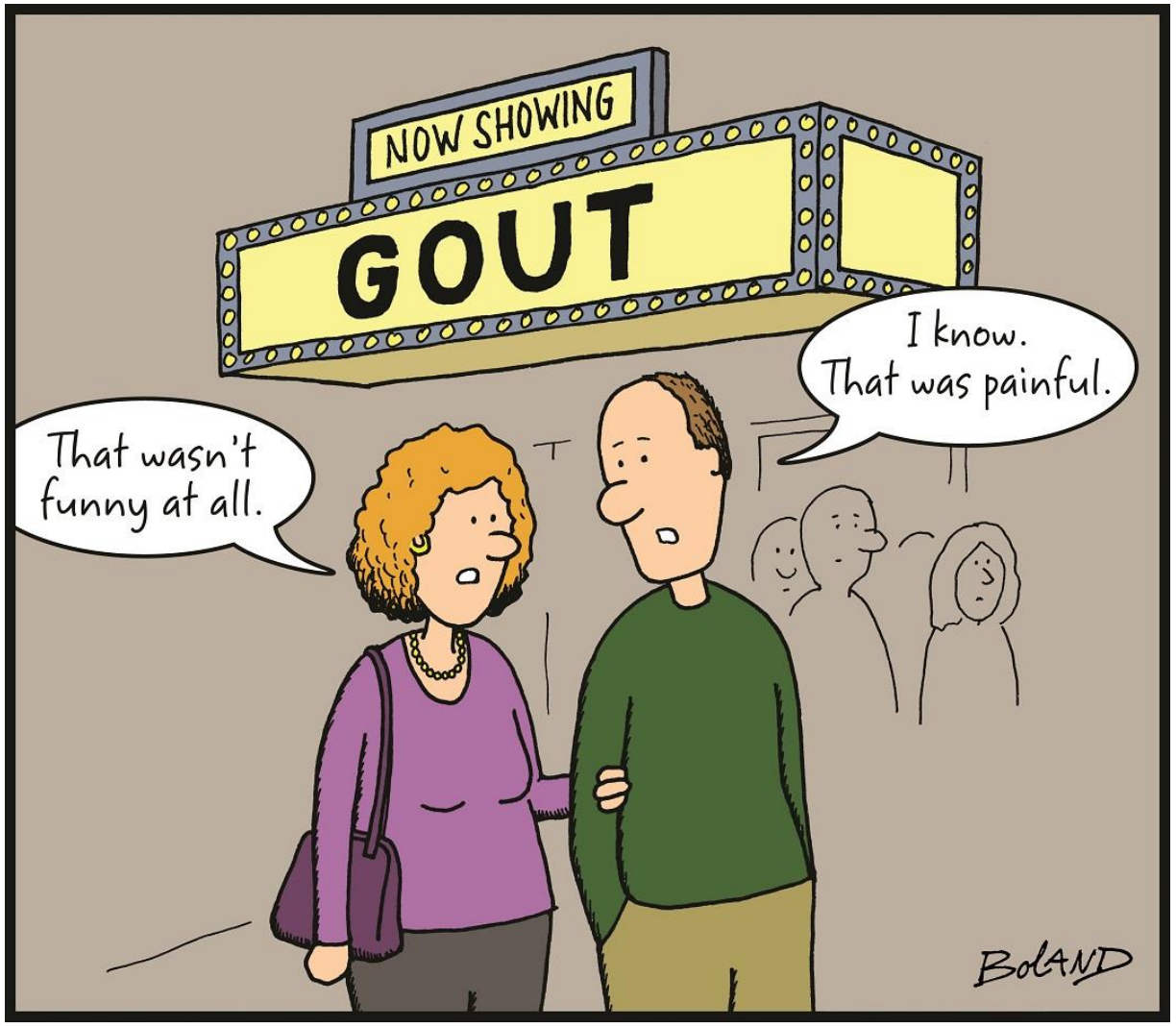

Supported by the Gout & Uric Acid Education Society. GoutEducation.org
Illustration by Bol's Eye Comics.

