Fred Hutch Cancer Center

Supportive care in myeloma: Why are there so many pills??

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PNW MM Fighters – March 25, 2023

UW Medicine

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Disclosures

- Consulting: BMS/Celgene, Caribou Biosciences, Genentech/ Roche, Janssen Oncology, Sanofi Pasteur, SparkCures

- Research funding: Pack Health

- Every patient's case is different – your healthcare team knows the details of your specific treatment better than I do!

Agenda

- 20 min: Infection prevention in myeloma
- 5 min: Blood clot prevention in myeloma
- 10 min: Dex, dex, and more dex….
- 25 min: Question & answer session

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Microbiology 101 for the patient with MM

- **Bacterial infections:**
  - Historically the scariest type of infection (e.g., “septic shock” or “*C diff*” for those of you who have been hospitalized)
  - Most likely to occur during prolonged neutropenia, i.e.:
    - Absolute neutrophil count (ANC) < 500 cells / microliter
    - Prolonged, meaning likely to last more than one week
  - General principles of treatment:
    - Antibiotics, either oral or intravenous
    - In some cases, e.g., urinary bacteria without symptoms, can observe

Abbreviations: C diff, *Clostridium difficile*.

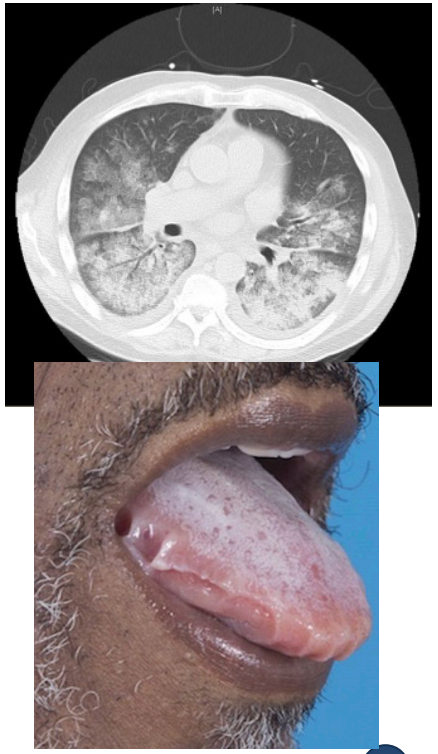
Microbiology 101 for the patient with MM

- **Viral infections:**
  - **Before March 2020:**
    - Respiratory viruses: influenza and RSV
    - Painful viruses: VZV, a.k.a. chickenpox & shingles
    - Rare cases such as allo transplant: CMV reactivation
  - **After March 2020:** All the above, plus COVID-19
  - General principles of treatment:
    - Pills when we have them, for example Tamiflu® (oseltamivir) for mild influenza or Paxlovid® (nirmatrelvir / ritonavir) for mild COVID-19
    - Acyclovir or valacyclovir (Valtrex®) for VZV (shingles)

Abbreviations: VZV, varicella zoster virus.

Microbiology 101 for the patient with MM

- **Fungal infections:**
  1. **PJP**, formerly called PCP (*Pneumocystis*):
     - One of the first AIDS-defining illnesses (under different circumstances) in the 1980s
     - Main risk: prolonged steroids
  2. **Thrush** caused by *Candida albicans*:
     - Commonly associated with any type of immunosuppression, particularly T-cell drugs
     - Risk factors: any of our drugs
     - In my experience: AL amyloidosis as well

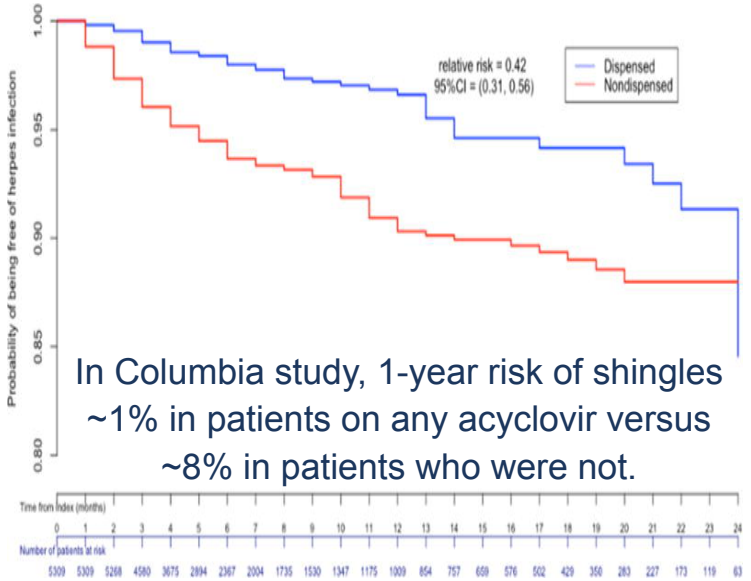


Abbreviations: PJP, *Pneumocystis jirovecii* pneumonia.

Swan CD, Reid AB. IDCases. 2014;1(3):32-5. PMID: 26955521.
Williams MU et al. BMJ Case Rep. 2018;11(1):e225923. PMID: 30580294.

Virus protection in MM – VZV (shingles)

- **Why might I be on acyclovir or valacyclovir (Valtrex®)?**
  - To prevent shingles reactivation while on proteasome inhibitors such as bortezomib (Velcade®) or carfilzomib (Kyprolis®)
  - To prevent shingles reactivation while on CD38 mAbs such as daratumumab (Darzalex®) or isatuximab (Sarclisa®)

