Symptoms
  - Myalgias
    - Primarily in BLE
  - Cramping
    - Primarily in BLE
    - Worse at night
  - Arthralgia
    - Left hand
    - Bilateral knees
  - Fatigue
  - BLE swelling
  - HA

- Management
  - Tylenol/Ibuprofen
    - Caution bleeding risk
  - Heat
  - BLE doppler studies to r/o DVT
  - Orthopedics consult for joint pain given history of RA
  - Transitioned to second generation BTKi

Patient Case C.D.

- Acalabrutinib Symptoms
  - Myalgias
    - Primarily in BLE, less severe
    - Essentially resolved by the end of C2
  - Fatigue
  - Ecchymosis
- Management
  - Acetaminophen/Ibuprofen
- Continues to do well

BTKi: Select Non-Heme Adverse Effects

Ibrutinib

- Afib
- Diarrhea
- Hypertension
- Rash
- ***Arthralgias***

Acalabrutinib

- Headaches
- Diarrhea

Zanubrutinib

- Hypertension
- Rash

ARTHRALGIAS

Ibrutinib >> Acalabrutinib > Zanubrutinib

Am J Hematol. 2019 Dec; 94(12): 1353–1363.

J Clin Oncol. 2021 Nov 1;39(31): 3441-3452.

Future Oncol. 2020 Apr;16(10):517-523.

