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SPOTLIGHT ON MYELOPROLIFERATIVE NEOPLASMS (MPNs)

Aaron T. Gerds, MD, MS
Associate Professor of Medicine, Hematology & Medical Oncology
Deputy Director for Clinical Research
Cleveland Clinic Taussig Cancer Institute
Medical Director
Case Comprehensive Cancer Center Clinical Research Office
Cleveland, OH

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WELCOMING REMARKS

SPOTLIGHT ON MYELOPROLIFERATIVE NEOPLASMS (MPNs)

Lizette Figueroa-Rivera, MA
Senior Director, Education & Support
The Leukemia & Lymphoma Society
Rye Brook, NY

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WELCOMING REMARKS

SPOTLIGHT ON MYELOPROLIFERATIVE NEOPLASMS (MPNs)

This program is supported by

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PRESENTATION

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DISCLOSURES

SPOTLIGHT ON MYELOPROLIFERATIVE NEOPLASMS (MPNs)

Aaron T. Gerds, MD, MS

The following relationships have ended and have been mitigated prior to this presentation:

Consulting/Advisory: AbbVie, BMS, CTI Biopharma, Imago, Morphosys, Novartis, PharmaEssentia, Sierra Oncology/GSK

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Objectives

1. The different types of MPNs
2. Therapies for MPNs
3. Current Research and Clinical Trials
4. Managing Side Effects

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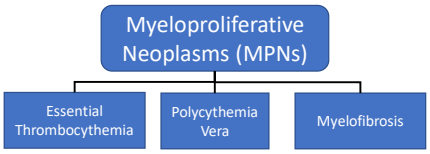
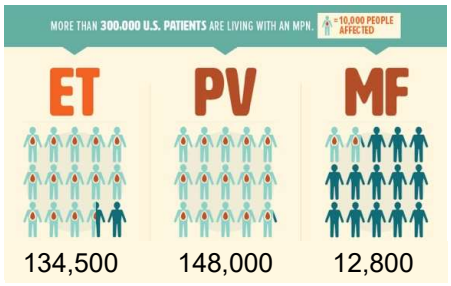
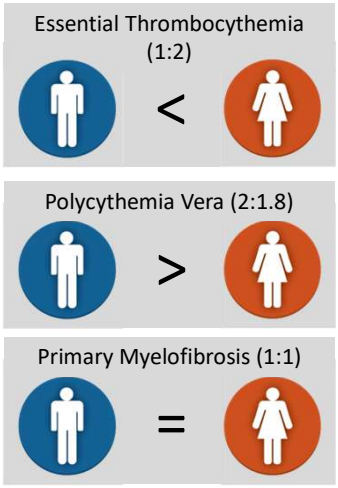
Overview of MPNs







Median age at Diagnosis:

ET	56 years
PV	61 years
MF	65 years

Treatment Options

Phlebotomy

Medication
- JAKi
- Interferons
- Anagrelide
- Hydroxyurea

Hematopoietic Cell Transplantation

Mehta L, et al. *Leuk Lymphoma*. 2014;55:595–600

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What are the MPNs?

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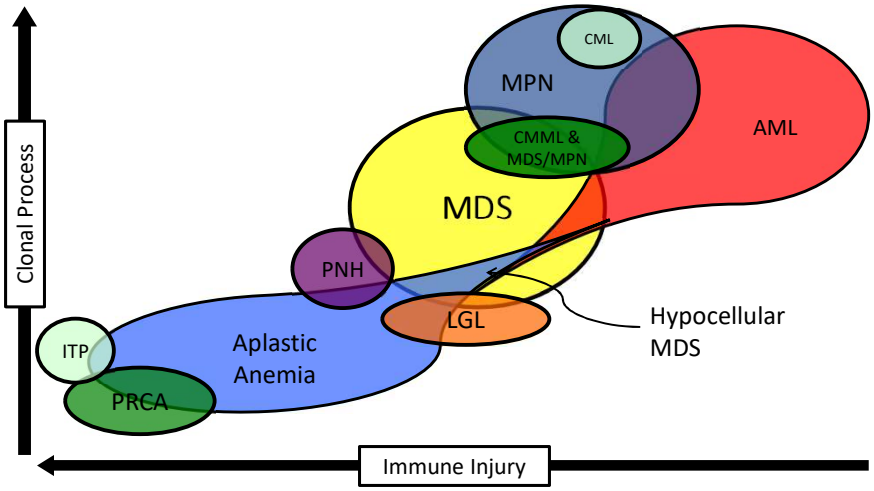
What is a cancer?

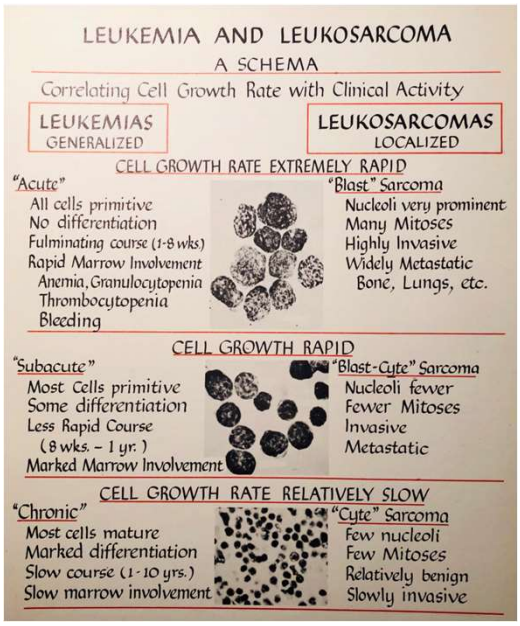
Oxford dictionary: The disease caused by an uncontrolled division of abnormal cells in a part of the body (from Latin *cancr* meaning crab)

Mural Study for Cancer, 1948; Clarence Van Duzer (1920–2009)

Spectrum of Marrow Failure



Gerds, AT. *Curr Hematol Malig Rep*. 2014 Dec;9(4):400–6



A classification of leukemia and lymphoma presented at the 1949 American Medical Association Annual Meeting in Atlantic City

Courtesy of David Steensma

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2022 ICC Classification

Myeloid Neoplasms

- Acute Myeloid Leukemia
- Myelodysplastic Syndromes
- Myeloproliferative Neoplasms
- Mastocytosis
- MDS/MPN Overlap Syndromes
- Myeloid neoplasms with germ line predisposition
- Myeloid/lymphoid neoplasms with eosinophilia and rearrangement of *PDGFRA*, *PDGFRB*, or *FGFR1*, or with *PCM1-JAK2*

Arber et al. *Blood* 2022. *epub ahead of print.*

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Myeloid Neoplasms

- Acute Myeloid Leukemia
- Myelodysplastic Syndromes
- Myeloproliferative Neoplasms
  - Chronic myeloid leukemia, *BCR::ABL1*⁺
  - Chronic neutrophilic leukemia
  - Polycythemia vera
  - Essential thrombocythemia
  - Primary myelofibrosis
    - PMF, prefibrotic/early stage
    - PMF, overt fibrotic stage
  - Chronic eosinophilic leukemia, NOS
  - Myeloproliferative neoplasm, unclassifiable
- Mastocytosis
- MDS/MPN Overlap Syndromes
- Myeloid neoplasms with germ line predisposition
- Myeloid/lymphoid neoplasms with eosinophilia and rearrangement of *PDGFRA*, *PDGFRB*, or *FGFR1*, or with *PCM1-JAK2*

2022 ICC Classification

Arber et al. *Blood*.2022015850.