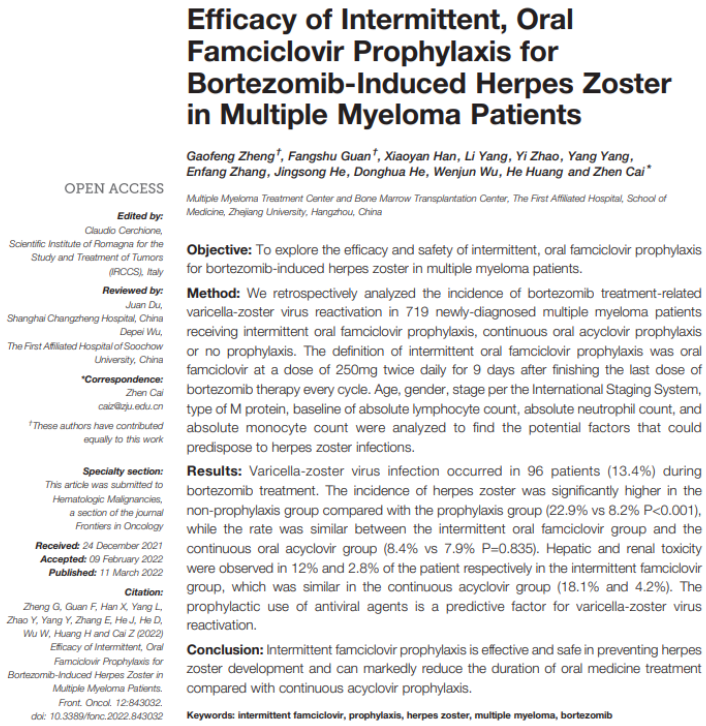


In Columbia study, 1-year risk of shingles ~1% in patients on any acyclovir versus ~8% in patients who were not.

Leng S et al. Leuk Lymphoma. 2018;59(10);2465-2469. PMID: 29390929.

Which shingles medication & what dose?

- **No head-to-head studies, so up to you and your healthcare team:**
  - Acyclovir was historically dosed twice, daily, but at Fred Hutch we're transitioning to 400mg once-daily!
  - No real evidence that Valtrex® has lower rate of side effects
- **What about famciclovir?** Thanks Connie for this interesting study!
- FYI: All 3 meds cost about the same



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Efficacy of Intermittent, Oral Famciclovir Prophylaxis for Bortezomib-Induced Herpes Zoster in Multiple Myeloma Patients

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Multiple Myeloma Treatment Center and Bone Marrow Transplantation Center, The First Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou, China

Objective: To explore the efficacy and safety of intermittent, oral famciclovir prophylaxis for bortezomib-induced herpes zoster in multiple myeloma patients.

Method: We retrospectively analyzed the incidence of bortezomib treatment-related varicella-zoster virus reactivation in 719 newly-diagnosed multiple myeloma patients receiving intermittent oral famciclovir prophylaxis, continuous oral acyclovir prophylaxis or no prophylaxis. The definition of intermittent oral famciclovir prophylaxis was oral famciclovir at a dose of 250mg twice daily for 9 days after finishing the last dose of bortezomib therapy every cycle. Age, gender, stage per the International Staging System, type of M protein, baseline of absolute lymphocyte count, absolute neutrophil count, and absolute monocyte count were analyzed to find the potential factors that could predispose to herpes zoster infections.

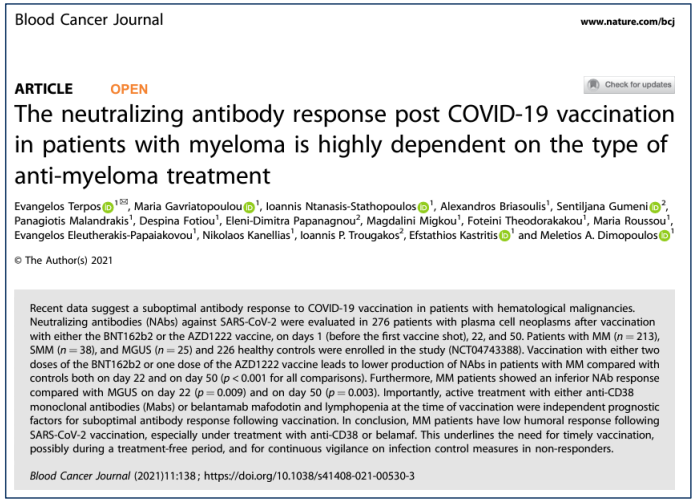
Results: Varicella-zoster virus infection occurred in 96 patients (13.4%) during bortezomib treatment. The incidence of herpes zoster was significantly higher in the non-prophylaxis group compared with the prophylaxis group (22.9% vs 8.2% P<0.001), while the rate was similar between the intermittent oral famciclovir group and the continuous oral acyclovir group (8.4% vs 7.9% P=0.835). Hepatic and renal toxicity were observed in 12% and 2.8% of the patient respectively in the intermittent famciclovir group, which was similar in the continuous acyclovir group (18.1% and 4.2%). The prophylactic use of antiviral agents is a predictive factor for varicella-zoster virus reactivation.

Conclusion: Intermittent famciclovir prophylaxis is effective and safe in preventing herpes zoster development and can markedly reduce the duration of oral medicine treatment compared with continuous acyclovir prophylaxis.

Keywords: intermittent famciclovir, prophylaxis, herpes zoster, multiple myeloma, bortezomib

Virus protection in MM – COVID-19

- **MM therapies, in particular CD38 antibodies (Darzalex®, Sarclisa®), likely increase the risk of both:**
  - Lack of protective response to COVID-19 vaccinations, even with booster
  - Prolonged shedding (meaning positive tests) even after clinical recovery
- **Unfortunately, Evusheld® no longer helpful as a preventive strategy**
  - Hopefully newer formulations coming!