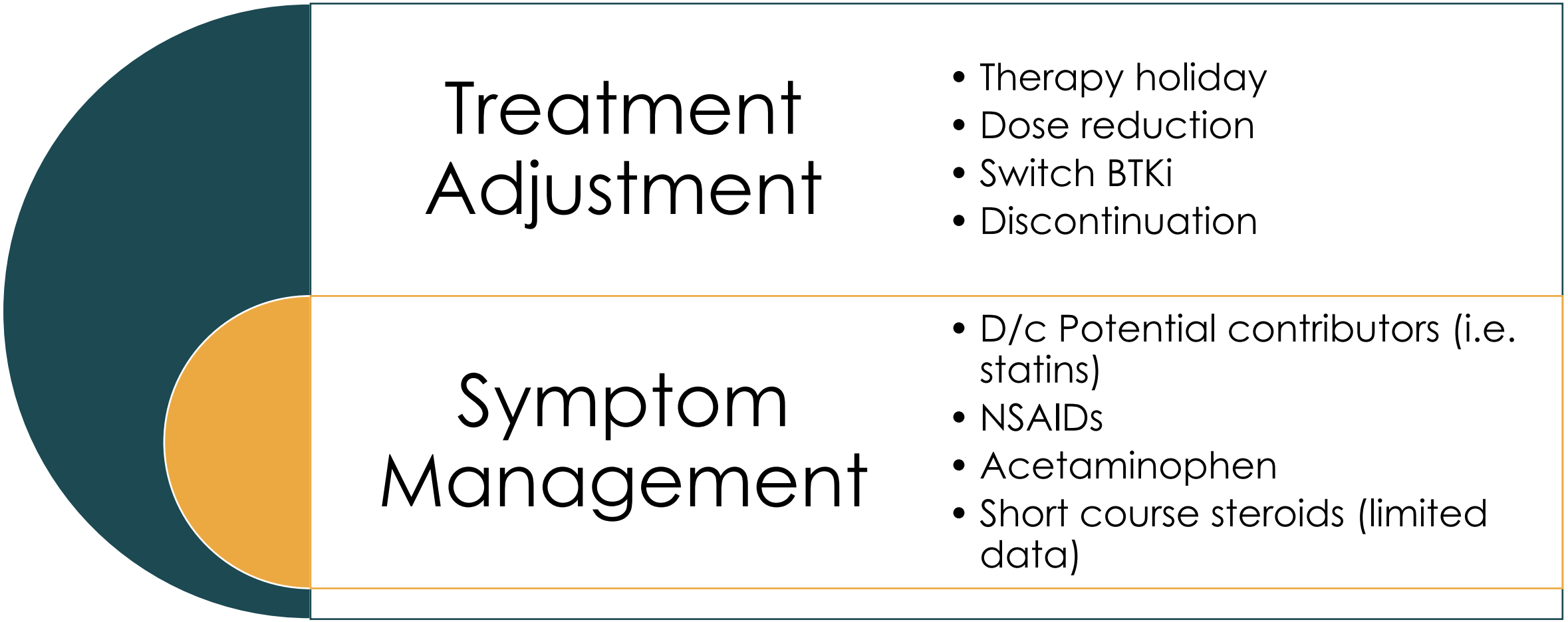
Arthalgia Incidence and Presentation

- Higher risk associated with:
  - Younger > Older
  - Female > Male
  - Frontline BTKi (ibrutinib)
  - H/o autoimmune disease
- Risk of development increases with time
  - Median onset ~34.5 months in single center study (n=214)
- Mostly mild (grades 1-2, CTCAE v. 5.0)
- No formal guidelines or consensus

Clin Lymphoma Myeloma Leuk. 2020 Jul;20(7):438-444.e1

Common Terminology Criteria for Adverse Events (CTCAE), 2017

Management of Arthalgias



Clin Lymphoma Myeloma Leuk. 2020 Jul;20(7):438-444.e1

Audience Response Question (Thought Question)

- I.J. was initiated on ibrutinib 3 months ago and is now presenting with dull, diffuse muscle aches. No other new medications have been started. I.J. is suspicious that the ibrutinib is the cause and wants to completely discontinue the medication. What other options can you provide for I.J.?