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Myeloid Neoplasms

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- Myeloproliferative Neoplasms
  - Chronic myeloid leukemia, *BCR::ABL1*⁺
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2022 ICC Classification

Arber et al. *Blood* 2022. *epub ahead of print*.

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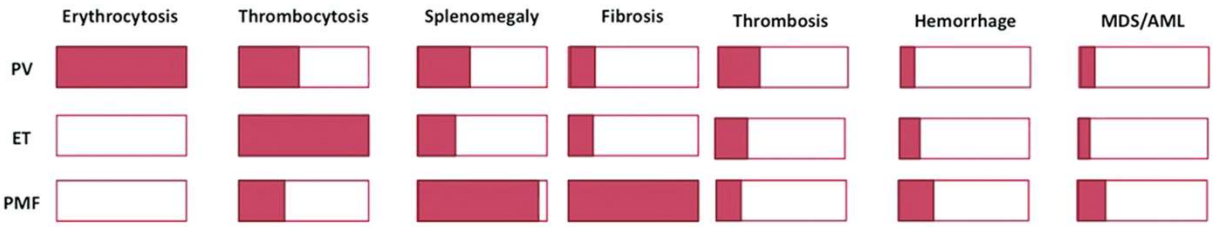
MPN: Overlap in clinical presentation and progression



Kiladjian JJ. *Hematology* 2012;2012:561–566

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EDITORIAL

Some Speculations on the Myeloproliferative Syndromes

It is possible that these various conditions—"myeloproliferative disorders"—are all somewhat variable manifestations of proliferative activity of the bone marrow cells, perhaps due to a hitherto undiscovered stimulus.

Myelostimulatory Factor(s) → Bone marrow → Potential bone marrow

Syndromes	Erythroblasts	Granulocytes	Megakaryocytes	Fibroblasts	Myeloid metaplasia of spleen and liver
Chronic Granulocytic Leukemia	±	+++	+ to +++	+	++
Polycythemia Vera	+++	++	++ to +++	+ to +++	+ to +++
Idiopathic or Agnogenic Myeloid Metaplasia of Spleen	±	±	+++	+ to +++	+++
Megakaryocytic Leukemia	±	±	+++	+	+ to +++
Erythroleukemia (including diGuglielmo syndrome)	+++	+	±	±	+ to +++

Degrees of Proliferation: + slight, ++ moderate, +++ marked

Dameshek W. *Blood*. 1951 Apr;6(4):372–5.
Blood. 2016 Feb 11;127(6):663.

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Activating mutation in the tyrosine kinase JAK2 in polycythemia vera, essential thrombocythemia, and myeloid metaplasia with myelofibrosis

Ross L. Levine,[1,2,11] Martha Wadleigh,[2,11] Jan Cools,[6] Benjamin L. Ebert,[2,8] Gerlinde Wernig,[1] Brian J.P. Huntly,[1] Titus J. Boggon,[4] Iwona Wlodarska,[5] Jennifer J. Clark,[1] Sandra Moore,[1] Jennifer Adelsperger,[1] Sumin Koo,[1] Jeffrey C. Lee,[8] Stacey Gabriel,[8] Thomas Mercher,[1] Alan D'Andrea,[3] Stefan Fröhling,[1] Konstanze Döhner,[7] Peter Marynen,[6] Peter Vandenberghe,[6] Ruben A. Mesa,[9] Ayalew Tefferi,[9] James D. Griffin,[2] Michael J. Eck,[4] William R. Sellers,[2,8] Matthew Meyerson,[2,8] Todd R. Golub,[5,8,10] Stephanie J. Lee,[2,*] and D. Gary Gilliland[1,2,10,*]

CANCER CELL : APRIL 2005 · VOL. 7 · COPYRIGHT © 2005 ELSEVIER INC. DOI 10.1016/j.ccr.2005.03.023

The NEW ENGLAND JOURNAL of MEDICINE

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ORIGINAL ARTICLE

A Gain-of-Function Mutation of *JAK2* in Myeloproliferative Disorders

Robert Kralovics, Ph.D., Francesco Passamonti, M.D., Andreas S. Buser, M.D., Soon-Siong Teo, B.S., Ralph Tiedt, Ph.D., Jakob R. Passweg, M.D., Andre Tichelli, M.D., Mario Cazzola, M.D., and Radek C. Skoda, M.D.

N Engl J Med 2005; 352:1779-1790 | April 28, 2005 | DOI: 10.1056/NEJMoa051113

Share:

JAK2^{V617F} is present in:
- 97% of PV patients
- 50%-60% of ET/MF patients

letters to nature

A unique clonal *JAK2* mutation leading to constitutive signalling causes polycythaemia vera

Chloé James[1,*], Valérie Ugo[1,2,3,*], Jean-Pierre Le Couédic[1,*], Judith Staerk[4], François Delhommeau[1,5], Catherine Lacout[1], Loïc Garçon[1], Hana Raslova[1], Roland Berger[5], Annelise Bennaceur-Griscelli[1,6], Jean Luc Villeval[1], Stefan N. Constantinescu[4], Nicole Casadevall[1,3] & William Vainchenker[1,7]

NATURE | VOL 434 | 28 APRIL 2005 | www.nature.com/nature

→ Acquired mutation of the tyrosine kinase JAK2 in human myeloproliferative disorders

Lancet 2005; 365: 1054–61

*These authors contributed equally to this study

Eubanna Baxter, Linda M Scott*, Peter J Campbell*, Clare East, Nasios Fourouclas, Sheila Swanton, George S Vassiliou, Anthony J Bench, Elaine M Boyd, Natasha Curtin, Mike A Scott, Wendy N Erber, the Cancer Genome Project†, Anthony R Green*

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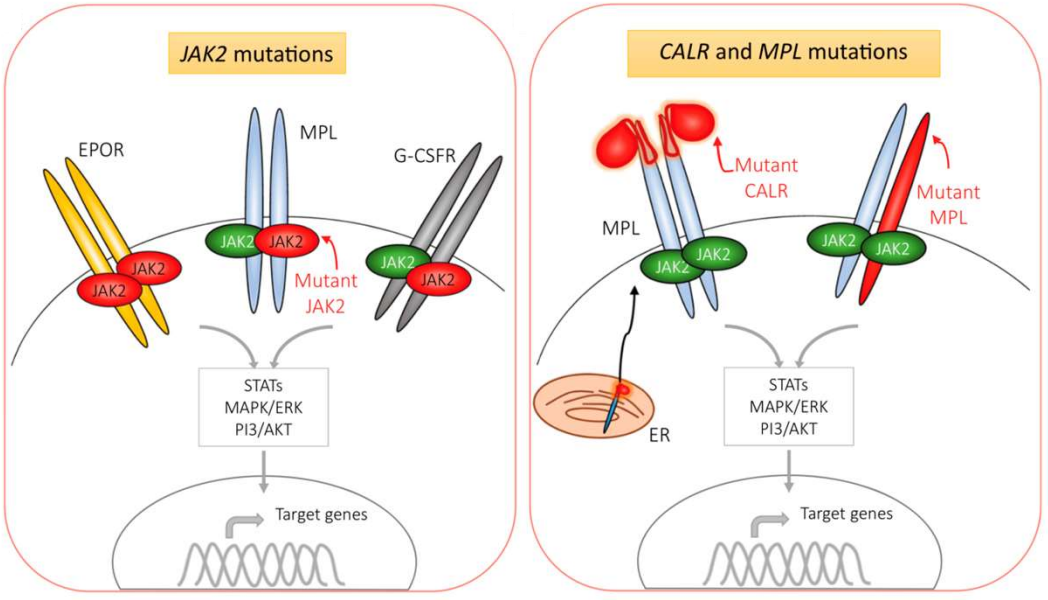

Nangalia J, Green AR. Hematology Am Soc Hematol Educ Program. 2017 Dec 8;2017(1):470–479.