Blood Cancer Journal www.nature.com/bcj

ARTICLE OPEN

The neutralizing antibody response post COVID-19 vaccination in patients with myeloma is highly dependent on the type of anti-myeloma treatment

Evangelos Terpos[1✉], Maria Gavriatopoulou[1], Ioannis Ntanasis-Stathopoulos[1], Alexandros Briasoulis[1], Sentiljana Gumeni[2], Panagiotis Malandrakis[1], Despina Fotiou[1], Eleni-Dimitra Papanagnou[2], Magdalini Migkou[1], Foteini Theodorakakou[1], Maria Roussou[1], Evangelos Eleutherakis-Papaiakovou[1], Nikolaos Kanellias[1], Ioannis P. Trougakos[2], Efstathios Kastritis[1] and Meletios A. Dimopoulos[1]

Recent data suggest a suboptimal antibody response to COVID-19 vaccination in patients with hematological malignancies. Neutralizing antibodies (NAbs) against SARS-CoV-2 were evaluated in 276 patients with plasma cell neoplasms after vaccination with either the BNT162b2 or the AZD1222 vaccine, on days 1 (before the first vaccine shot), 22, and 50. Patients with MM ($n = 213$), SMM ($n = 38$), and MGUS ($n = 25$) and 226 healthy controls were enrolled in the study (NCT04743388). Vaccination with either two doses of the BNT162b2 or one dose of the AZD1222 vaccine leads to lower production of NAbs in patients with MM compared with controls both on day 22 and on day 50 ($p < 0.001$ for all comparisons). Furthermore, MM patients showed an inferior NAb response compared with MGUS on day 22 ($p = 0.009$) and on day 50 ($p = 0.003$). Importantly, active treatment with either anti-CD38 monoclonal antibodies (Mabs) or belantamab mafodotin and lymphopenia at the time of vaccination were independent prognostic factors for suboptimal antibody response following vaccination. In conclusion, MM patients have low humoral response following SARS-CoV-2 vaccination, especially under treatment with anti-CD38 or belamaf. This underlines the need for timely vaccination, possibly during a treatment-free period, and for continuous vigilance on infection control measures in non-responders.

Blood Cancer Journal (2021)11:138; https://doi.org/10.1038/s41408-021-00530-3

FDA announces Evusheld is not currently authorized for emergency use in the U.S.

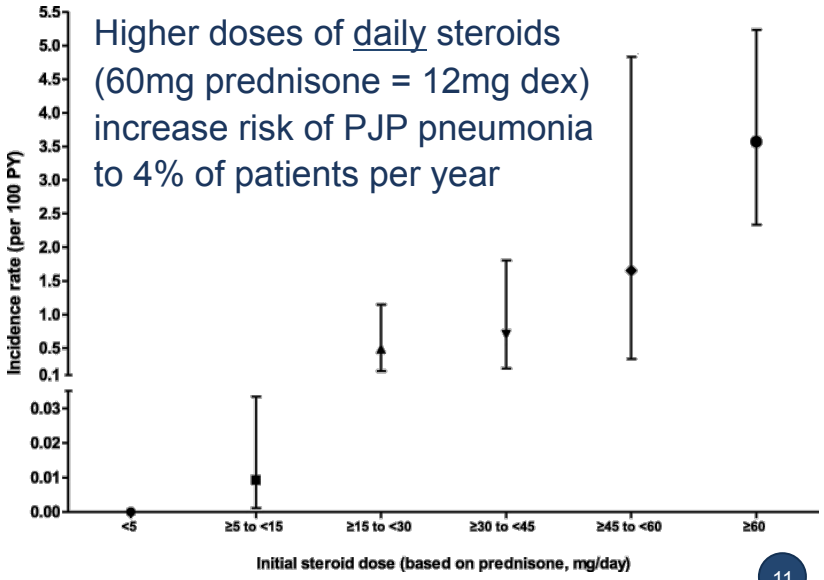
Update [1/26/2023] The U.S. Food and Drug Administration today revised the Emergency Use Authorization (EUA) for Evusheld (tixagevimab co-packaged with cilgavimab) to limit its use to when the combined frequency of non-susceptible SARS-CoV-2 variants nationally is less than or equal to 90%. Based on this revision, **Evusheld is not currently authorized for use in the U.S. until further notice by the Agency.**

Terpos E et al. Blood Cancer J. 2021. 11(8):138. PMID: 34341335.

FDA. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-evusheld-not-currently-authorized-emergency-use-us> Accessed 7 Mar 2023.

Fungal prevention in MM – PJP (*Pneumocytis*)

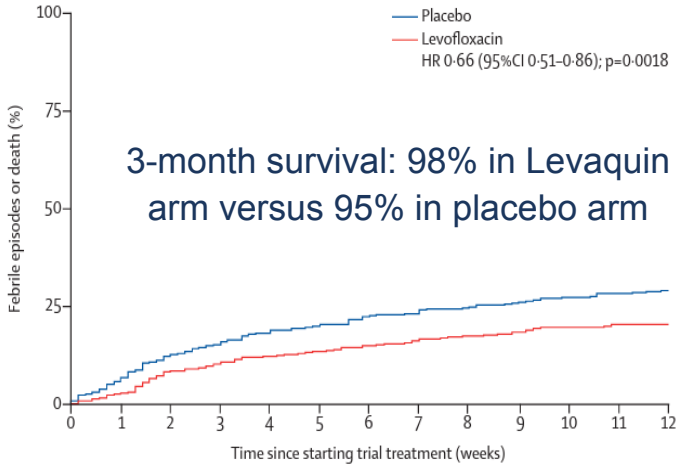
- **Why might I be on Bactrim® or Septra®?***
  - Generic name: Sulfamethoxazole / trimethoprin
  - To prevent PJP pneumonia when T-cells are depleted *(myeloma cells are B-cell lineage)*
  - Biggest risk factor: Daily, not weekly, dexamethasone use
  - We generally don't use this outside of transplant, CAR-T therapy, etc.



* Atovaquone (Mepron ®) liquid can be used for patients with sulfa allergies.
Park JW et al. Arthritis Res Ther. 2019;21(1):207. PMID: 31521185.