Audience Response Question (Thought Question)

- I.J. was initiated on ibrutinib 3 months ago and is now presenting with dull, diffuse muscle aches. No other new medications have been started. I.J. is suspicious that the ibrutinib is the cause and wants to completely discontinue the medication. What other options can you provide for I.J.?
  - Important to continue therapy
  - Consider: switching BTKi or decreasing dose
  - Add-on: acetaminophen or NSAID to help control pain

The Importance of Opportunistic Infection Prophylaxis

Common Opportunistic Infections

VIRAL

Shingles (Herpes Zoster)

Herpes Simplex Virus (HSV)

Cytomegalovirus (CMV)

FUNGAL

Thrush (Candidiasis)

Molds (Aspergillus, Mucormycosis)

BACTERIAL

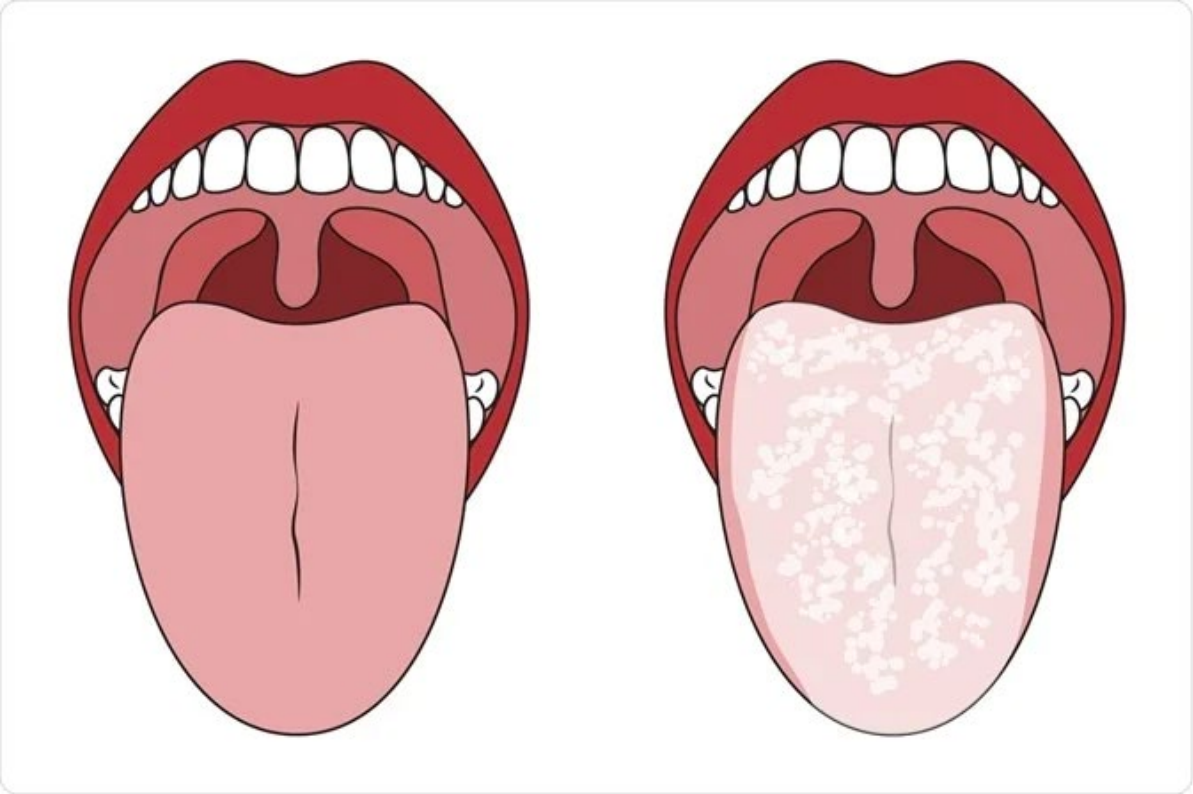
Gram- and + Bacteria (including *Pseudomonas Aeruginosa*)