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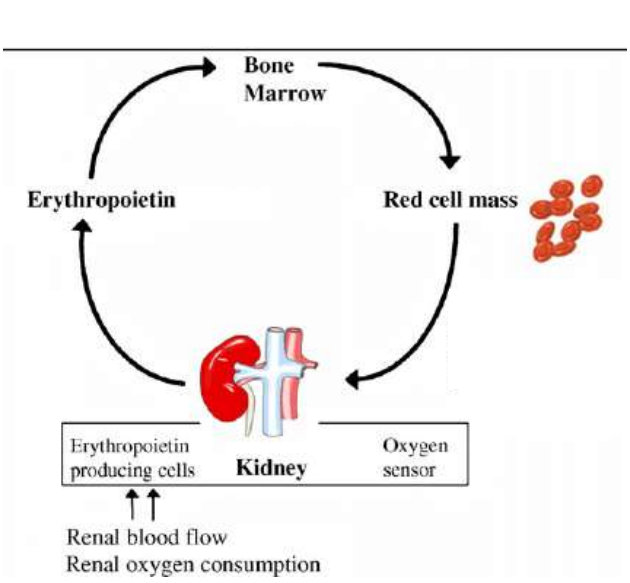

Brady L. Stein, MD, MHS; Alison R. Moliterno, MD. *JAMA*. 2010;303(24):2513–2518.

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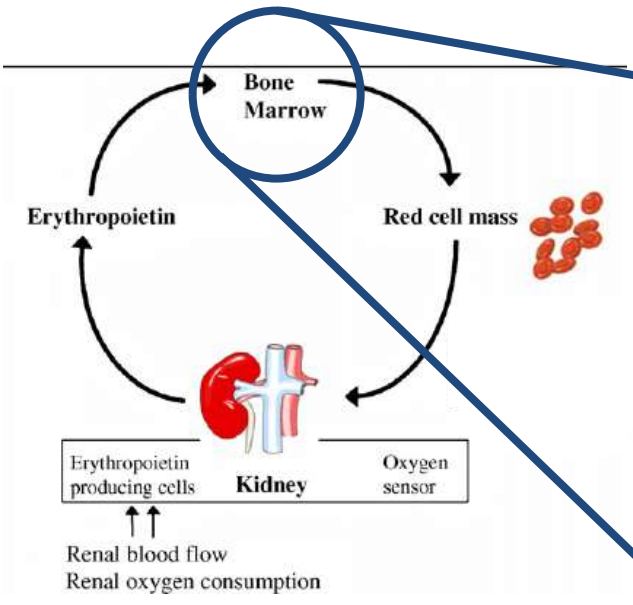

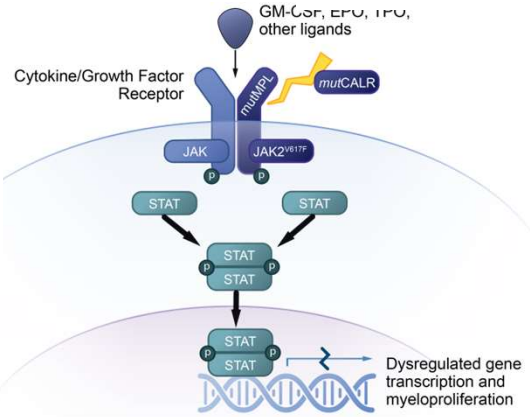

Brady L. Stein, MD, MHS; Alison R. Moliterno, MD. *JAMA*. 2010;303(24):2513–2518.

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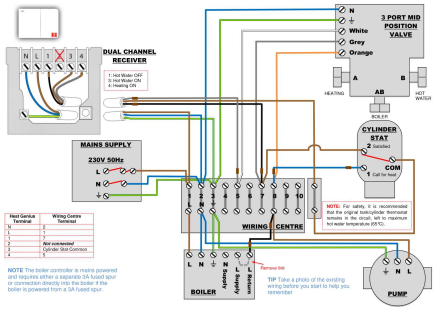

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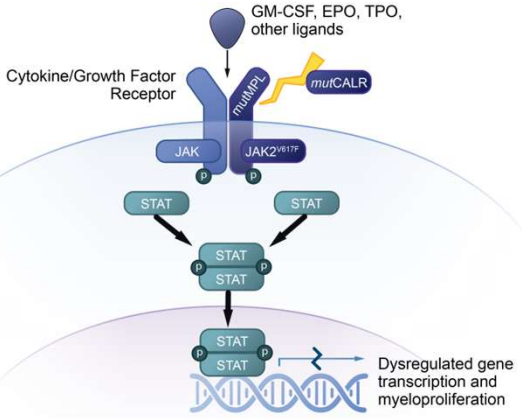

Brady L. Stein, MD, MHS; Alison R. Moliterno, MD. *JAMA*. 2010;303(24):2513–2518.

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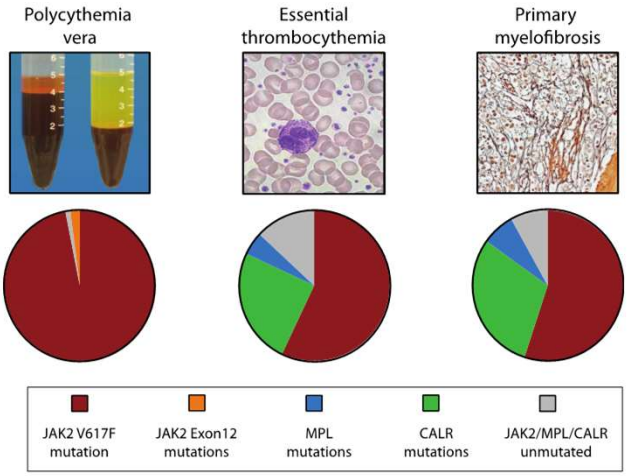
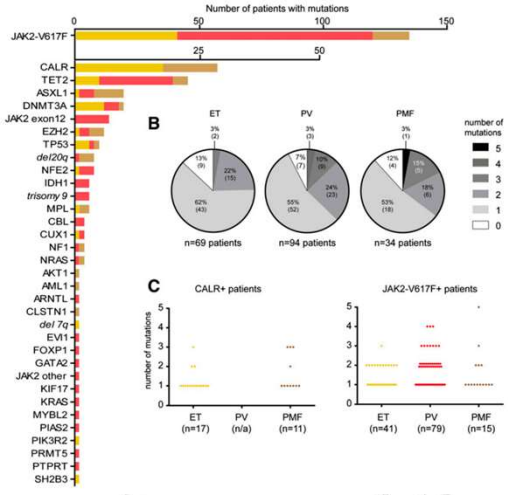
Mutational Landscape in MPNs





Nangalia J, Green TR. *Hematology Am Soc Hematol Educ Program.* 2014;2014:287–296.
Lundberg P et al. *Blood* 2014 123:2220-2228