Bacterial prevention in MM – Levaquin

- **Why might I be on levofloxacin (Levaquin®) antibiotics?**
  - Commonly: During prolonged neutropenia, e.g. with traditional chemotherapy and/or transplant
  - Unique: t(11;14) amyloidosis or MM receiving venetoclax
  - More controversial: First 3 months of for all newly diagnosed MM patients
    - Slightly lower risk of death, **BUT…**



Drayson MT et al. Lancet Oncol. 2019;20(12):1760-1772. PMID: 31668592/

Bacterial prevention in MM – Levaquin

- **Why <u>don't</u> most US centers use Levaquin prophylaxis with all newly diagnosed patients for the first 3 months?**
  - Increased pill burden, possible *C diff* risk
  - Fluoroquinolones are associated with a real risk of tendinopathy (i.e., painful Achilles tendon in heel) that can be problematic

	Levofloxacin group			Placebo group		
	Grade 1–2 (n=37)	Grade 3 (n=26)	Grade 4 (n=8)	Grade 1–2 (n=17)	Grade 3 (n=14)	Grade 4 (n=3)
Musculoskeletal and connective tissue disorders						
Chest wall pain	0	0	0	0	1 (7%)	0
Myalgia	1 (3%)	0	0	0	0	0
Neck pain	1 (3%)	0	0	0	0	0
Extremity pain	1 (3%)	0	0	0	0	0
Tendonitis	3 (8%)	2 (8%)	0	0	0	0
Other	0	1 (4%)	0	0	0	0

Grade 1: Mild

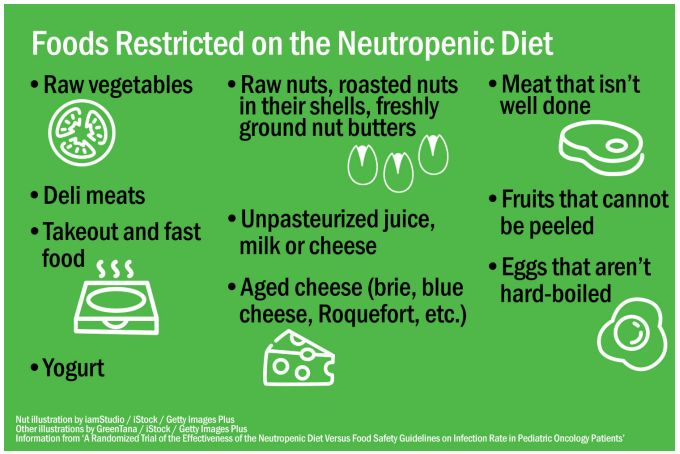
Grade 2: Interferes with doing day-to-day activities independently

Grade 3: Interferes with basic physical function (e.g., walking)

Drayson MT et al. Lancet Oncol. 2019;20(12):1760-1772. PMID: 31668592/

What about neutropenic diets?

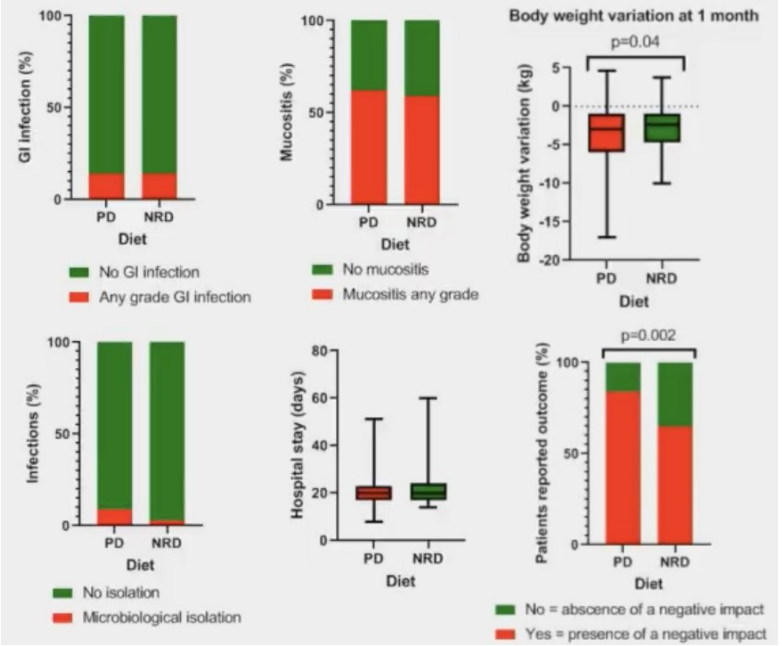
- **Neutropenic diets:** A mainstay of cancer care for decades, including likely for many of you
- **Evidence in their favor:** Barely any
- **Reasons why maybe unhelpful:**
  - Hard enough to eat anything as it is during chemo & transplant
  - In my experience, bacterial infections normally from oral/gut bacteria and NOT from external food



Jones B. <https://www.cancertodaymag.org/cancer-talk/questioning-an-entrenched-practice/> Accessed 6 Mar 2023.

The latest proof of harm from neutropenic diets

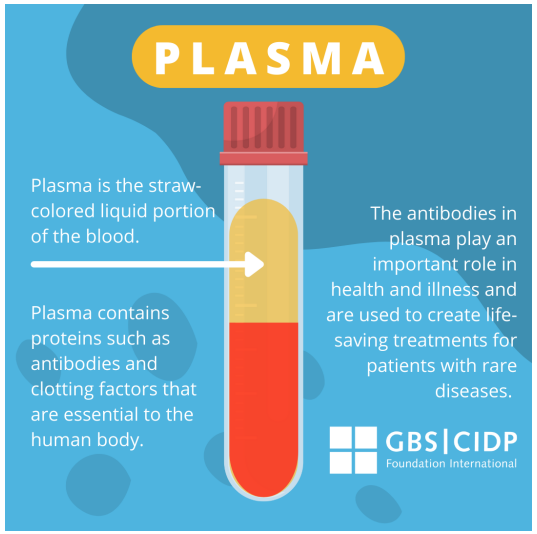
- **NEUTRODIET** study presented at #ASH22 last December
- Patients undergoing any type of transplantation or high-dose chemotherapy were randomized to:
  - PD: “Protective diet” (neutropenic)
  - NRD: Non-restrictive diet
- **No difference in infections**
  - However, non-restricted patients lost less weight and felt better!



Stella F et al. Blood. 2022. 140(Suppl_1):417-419.

What about IVIG (IV immunoglobulin)?