OTHER

***Pneumocystis jirovecii*/ *Pneumocystis carini* pneumonia (PJP/PCP)**

Oral Candidiasis (Thrush)

- Symptoms:
  - White patches on the inner cheeks, tongue, roof of the mouth, and throat
  - Redness or soreness
  - Cotton-like feeling in the mouth
  - Loss of taste
  - Pain while eating or swallowing
  - Cracking and redness at the corners of the mouth



Oral Candidiasis* Prophylaxis and Treatment

**Oral candidiasis due to Candida albicans*

Prophylaxis

- Fluconazole 200-400mg PO daily
- Nystatin swish and swallow
- Clotrimazole troche

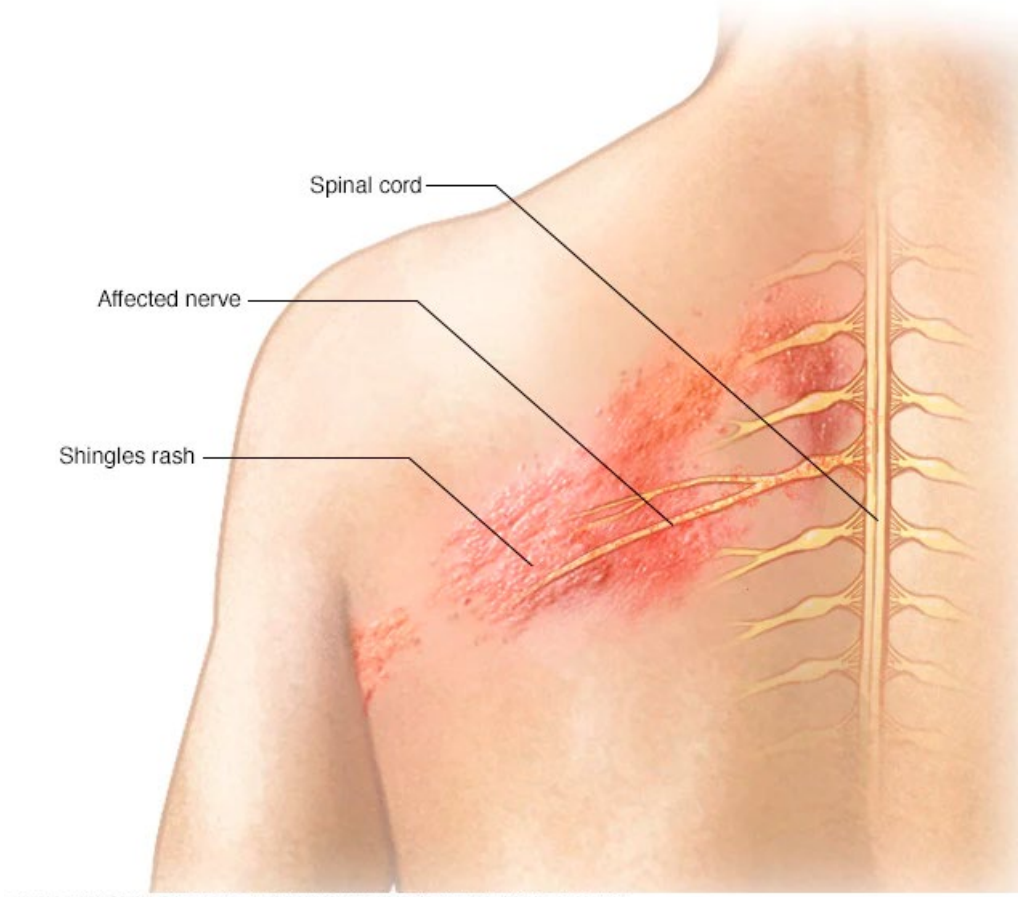
Treatment: 7-14 day course

- Fluconazole 200mg PO loading dose, then 100-200mg PO daily
- Nystatin swish and swallow 400,000-600,000 units four times daily
- Clotrimazole troche 10mg dissolved in mouth five times daily

National Comprehensive Cancer Network. Prevention and Treatment of Cancer-Related Infections (Version 1.2021). https://www.nccn.org/professionals/physician_gls/pdf/infections.pdf. Accessed March 18, 2022.

Herpes Zoster (Shingles)

- Symptoms:
  - Rash: pain, itching, or tingling in the area
  - Fever
  - Headache
  - Chills
  - Upset stomach



Shingles Prophylaxis and Treatment

Prophylaxis

- Acyclovir 400mg PO once-twice daily
- Valacyclovir 500 –1000mg PO once-twice daily
- **In alloSCT, can be used to as prophylaxis for CMV as well*