GOUT

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PHARMACOTHERAPY III (728-655) – FALL 2021

RESOURCES

- Pharmacotherapy: A Pathophysiologic Approach, 11e, Chapter 109: Gout
- 2020 American College of Rheumatology Guideline for Management of Gout

LEARNING OBJECTIVES

1. Explain the pathophysiology of hyperuricemia
2. Identify drugs that may increase uric acid
3. Recognize risk factors for development of gout
4. List the clinical characteristics and treatment goals for gout
5. Explain the following for colchicine: mechanism of action, adverse effects, acute attack dosing, threshold for renal dose reduction, and drug-drug interactions
6. Compare and contrast the risks and benefits associated with the drugs used in management of gout (acute and prevention)
7. Memorize the initial dose for xanthine oxidase inhibitors (allopurinol and febuxostat)
8. Identify patients that meet criteria for urate-lowering therapy for prevention of gout
9. Describe why anti-inflammatory acute gout prophylaxis is needed and how long it should be used for
10. Determine the goal for serum uric acid in a patient with gouty arthritis
11. Given a patient specific scenario, develop an appropriate pharmacotherapy plan for treatment and prevention of gout

PATIENT CASE

CC: "My toe is on fire"

HPI: RH is a 78-yo male who presents to the ED. RH states, "I think I'm paying the price for my fun at Oktoberfest." He reports having spent the weekend indulging on beer and sausage. Approximately 3 hours ago, he awoke to sudden excruciating pain in his right big toe. Over the past hour, his toe has become red, swollen, and so painful that he cannot walk. This is his first time experiencing these symptoms.

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BP 120/60 mm Hg
Weight 88 kg, Height 5'6", BMI 31.2
Uric acid = 9.3 mg/dL; CrCl = 42 ml/min

SH:
Patient typically drinks "a can of beer or two" daily but drank significantly over the past weekend

WHAT IS GOUT?

- Broad term for a spectrum of several clinical conditions:
  - Gouty arthritis
  - Monosodium urate crystals deposited in tissues (i.e. tophi)
  - Interstitial kidney disease and uric acid nephrolithiasis

BACKGROUND

Affects 4% of U.S. adult population

New cases of gout cost $27.4 million annually in the U.S.