- **IVIG is basically a pooled "transfusion" of antibodies from other donors.**
- Helpful in "immunoparesis," meaning normal plasma cells aren't making normal antibodies
  - Reason #1: Myeloma cells crowding them out
  - Reason #2: Targeted by our myeloma drugs
- **So whom do we prescribe IVIG to?**
  - Commonly: After CAR-T therapy (Abecma®, (Carvykti®) or bispecific antibodies (Tecvayli®)
  - Less commonly: Frequent infections, particularly viral infections several times per year



GBS/CIDP Foundation International. <https://www.gbs-cidp.org/plasma-please/> Accessed 7 Mar 2023.

Agenda

- 20 min: Infection prevention in myeloma
- **5 min: Blood clot prevention in myeloma**
- 10 min: Dex, dex, and more dex….
- 25 min: Question & answer session

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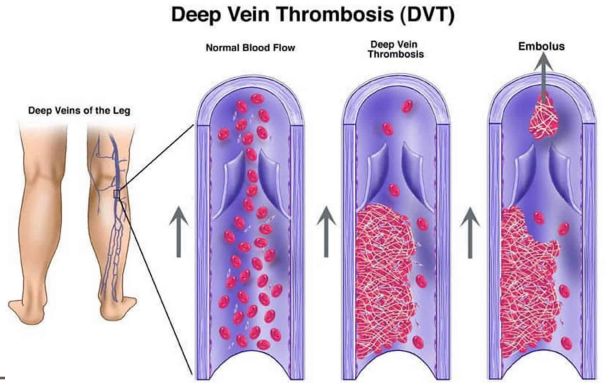
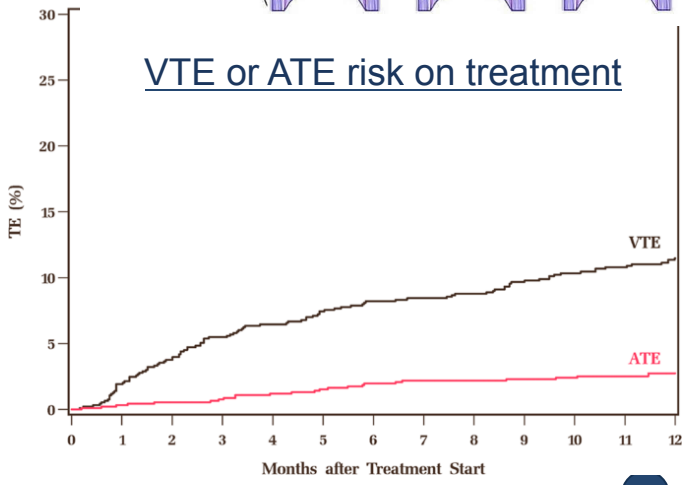
MM and blood clots

- **Venous (VTE):** Blood clots in legs, arms, or lungs (PE)
- **Arterial (ATE):** Strokes & heart attacks
- **Most relevant for IMID pills**: Lenalidomide (Revlimid®) or Pomalidomide (Pomalyst®)
- **Historical thinking**: Risk is highest while on multidrug therapy
- **My thinking**: Risk of clot lasts for as long as the IMID does

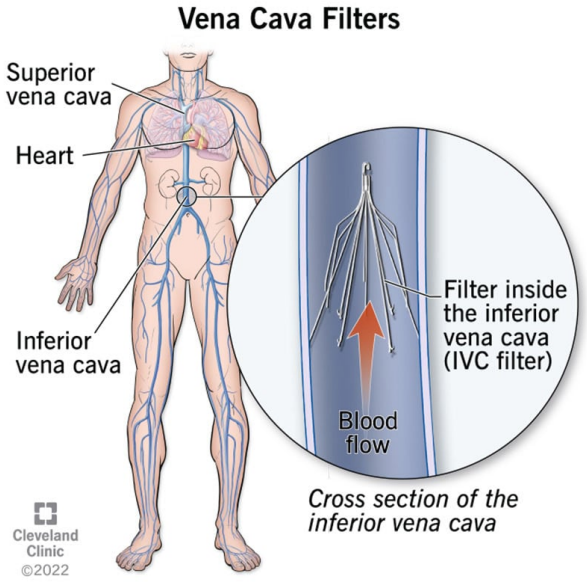




Baljevic M, Sborov DW, Lim MY, et al. J NCCN. 2022;20(1):91-95. PMID: 34991076.
Chakraborty R, Rybicki L, Valent J, et al. Blood Cancer J. 2021;11(6):121. PMID: 34172719.
Abbreviations: VTE, venous thromboembolism; ATE, arterial thromboembolism; IMID, immunomodulatory imide drug; PE, pulmonary embolism..

How might we lower the risk of blood clots?

- **Oral options:**
  - Aspirin, either 81mg (baby) or 325mg daily
  - Apixaban (Eliquis®) every 12 hours
  - Rivaxoraban (Xarelto®) once per day
- **Non-oral options:**
  - Enoxaparin (Lovenox®), an injectable derivative of heparin, once per day
  - Compression stockings, encouraging mobility, or even IVC filters [1]



Cleveland Clinic. <https://my.clevelandclinic.org/health/treatments/17609-vena-cava-filters> Accessed 9 Mar 2023.
Abbreviations: IVC, inferior vena cava.

Can we predict who will get blood clots?

- **Several risk models: SAVED, IMPEDE-VTE, PRISM**
  - Each independently validated but each a bit messy to implement

	SAVED	IMPEDE-VTE	PRISM
Older age	Higher	*N/A*	*N/A*
Certain race	Lower if Asian	Lower if Asian	Higher if Black
Obesity	*N/A*	Higher	*N/A*
History of VTE	Higher	Higher	Higher
Procedures / immobility	Higher	Higher	Higher
Abnormal cytogenetics	*N/A*	*N/A*	Higher
MM-related meds	Higher if dex/IMID	Higher if IMID or EPO	Higher if IMID
Already on aspirin	*N/A*	Lower	*N/A*

Li A, Wu Q, Luo S, et al. J NCCN. 2019;17(7):840-847. PMID: 31319391.
Sanfilippo KM, Luo S, Wang T, et al. Am J Hematol. 2019;94(11):1176-1184. PMID: 31379000.
Chakraborty R, Rybicki L, Wei W, et al. Blood. 2022;140(23):2443-2450. PMID: 35772005.