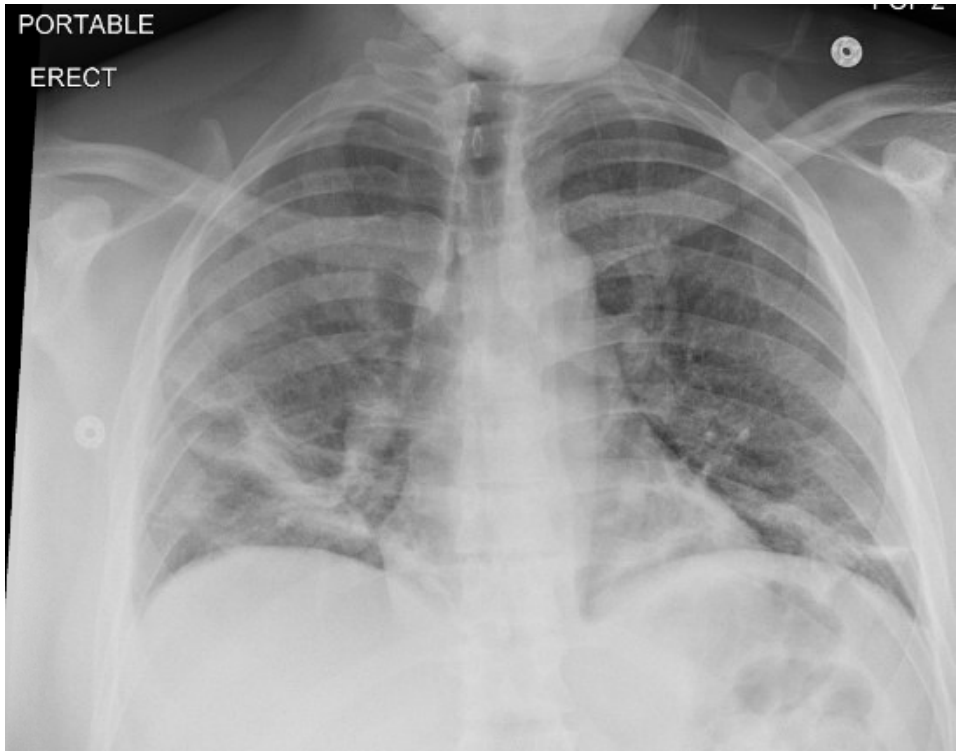
Treatment

- Uncomplicated = 7-10 day course
  - Valacyclovir 1000mg PO three times daily
  - Famciclovir 500mg PO three times daily
  - Acyclovir 800mg PO five times daily
- Complicated, including retinitis, meningitis = 10-14 day course
  - Acyclovir 10-15mg/kg IV every 8 hours

National Comprehensive Cancer Network. Prevention and Treatment of Cancer-Related Infections (Version 1.2021). https://www.nccn.org/professionals/physician_gls/pdf/infections.pdf. Accessed March 18, 2022.

Pneumocystis pneumonia (PJP/PCP)

- Symptoms:
  - Fever
  - Cough
  - Difficulty breathing
  - Chest pain
  - Chills
  - Fatigue (tiredness)



PJP/PCP Prophylaxis and Treatment

Prophylaxis

- Sulfamethoxazole-trimethoprim (TMP-SMX): 1 DS tablet PO MWF
- Atovaquone: 1500mg PO daily
- Pentamidine: 300mg IV or inhaled once monthly
- Dapsone: 100mg PO daily

Treatment: 21 day course

- TMP-SMX: 15-20mg/kg/day IV or PO given as 3-4 divided doses
- Consider adjuvant steroids: prednisone 40mg PO twice daily

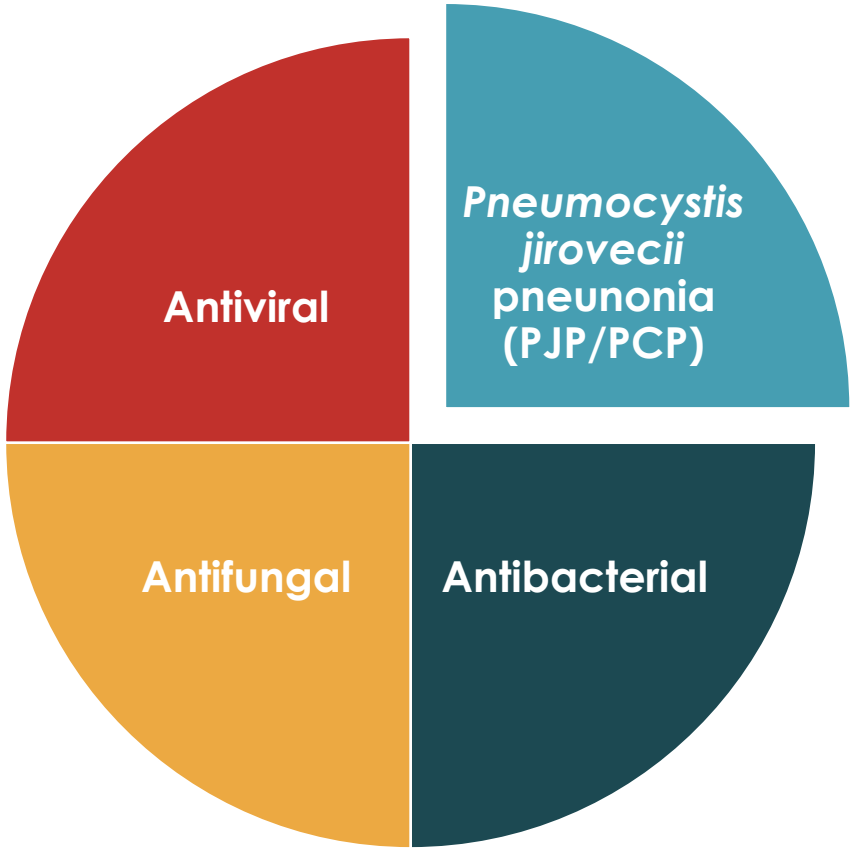
National Comprehensive Cancer Network. Prevention and Treatment of Cancer-Related Infections (Version 1.2021). https://www.nccn.org/professionals/physician_gls/pdf/infections.pdf. Accessed March 18, 2022.