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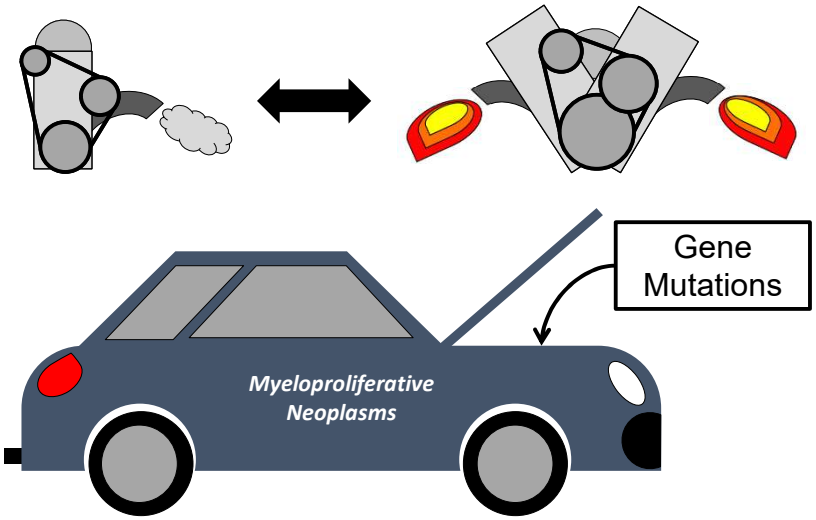

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Symptom Burden in the MPNs?

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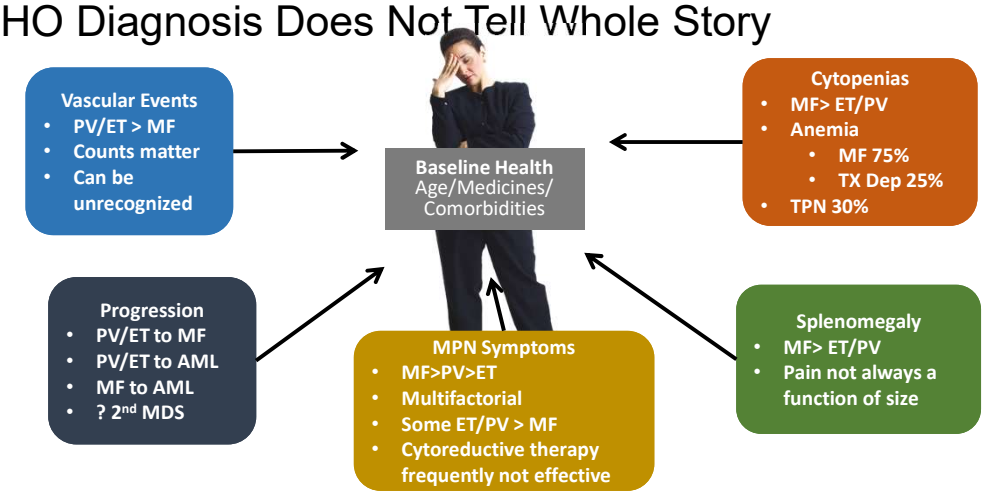
Assessing MPN Burden
WHO Diagnosis Does Not Tell Whole Story



MPN = myeloproliferative neoplasm; WHO = World Health Organization; PV = polycythemia vera; ET = essential thrombocytopenia; MF = myelofibrosis; AML = acute myeloid leukemia; MDS = myelodysplastic syndrome; TPN = total parenteral nutrition.

Slide courtesy of Ruben A Mesa, MD

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MYELOPROLIFERATIVE NEOPLASM SYMPTOM ASSESSMENT FORM
TOTAL SYMPTOM SCORE (MPN-SAF TSS-10 ITEMS)[2]
(Recommended for monitoring symptoms during the course of treatment)

Symptom	1 to 10 (0 if absent) ranking 1 is most favorable and 10 least favorable
Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your WORST level of fatigue during past 24 hours	(No Fatigue) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)

Circle the one number that describes how, during the past week how much difficulty you have had with each of the following symptoms

Filling up quickly when you eat (early satiety)	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)
Abdominal discomfort	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)
Inactivity	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)
Problems with concentration-compared to prior to my MPD	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)
Numbness/Tingling (in my hands and feet)	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)
Night sweats	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)
Itching (pruritus)	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)
Bone pain (diffuse not joint pain or arthritis)	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)
Fever (>100 F)	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Daily)
Unintentional weight loss last 6 months	(Absent) 0 1 2 3 4 5 6 7 8 9 10 (Worst Imaginable)

Emanuel RM et al. *J Clin Oncol*. 2012 Nov 20;30(33):4098–103.

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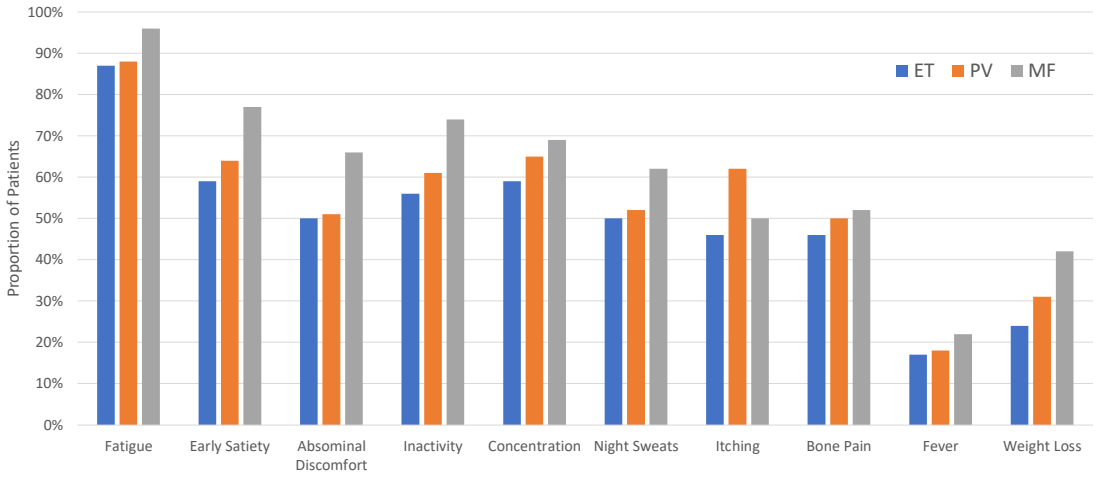
Symptoms by Disease Type



Emanuel RM et al. *J Clin Oncol*. 2012 Nov 20;30(33):4098–103.

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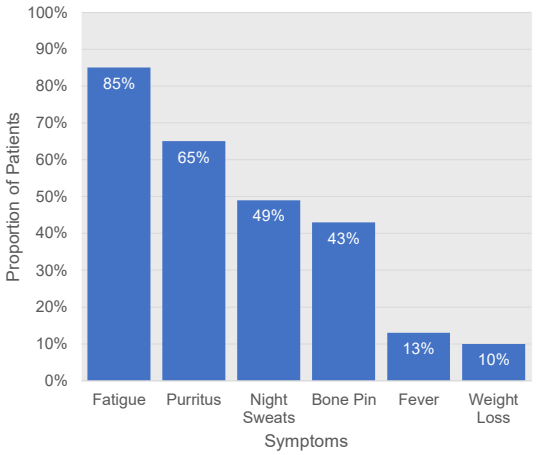
Symptoms of PV at Presentation

- PV is associated with significant symptom burden
  - Fatigue is the most common and intense symptom reported
  - Some patients may experience intractable pruritus, which can be debilitating
- Splenomegaly is observed in 30-40% of patients at presentation



Mesa RA et al. *Cancer.* 2007;109:68–76., Emanuel RM et al. *J Clin Oncol.* 2012;4098–4098., Johansson R et. Al. *Leuk Lymphoma.* 2012;53:441–444. Scherber R et al. *Blood.* 2011;118:401-408. Passamonti F. *Blood.* 2012;120:275–284.