What about carfilzomib (Kyprolis®)?

- **K, and especially K+R, might raise risk of thrombosis:**
  - ASPIRE: 6.6% risk with **KR**d versus 3.9% with Rd
  - ENDURANCE: 4.9% with **KR**d versus 2.1% with VRd
  - FORTE: 13% with **KR**d-ASCT vs 4% with KCd-ASCT
  - FORTE: 3% with **KR** maintenance vs 1% with R maintenance
- **Why is this the case?**
  - Carfilzomib causes endothelial (blood vessel) dysfunction
  - May also explain heart and blood pressure issues

Stewart AK, Dimopoulos MA, Masszi T, et al. JCO. 2016;34(32):3921-3930. PMID: 27601539.
Gay F, Musto P, Rota-Scalabrini D, et al. Lancet Oncol. 2021;22(12):1705-1720. PMID: 34774221.
Kumar SJ, Jacobus SJ, Cohen AD, et al. Lancet Oncol. 2020;21(10:1317-1330. PMID: 32866432.
Kastritis E, Laina A, Georgiopoulos G, et al. Leukemia. 2021;35(5):1418-1427.

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Does stronger VTE prevention do better?

- **Yes, at least with Kyprolis + Revlimid:**
  - VRd + aspirin: 5% risk of VTE
  - KRd + aspirin: 16% risk of VTE
  - KRd + rivaroxaban: 5% risk of VTE
- **Limitations of this analysis:**
  - Not a randomized study of aspirin versus a newer pill
  - Blood clots weren't checked per protocol, only for symptoms

Piedra K, Peterson T, Tan C, et al. Br J Haematol. 2022;196(1):105-109. PMID: 34396516.

So what do I say for blood clot prevention?

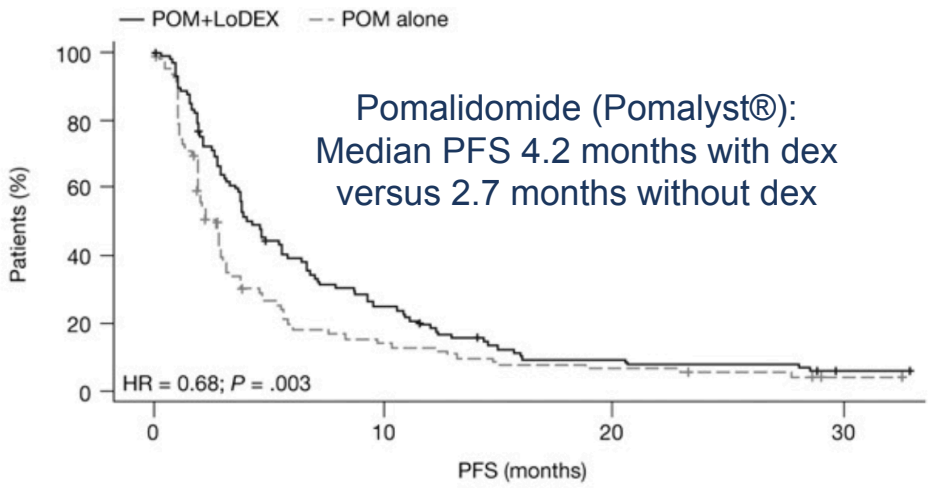
- **During induction therapy:**
  - Apixaban (Eliquis®) for most (Rivaroxaban = Xarelto® is once-daily but has a potentially slightly higher bleeding risk)
  - Baby aspirin if a big bleeding risk or bad insurance
  - If not on Revlimid®, I don't use a particular medication at all
- **During maintenance:**
  - Baby aspirin for most, unless aspirin allergy
  - Lifestyle: spell out your name with legs while on the plane!

Agenda

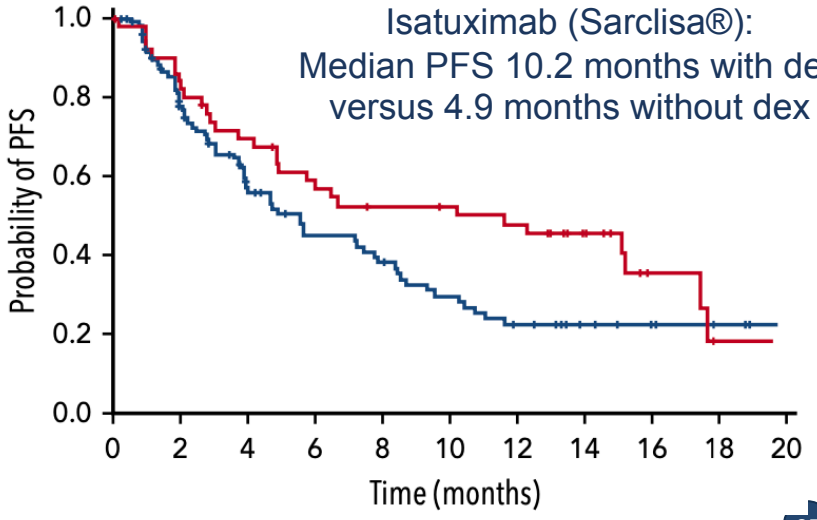
- 20 min: Infection prevention in myeloma
- 5 min: Blood clot prevention in myeloma
- **10 min: Dex, dex, and more dex….**
- 25 min: Question & answer session

Why do we use dexamethasone?