Risk Factors For Opportunistic Infection

- Prolonged periods of neutropenia
- HSV-seropositive patients receiving chemotherapy
- Number of prior therapies
- High dose corticosteroids
  - Backbone of ICI IrAE management
- T-cell depleting therapy (Fludarabine)
- HBsAg-positive and/or HBcAb-positive
- Prolonged periods of lymphopenia
- Duration of therapy

National Comprehensive Cancer Network. Prevention and Treatment of Cancer-Related Infections (Version 1.2021).
Rogers, K.A., Mousa, L., Zhao, Q. *et al.* Incidence of opportunistic infections during ibrutinib treatment for B-cell malignancies. *Leukemia* **33,** 2527–2530 (2019). https://doi.org/10.1038/s41375-019-0481-1

What is the usual opportunistic infection prophylaxis?



- General considerations:
  - Disease state
  - Treatment regimen, including intensity
  - Patient specific factors (comorbidity, age)
  - Drug interactions

Example Prophylaxis: CLL

REGIMEN	Antiviral: Acyclovir 400 mg BID	Antifungal: Fluconazole 200 mg QD while neutropenic	Antibacterial: Levofloxacin 500 mg QD while neutropenic	PJP/PCP Prophylaxis: TMP-SMX 1 tablet MWF
BTKi	yes	consider	consider	consider
PI3K Inhibitor	yes	yes	yes	yes
Venetoclax – Obinutuzumab*	yes	yes	yes	yes
Bendamustine-Rituximab*	yes	yes	yes	yes

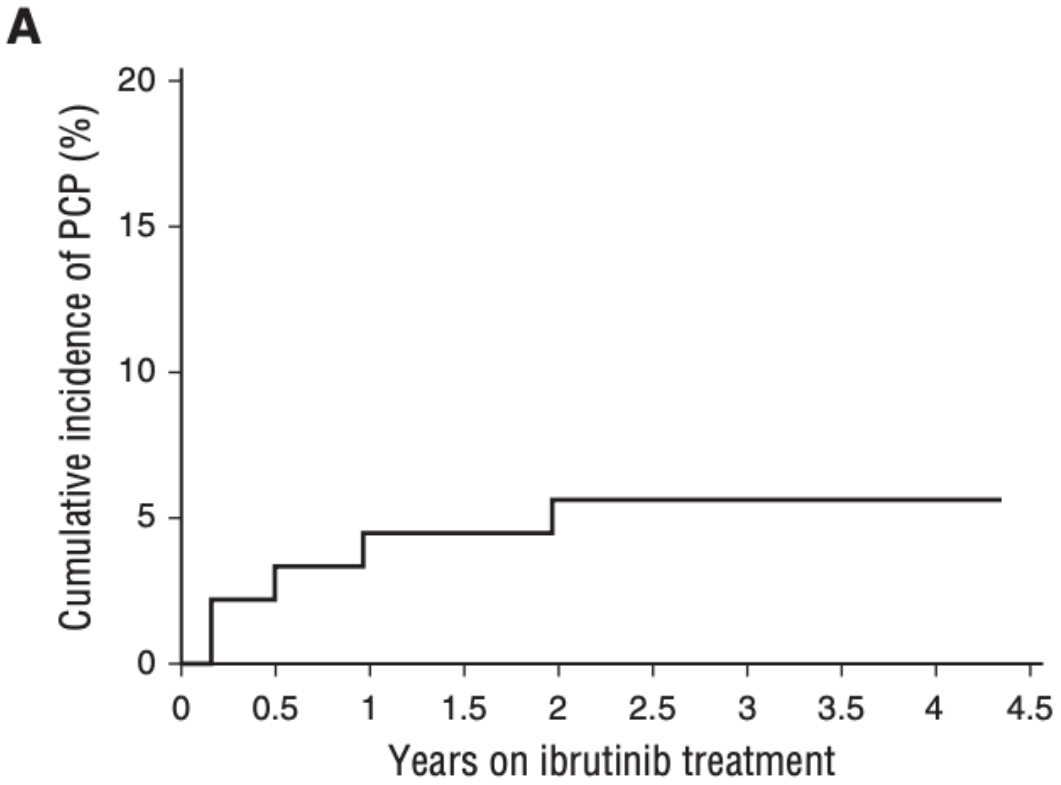
* For patients with latent Hepatitis B, antiviral prophylaxis with entecavir or tenofovir warranted

J Clin Oncol. 2018 Oct 20;36(30):3043-3054.