Primary care providers manage >90% of gout

Occurs more frequently in men than women

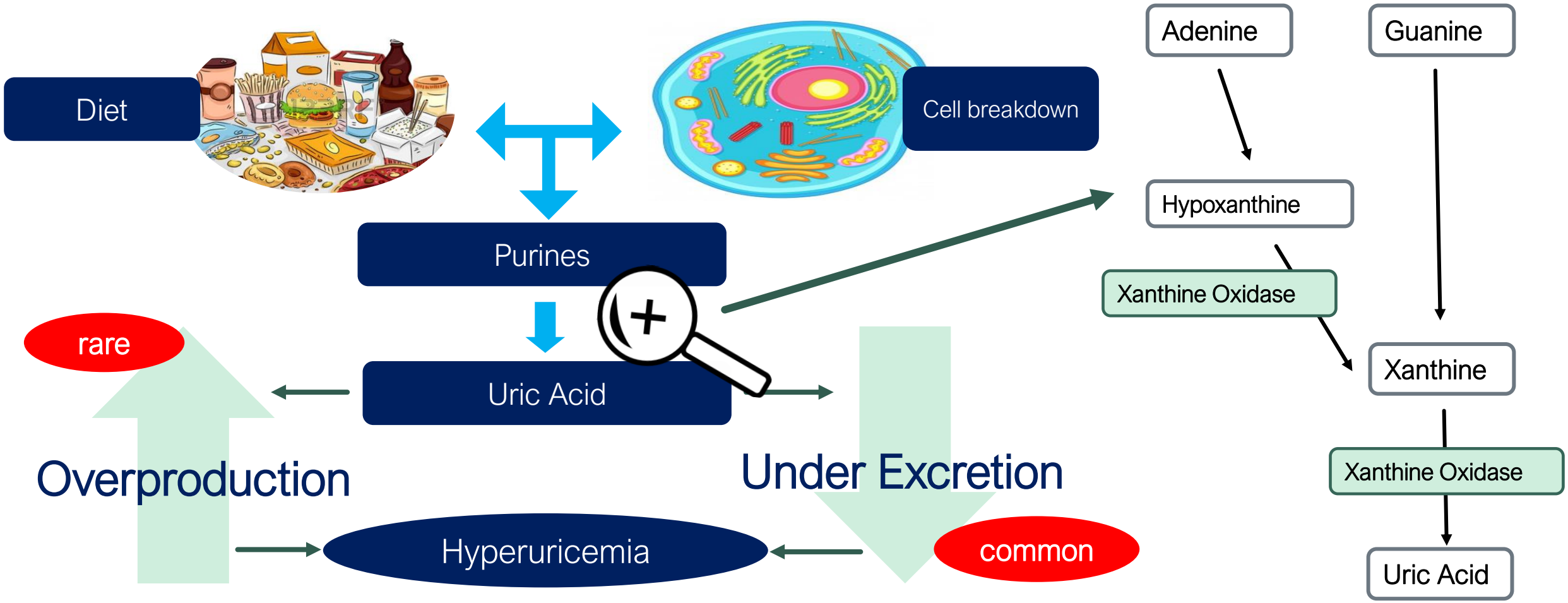
PATHOPHYSIOLOGY & HYPERURICEMIA

LEARNING OBJECTIVES #1-3

PATHOPHYSIOLOGY OF GOUT

- Gout is a clinical manifestation of hyperuricemia
  - Hyperuricemia = elevated serum urate (uric acid) concentration
- Gout may occur when serum urate concentration is “super-saturated” (generally >7 mg/dL)
  - Uric acid is deposited as “needle-like” crystals in the joints and/or soft tissues

PATHOPHYSIOLOGY OF HYPERURICEMIA



PATHOPHYSIOLOGY OF HYPERURICEMIA (IN WORDS)

- Production of uric acid is the terminal step in the degradation of purines (adenine, guanine). Purines come from diet and DNA in cells
- Purine metabolism is regulated by several enzyme systems – xanthine oxidase is an important enzyme in purine breakdown
- Abnormalities in regulatory system OR increased lysis and breakdown of cellular matter can lead to an overproduction of uric acid (rare)
- About two-thirds of daily uric acid production is excreted in urine, therefore under excretion can lead to hyperuricemia (common)

Drugs can decrease renal elimination or tubular transport of uric acid → increased serum uric acid

- Diuretics
- Nicotinic acid
- Ethanol
- Salicylates (<2 g/day)
- Cyclosporine
- Levodopa
- Cytotoxic agents
- Pyrazinamide
- Ethambutol

RISK FACTORS

- Age
- Male gender
- Kidney impairment
- Obesity
- Heart failure
- Acute alcoholism
- Hypothyroidism
- Hypertension
- Type 2 diabetes

KNOWLEDGE CHECK

Gout can occur when _____ is elevated.
Most commonly this is due to _____.

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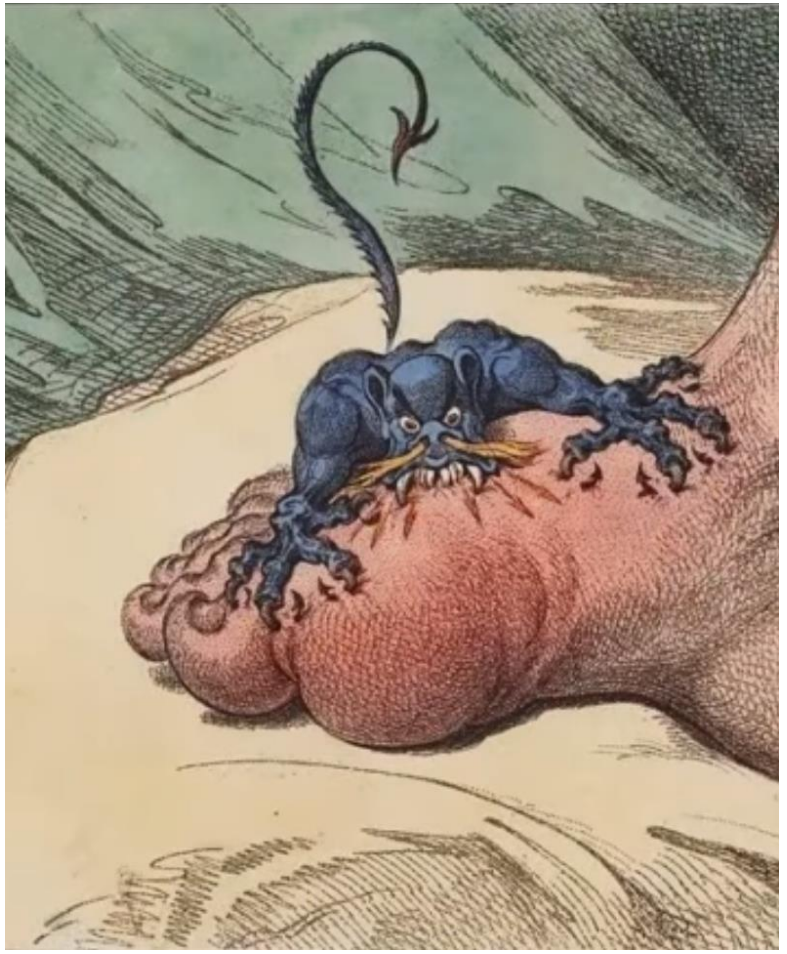
CLINICAL PRESENTATION