- Synergy with other anti-myeloma medications
- Can prevent infusion reactions, bone pain, or nausea



Pomalidomide (Pomalyst®):
Median PFS 4.2 months with dex
versus 2.7 months without dex



Isatuximab (Sarclisa®):
Median PFS 10.2 months with dex
versus 4.9 months without dex

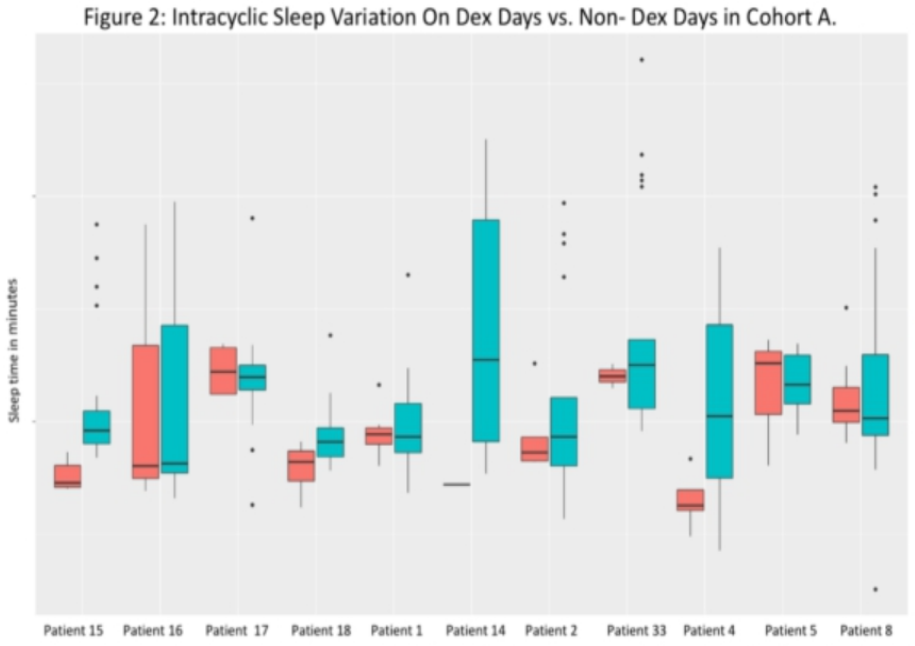
*PFS, progression-free survival (time without myeloma relapse or death).
Richardson PG et al. Blood 2014. PMID: 24421329.
Dimopoulos M et al. Blood 2021. PMID: 33080623.

Why do we hate dexamethasone?

- **Acute side effects**: Jitteriness, anxiety, insomnia, irritability, increased appetite, leg swelling, weight gain, and of course:
  "My partner is a monster on steroid days!"
- **Long-term issues as well, although most commonly studied with daily steroid use:**
  - Worsened bone health
  - Susceptibility to infections
  - Skin changes (acne, easy bruising)
  - Decreased core muscle strength
  - Pre-diabetes

Case study #1: Dex and insomnia

- Patients sleep 81 fewer minutes on dex days than on other days
- Insomnia more pronounced in younger patients
- Thankfully, overall sleep only dropped 6 minutes per night (on average)



Figures refer to Cohort A. Figure courtesy of Neha Korde, MD.
Hevroni G et al. JCO. 2021;39(15_suppl):8040. [#ASCO21 poster].

Case study #2: Dex and cataracts

- Among adults aged 60-70 in the DREAMM-2 study of Blenrep® (belantamab) in 3+ prior lines of therapy:

	US population	DREAMM-2 baseline
Cataracts	11-31%	60%
Glaucoma	1-4%	12%

- Risk factors: Steroids, steroids, steroids, & Velcade®

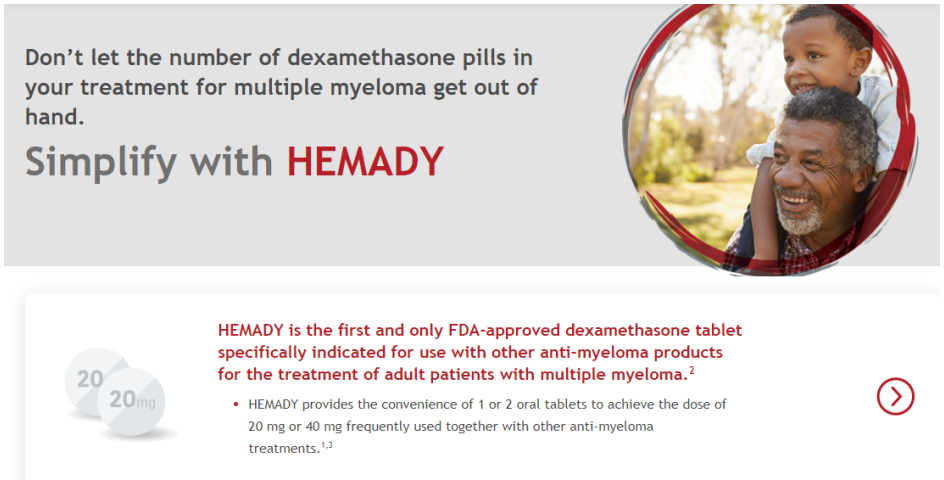
Baseline ocular conditions and BCVA for DREAMM-2 pooled analysis group (N=218)

		Present	Absent	Missing
	Any of the below ocular conditions, n (%)	196 (89.9)	22 (10.1)	0
	Ocular conditions by area of the eye effected, n (%)			
Cornea	– Keratopathy	103 (47.2)	115 (52.8)	0
Cornea	– Dry eye	43 (19.7)	175 (80.3)	0
Lens	– Cataract	130 (59.6)	82 (37.6)	6 (2.8)
Retina	– Age-related macular degeneration	8 (3.6)	49 (22.5)	161 (73.9)
Optic nerve	– Glaucoma	26 (11.9)	192 (88.1)	0
External / eyelid	– Blepharitis	45 (20.6)	169 (77.5)	4 (1.8)
	BCVA, n (%)			
Vision	– 20/30 or better	174 (79.8)	44 (20.2)	0
Vision	– Worse than 20/30 to 20/50 or better	28 (12.8)	190 (87.2)	0
Vision	– Worse than 20/50	16 (7.3)	202 (92.7)	0

Congdon N et al. Arch Ophth 2004. PMID: 15078665.
Gupta P et al. Invest Ophthal Vis Sci 2016. PMID: 27168366.
Slide courtesy of Dr. Rakesh Popat, MD. Presented at: Popat R et al. #IMS22 abstract OAB-049.

Why don’t they make 20-mg dex tabs?