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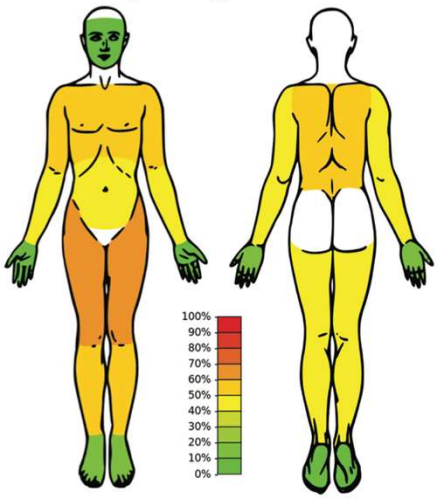
Distribution of Aquagenic Pruritus in PV



Siegel FP, Tauscher J, Petrides PE. *Am J Hematol.* 2013 Aug;88(8):665–9.

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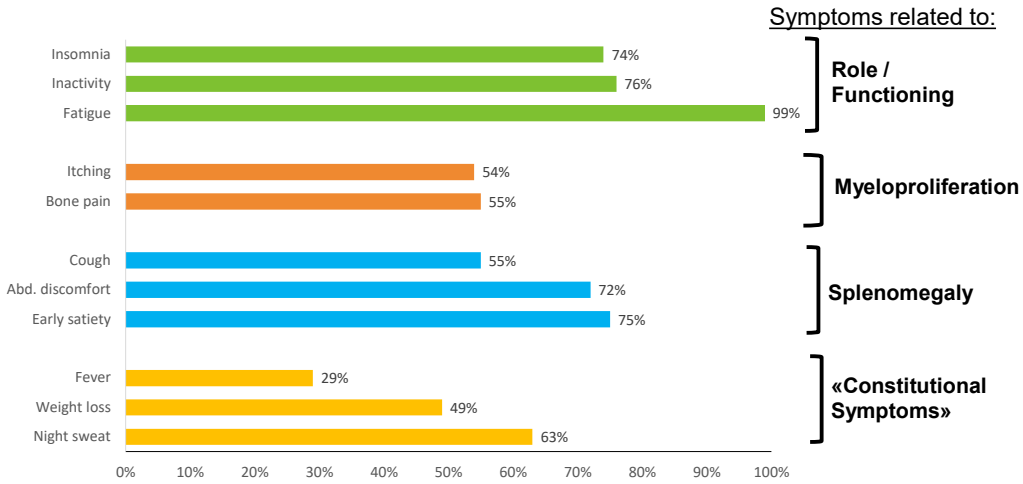
Symptomatic Burden in Myelofibrosis



Scherber R et al. *Blood* 2011;118(2):401–8.

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Cause and effect

Symptom	Cause
Organomegaly	Elevated red cell mass, extramedullary hematopoiesis, elevated cytokine levels
Pruritus/bone pain	Presumed 2/2 mast cell degranulation – histamine, prostaglandins, etc...(unproven)
Erythromelalgia or ocular migraine	Thrombocytosis
Fever	Elevated cytokine levels
Weight loss	Splenomegaly (early satiety), elevated cytokine levels
Hyperuricemia, gout, renal stones	Increased cell turnover
Fatigue	????, IL-6/IL-8, Multifactorial

Treatment for the MPNs

MPNS: "Clinical needs"-oriented current therapy

Clinical need	Drugs/intervention	
Anemia	• Corticosteroids • Danazol • Erythropoietin (ESAs)	• Thalidomide • Lenalidomide • Luspatercept
Symptomatic splenomegaly	• JAK inhibitors • Hydroxyurea	• IMIDs • Splenectomy/XRT
Extramedulary hematopoiesis	• Radiation therapy	• Hypomethylating agents
Hyperproliferative (early) disease	• Interferon	• Hydroxyurea
Risk of thrombosis	• Low-dose ASA	
Constitutional symptoms/QoL	• JAK inhibitors	Corticosteroids
Accelerated/blast phase	• Hypomethylating agents	
Improved survival	• Allo HCT	Ruxolitinib

Slide Courtesy of Srdan Verstovsek, MD, PhD

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Treatment for PV

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Risk-Stratification in PV

Risk Group	Factors	Treatment
Low	Age < 60 yrs No thrombosis Hx	Phlebotomy CV risk modification ASA
High	Age ≥ 60 yrs - *and/or* - Thrombosis history	Cytoreduction (± phlebotomy) CV risk modification ASA

Crisà E et al. *Ann Hematol*. 2010 Jul;89(7):691–9.

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National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2022
Polycythemia Vera

TREATMENT FOR HIGH-RISK POLYCYTHEMIA VERA[a]

High-risk →

- Manage cardiovascular risk factors (see MPN-H)
- Aspirin (81–100 mg/day)[c,d]
- Phlebotomy (to maintain hematocrit <45%)[e]

Regimens for cytoreductive therapy:
Preferred regimens:
Hydroxyurea
or
Peginterferon alfa-2a[j]
or
Other recommended regimen:
Ropeginterferon alfa-2b-njft for high-risk PV

→ Monitor for new thrombosis or bleeding
• Monitor response and signs/symptoms of disease progression (MPN-10; MPN-E 2 of 2) every 3–6 months or more frequently as clinically indicated[f,k,l]

→ Adequate response → Continue treatment

→ Inadequate response or Loss of response →

Potential indications for change of cytoreductive therapy:[g]
- Intolerance or resistance to hydroxyurea,[m] or peginterferon alfa-2a
- New thrombosis or disease-related major bleeding
- Frequent phlebotomy or intolerant of phlebotomy
- Splenomegaly
- Progressive thrombocytosis and/or leukocytosis
- Disease-related symptoms (eg, pruritus, night sweats, fatigue)

→ Preferred regimens:
Clinical trial
or
Ruxolitinib[n] (category 1 for high-risk PV)
or
Other recommended regimens:
Ropeginterferon alfa-2b-njft if not previously used
or
Hydroxyurea if not previously used
or
Peginterferon alfa-2a[j] if not previously used

→ Disease progression to MF/AML[h,i] → Post-PV MF, see MPN-2; Advanced phase MF/AML, see MF-4