National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf Accessed March 18, 2022.

National Comprehensive Cancer Network. Prevention and Treatment of Cancer-Related Infections (Version 1.2021). https://www.nccn.org/professionals/physician_gls/pdf/infections.pdf. Accessed March 18, 2022.

PJP/PCP Prophylaxis with BTKi: Yes or No?



- PJP/PCP prophylaxis not normally prescribed for patients on BTKi therapy
- 5 of 96 patients on ibrutinib monotherapy were diagnosed with PJP/PCP, none were on prophy
- Median time of onset: 6 months post-initiation of ibrutinib

Ahn, et al. Blood. 2016 Oct 13;128(15):1940-1943.

Patient Case E.F.

- 26-year-old male
- PMH/PSH: Gastritis, appendicitis, appendectomy
- Diagnosis: CD5+ Diffuse Large B-cell Lymphoma, double expressor phenotype
- Oncologic Background:
  - August 2018: developed worsening abdominal pain with BRBPR and fevers/chills
    - Multiple ED visits/hospitalizations to work up progressing symptoms
  - September 2018: presented to ED with acute abdominal pain fevers, and tachycardia. CT abd/pelvis showed a thickened loop of distal small bowel with associated abscess. Due to the location of the abscess, he ultimately underwent an exploratory laparotomy, partial small bowel resection with primary anastomosis, and drainage of an intra-abdominal abscess Intraoperative findings were consistent with a perforated small bowel with associated abscess. Pathology reflective of Diffuse Large B-cell Lymphoma
- Treatment:
  - R-CHOP X6 cycles + IT MTX x4 for CNS prophylaxis
    - Restaging PETCT following completion of C3 c/w CR1

Patient Case E.F.

- Following completion of C4 E.F. presents to ED with non-neutropenic fevers. Otherwise feeling well.
  - Tmax 101.7
  - Infectious work-up
    - Blood cultures
    - Urinalysis w/reflex culture
    - CXR
    - Labs
      - Lactic acid 2.4 (H)
  - Admit to oncology unit

Hospital Course

- Persistent fevers with unclear etiology
  - Empiric antibiotics
- New leukocytosis
- Non-productive cough/sore throat
  - CT imaging- findings concerning for PNA
- New hypoxia requiring supplemental 02
  - Increasing oxygenation requirements
- Bronchoscopy
  - +Pneumocystis Jirovecii
  - IV Bactrim + Prednisone

E.F. PCP treatment

- Started IV TMP-SMX with immediate resolution of fevers and improvement in hypoxia/SOB.
- O2 requirements weaned off over next several days
- Therapy delayed to allow for further improvement clinically
- Slow Prednisone taper
- Oral antibiotics sulfamethoxazole-trimethoprim 800-160mg 2 tablet PO QID x 3 weeks
- Completed 6th cycle of R-CHOP on 2/2020

Prophylaxis

- Clear benefit in patients with certain risk factors
- Generally well tolerated
- Cost effective
- Consider drug interactions
- More research is needed with continued advances in targeted therapies

Audience Response Question (ARS)

- K.L. has been newly diagnosed with CLL and has been offered treatment with acalabrutinib. What prophylaxis should K.L. be offered?
  - A. Acyclovir 400mg PO twice daily
  - B. Sulfamethoxazole and trimethoprim 1 tablet Mondays, Wednesdays, and Fridays
  - C. Both A and B
  - D. None of the above

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  Acyclovir should be offered to K.L. with strong consideration for PCP/PJP prophylaxis with Bactrim DS.

Questions?

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