- They do! Hemady® is equivalent to 4-mg tabs x5 (Bashir 2020)
- However, the GoodRx cost for 160mg is $200 vs $15…



Bashir Q et al. CLML. 2020. 20(11):768-773. PMID: 32900662.
No endorsement intended. Prices from goodrx/dexamethasone or goodrx.com/hemady

Can we lower the dose of dex?

- **What most trials use:**
  - Dex 40mg weekly for most patients
  - Dex 20mg weekly for patients aged ≥ 75
- **My personal non-evidence-based style:**
  - Start with the above, but dex 20mg if aged ≥ 70
  - *Any* issues with 40mg? Drop to 20mg immediately.
  - *Any* issues with 20mg? Drop to 12mg immediately.
  - *Any* issues thereafter? Stop altogether.

Can we adjust the dose of dex?

- **Certainly worth considering**
  - Dex 20mg on back-to-back days (versus dex 40mg once weekly) might help with steroid “let down”
  - As early in the morning as possible is the most “natural” dosing
- **What if you get dex in clinic as an allergy pre-medication?**
  - Ask if you can take the dex at home before driving in (or if you can stop!)

TABLE 1.
SUGGESTED DOSE SCHEDULING CHANGES FOR WEEKLY DEXAMETHASONE[a]

WEEKLY DOSE[a]	RECOMMENDED ADJUSTMENT	ALTERNATE ADJUSTMENT
40 mg on day 1	20 mg on days 1–2	20 mg on day 1, 12 mg on day 2, and 8 mg on day 3
20 mg on day 1	12 mg on day 1 and 8 mg on day 2	12 mg on day 1 and 4 mg on days 2–3
12 mg on day 1	8 mg on day 1 and 4 mg on day 2	8 mg on day 1 and 2 mg on days 2–3

[a] By mouth or IV
Note. Based on information from Faiman et al., 2008; Larocca & Palumbo, 2015; Zweegman et al., 2014.

EDITORIALS

Maximizing Home Time for Persons With Cancer

Check for updates

Rahul Banerjee, MD[1]; Manju George, MVSc, PhD[2]; and Arjun Gupta, MD[3]

Show More

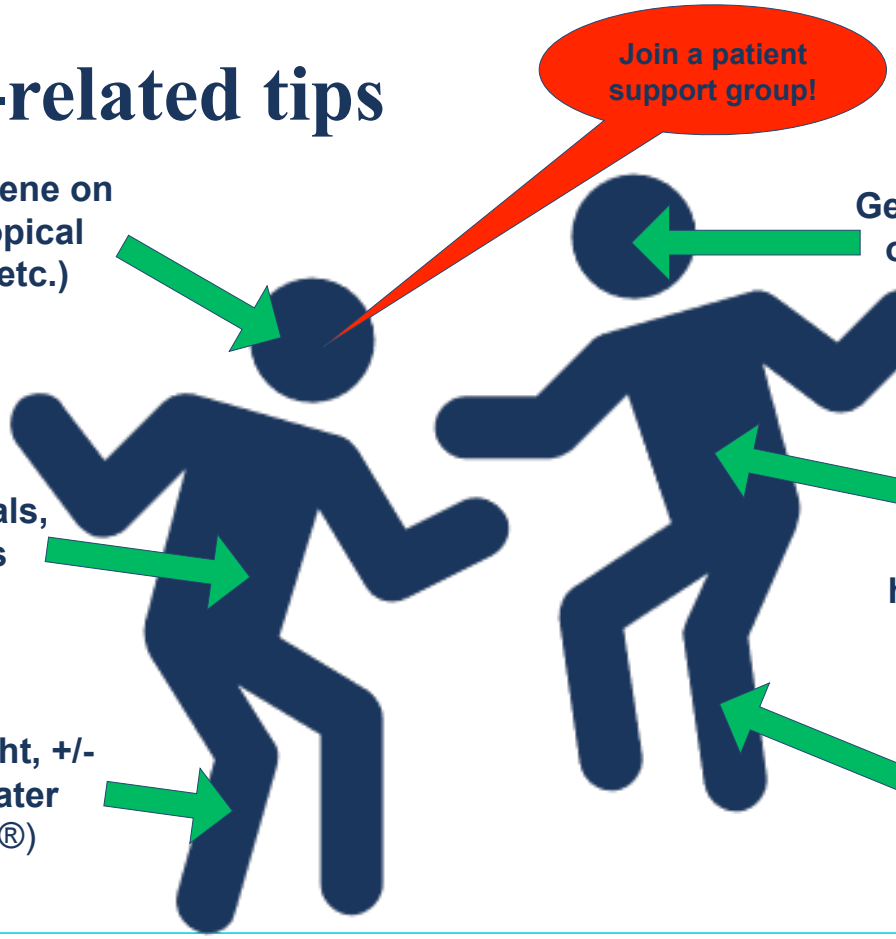
King T, Faiman B. Clin J Oncol Nurs 2017. 21(2):240-249. PMID: 28315528.

Can we stop the dex altogether?

- **With induction:** Great study of older patients with MM who were somewhat frail (Larocca 2021)
  - Arm 1: Lenalidomide (Revlimid®) + dex for 9 months, then lower-dose lenalidomide maintenance indefinitely
  - Arm 2: Lenalidomide (Revlimid®) + dex indefinitely
  - Results: Equal efficacy, fewer issues with ↓ blood counts
- **With maintenance:** Absolutely!
  - *Exception: 1-2 cycles of "consolidation" after transplant, if used*

Larocca A et al. Blood. 2021. 137(22):3027-3036. PMID: 33739404.

Other dex-related tips



@rahulbanerjeemd

Fred Hutch
Cancer Center

Thank you!

> "In 2005, a man diagnosed with multiple myeloma asked me if he would be alive to watch his daughter graduate from high school in a few months. In 2009, bound to a wheelchair, he watched his daughter graduate from college. The wheelchair had nothing to do with his cancer. The man had fallen down while coaching his youngest son's baseball team."
>
> — Siddhartha Mukherjee, The Emperor of All Maladies: A Biography of Cancer

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