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Treatment for ET

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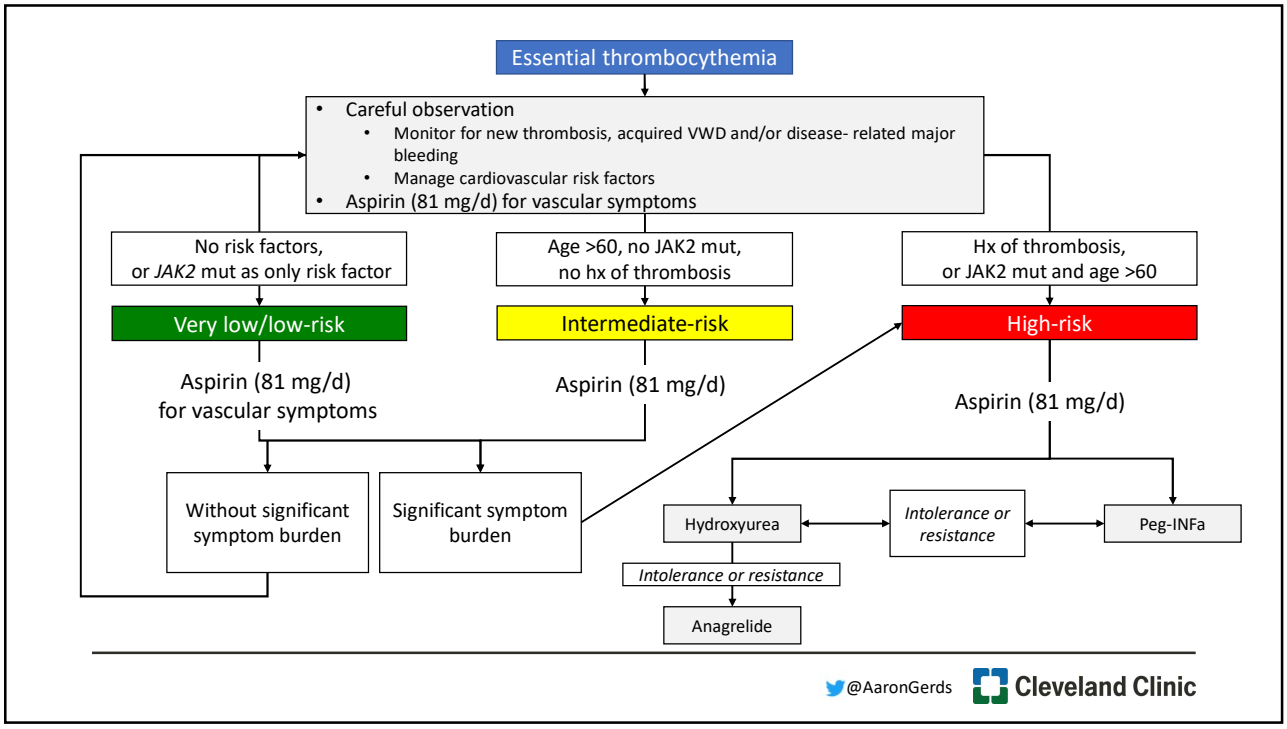

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Treatment for MF

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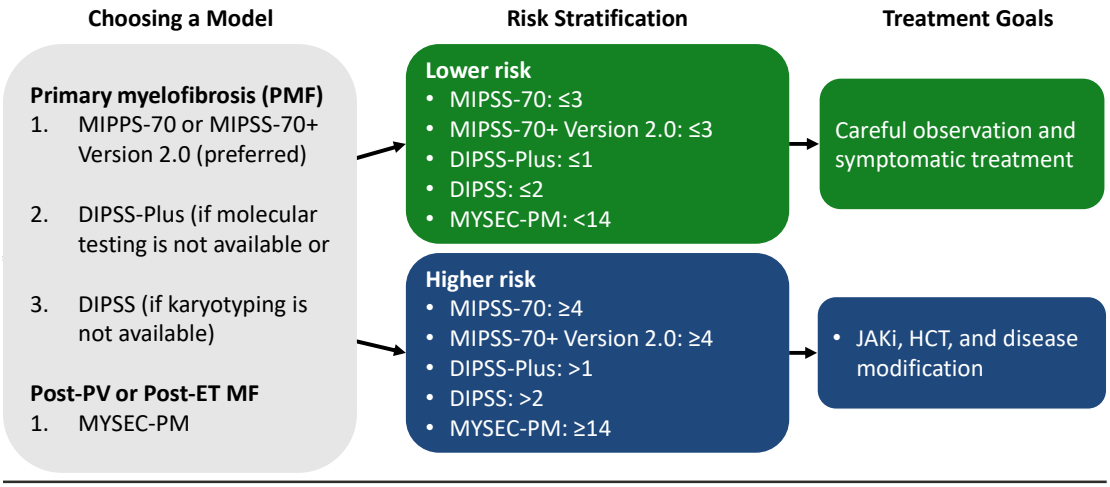
What Model to Use and When?



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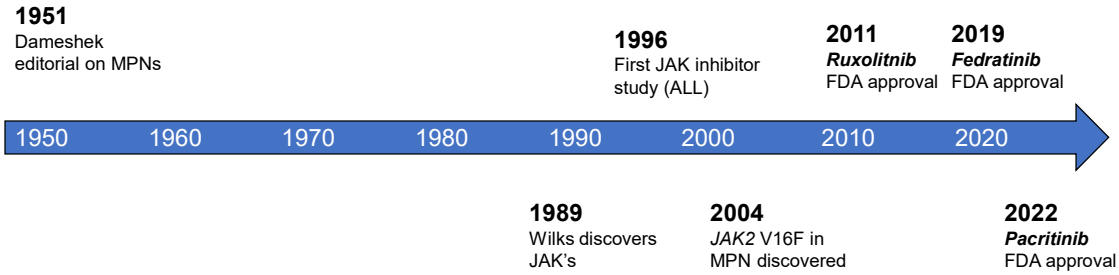
JAK Inhibitors for Myelofibrosis



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JAKi with regulatory approval for MF

- Ruxolitinib
  - COMFORT-1
    - Vs placebo in intermediate-2/high-risk myelofibrosis
  - COMFORT-2
    - Vs best available therapy in intermediate-2/high risk myelofibrosis
- Fedratinib
  - JAKARTA
    - Vs placebo in intermediate-2/high-risk myelofibrosis
  - JAKARTA-2
    - Open-label phase 2 study in post-ruxolitinib myelofibrosis
- Pacritinib
  - PERSIST-2
  - PAC 203

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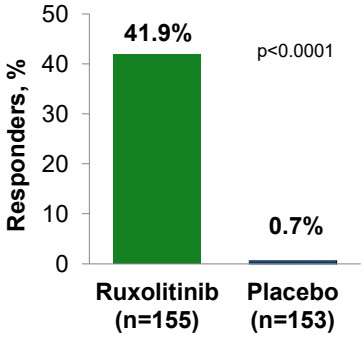
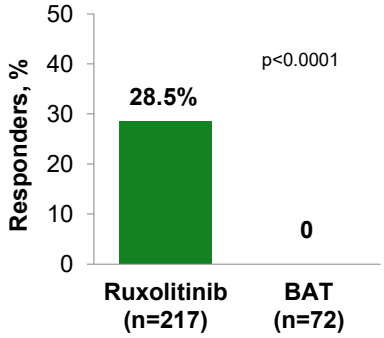
Spleen Volume Reduction

COMFORT-I
(Week 24)



COMFORT-II
(Week 48)



Response: ≥35% reduction by MRI/CT

Verstovsek S et al. *N Engl J Med.* 2012;366:799–807.
Harrison C et al. *N Engl J Med.* 2012;366:787–798.c

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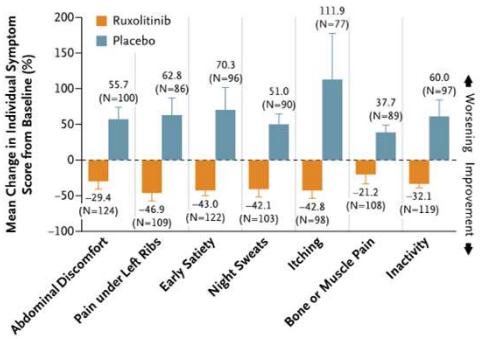
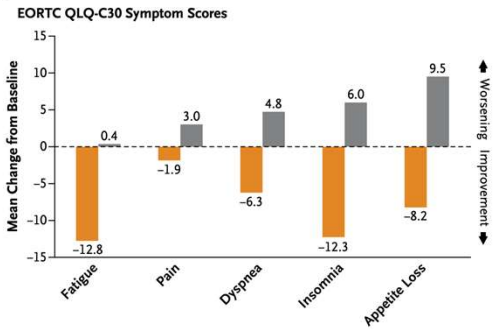
Symptom Burden Improvement

COMFORT-I
(Week 24)



COMFORT-II
(Week 48)



Verstovsek S et al. *N Engl J Med.* 2012 Mar 1;366(9):799–807.
Harrison C et al. *N Engl J Med*. 2012 Mar 1;366(9):787–98.

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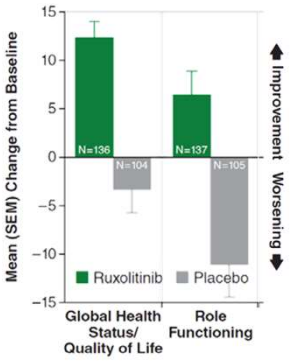
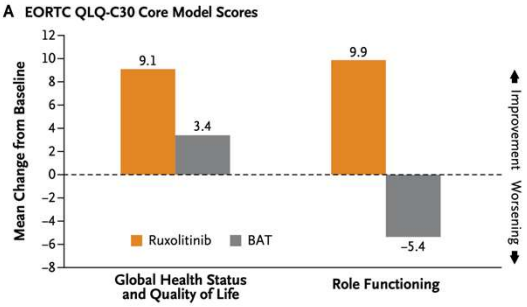
Quality of Life Improvement

COMFORT-I
(Week 24)



COMFORT-II
(Week 48)

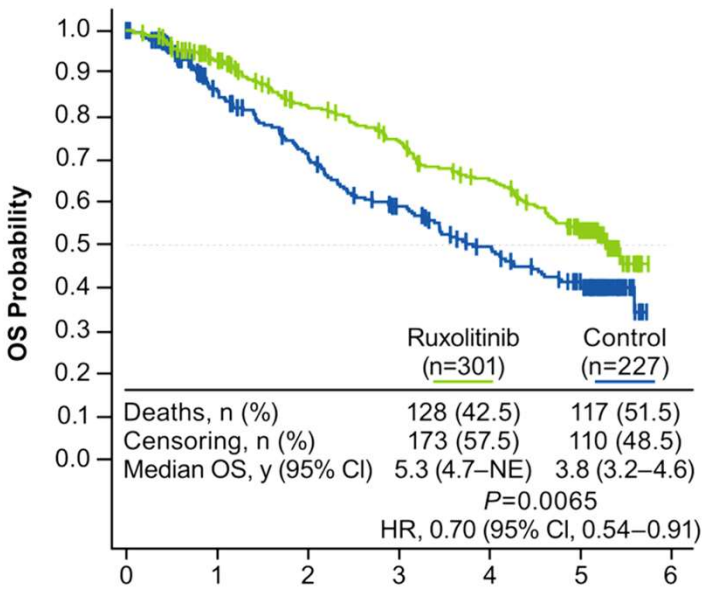


EORTC QLQ-C30 Core Model Scores

Verstovsek S et al. *N Engl J Med*. 2012 Mar 1;366(9):799–807.
Harrison C et al. *N Engl J Med*. 2012 Mar 1;366(9):787–98.

Survival in MF with Ruxolitinib

Median time on ruxolitinb in the COMFORT studies was ~3 years



Verstovsek S et al., *J Hematol Oncol*. 2017 Sep 29;10(1):156.

Emerging Treatments

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Taussig Cancer Institute

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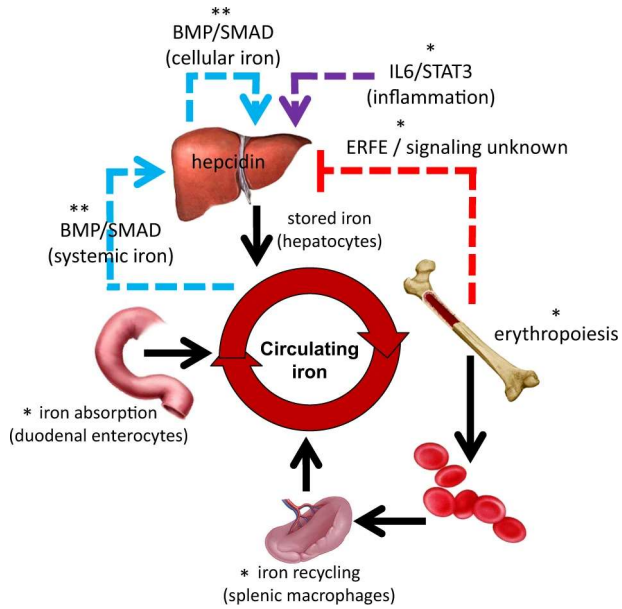

Ginzberg et al. *Leukemia* volume 32, pages 2105–2116 (2018)

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Momelotinib (hepcidin-blocker to treat anemia in MF)

expanded erythropoiesis = low hepcidin

suppressed erythropoiesis = high hepcidin

low inflammation = low hepcidin

high inflammation = high hepcidin

Iron overload

Iron deficiency

Rusfertide (hepcidin-mimicker to treat PV)

Ginzberg et al. *Leukemia* volume 32, pages 2105–2116 (2018)

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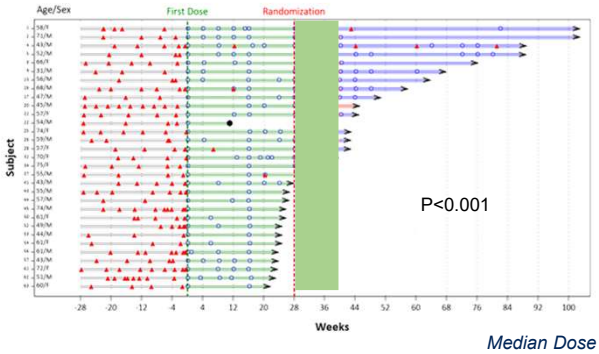
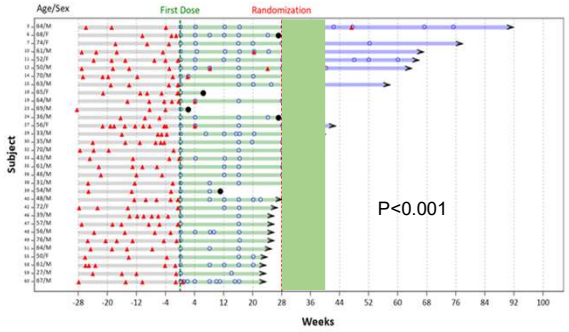
Effect of Rusfertide on Reducing Phlebotomy Frequency

PHLEBOTOMY ONLY (N=31, 49%)



PHLEBOTOMY + CYTOREDUCTIVE (N=32, 51%)



Median Dose 40-60 mg/week

During the first 28 weeks of treatment, **84% of patients did not require a phlebotomy,** 14% required one and 2% required two phlebotomies.

Data cut off Sept 30, 2021

2022 ASCO ANNUAL MEETING #ASCO22

PRESENTED BY: Ron Hoffman. Abstract # 7003

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY KNOWLEDGE CONQUERS CANCER

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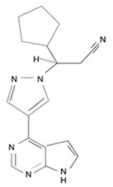
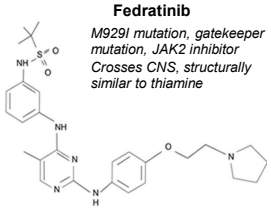
JAK Inhibitors for Myelofibrosis

Ruxolitinib



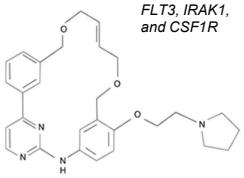
Fedratinib

M929I mutation, gatekeeper mutation, JAK2 inhibitor
Crosses CNS, structurally similar to thiamine



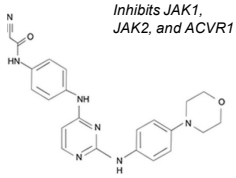
Pacritinib

Inhibits JAK2, FLT3, IRAK1, and CSF1R



Momelotinib

Inhibits JAK1, JAK2, and ACVR1



	IC_{50} (nanomolar)				AEs
	JAK1	JAK2	JAK3	TYK2	
Ruxolitinib	2.8	4.5	322	30	Cytopenias (anemia, thrombocytopenia), infection
Fedratinib	105	3	>1000	405	Wernicke encephalopathy
Pacritinib	1280	6	18.3	27	GI (diarrhea, nausea)
Momelotinib	11	18	155	17	Increased amylase/lipase, thrombocytopenia, PN

Duenas-Perez AB, Mead AJ. *Ther Adv Hematol*. 2015;6:186–201.

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MOMENTUM: Top-line Results

Wk 24 Endpoint	Test	MMB	DAN	p-value
TSS response rate (primary), %	Superiority	24.6	9.2	0.0095
TI rate, %	Non-inferiority	30.8	20.0	0.0064 (one-sided)
SRR ≥25%, %	Superiority	40.0	6.2	<0.0001
TSS change from BL*	Superiority	-9.36	-3.13	0.0014
SRR ≥35%, %	Superiority	23.1	3.1	0.0006
Zero transfusion rate, %	Superiority	35.4	16.9	0.0012

*Least-squares mean from mixed model for repeated measures.

Mesa R, et al. *Journal of Clinical Oncology* 2022 40:16_suppl, 7002–7002
Verstovsek S et al. *HemaSphere* 2022;6:S3;96–97; abstract S195.

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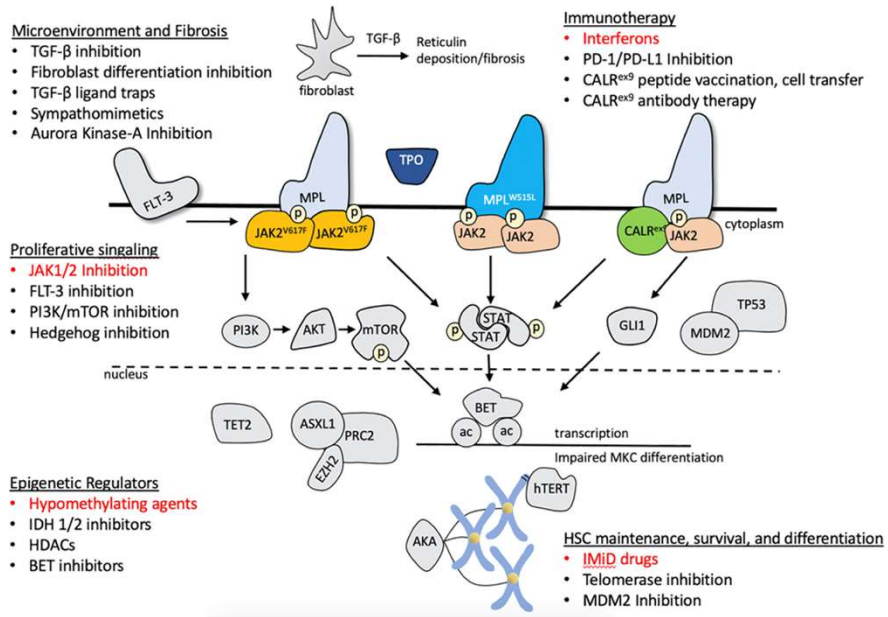

Schieber M, Crispino JD, Stein B. *Blood Cancer J.* 2019 Sep 11;9(9):74.

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The JAKi Barn Dance

Grab your partner…

- Ruxolitinib plus:
  - Danazol
  - IMIDS
  - Hypomethylating agents
  - Interferons
  - HDAC inhibitors
  - IDH 1/2 inhibitors
  - BCL inhibitors
  - BET inhibitors
  - PI3Kδ inhibitors
  - MDM2 ihibitors
  - LSD1 inhibitors
  - And the list goes on and on…

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Objectives

1. The different types of MPNs
2. Therapies for MPNs
3. Current Research and Clinical Trials
4. Managing Side Effects

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Thanks!

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Taussig Cancer Institute

L&MD
Leukemia & Myeloid Disorders Program

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Discussion

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ASK A QUESTION

SPOTLIGHT ON MYELOPROLIFERATIVE NEOPLASMS (MPNs)

Ask a question by phone:

Press star (*) 1 on your keypad to ask a question
To remove your question press star (*) 2 on your keypad

Ask a question by web:

Type your question in the “Ask a question” box under the speaker video window

Due to time constraints, we can only take one question per person.
Once you’ve asked your question, the operator will transfer you back into the audience line.

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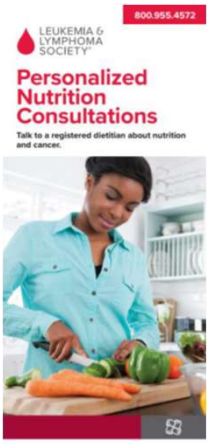
LLS EDUCATION & SUPPORT RESOURCES

HOW TO CONTACT US:

To contact an **Information Specialist** about disease, treatment and support information, resources and clinical trials:

Call: (800) 955-4572
Monday to Friday, 9 a.m. to 9 p.m. ET
Chat live online: www.LLS.org/InformationSpecialists
Monday to Friday, 10 a.m. to 7 p.m. ET
Email: www.LLS.org/ContactUs
All email messages are answered within one business day.

CLINICAL TRIAL SUPPORT CENTER
Work one-on-one with an LLS Clinical Trial Nurse Navigator who will help you find clinical trials and personally assist you throughout the entire clinical-trial process.
www.LLS.org/Navigation



NUTRITION CONSULTATIONS
Our registered dietitian has expertise in oncology nutrition and provides free one-on-one consultations by phone or email.
www.LLS.org/Consult.

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LLS EDUCATION & SUPPORT RESOURCES

Online Chats

Online Chats are free, live sessions, moderated by oncology social workers. To register for one of the chats below, or for more information, please visit **www.LLS.org/Chat**.

Education Videos

View our free education videos on disease, treatment, and survivorship. To view all patient videos, please visit **www.LLS.org/EducationVideos**.

Patient Podcast

The Bloodline with LLS is here to remind you that after a diagnosis comes hope. To listen to an episode, please visit **www.TheBloodline.org**.

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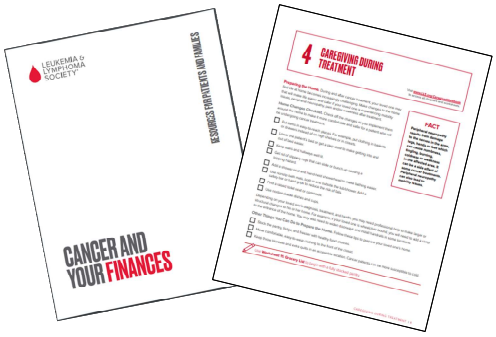
LLS EDUCATION & SUPPORT RESOURCES

The Leukemia & Lymphoma Society (LLS) offers the following financial assistance programs to help individuals with blood cancers: www.LLS.org/Finances



To order free materials: **www.LLS.org/Booklets**

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