LEARNING OBJECTIVE #4

ACUTE GOUTY ARTHRITIS

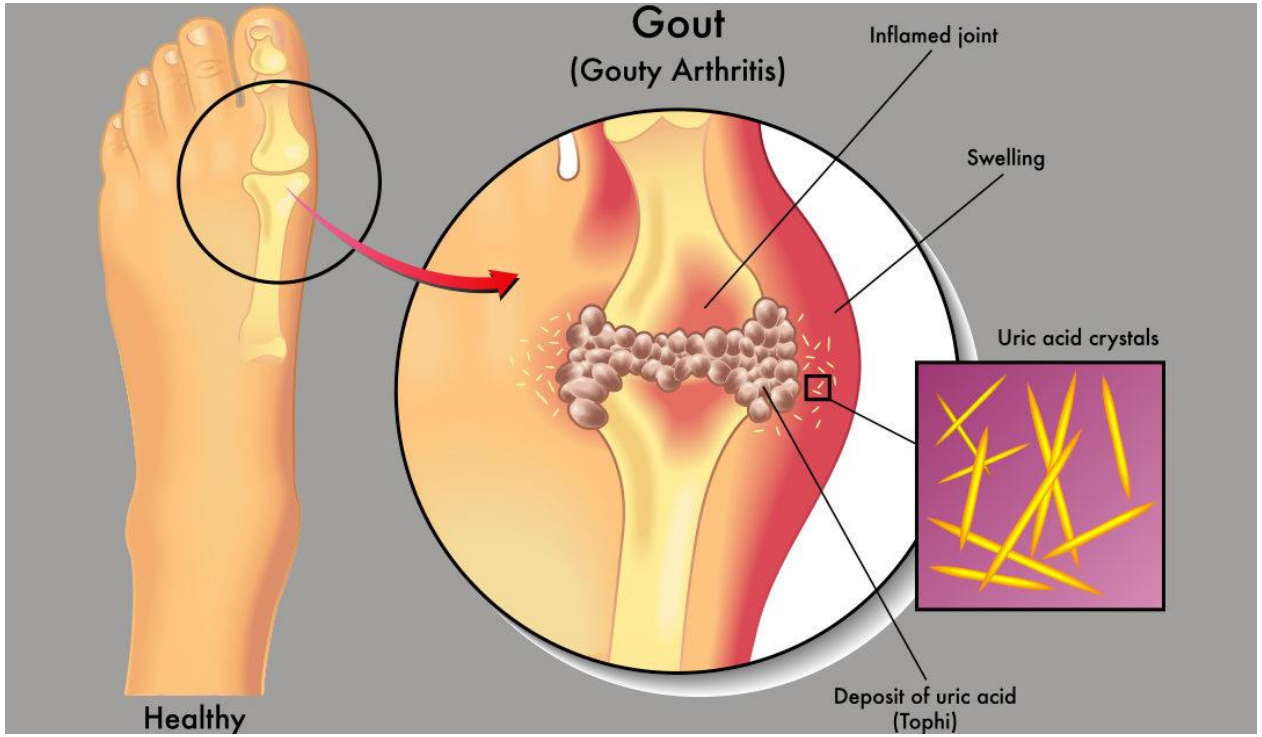
- Most common clinical manifestation of gout
- First attack is typically monoarticular
  - Common: first metatarsophalangeal joint (big toe)
  - Less common: foot, ankles, heels, knees, wrist, fingers, and elbows
- Diagnosis is typically made on clinical presentation rather than evaluating intraarticular fluid



ACUTE GOUTY ARTHRITIS

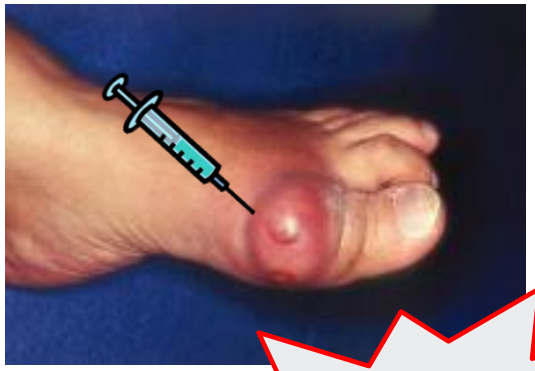
Signs and symptoms:

- Rapid onset of excruciating joint pain
- Erythema, warmth, and swelling at the affected joint
- Fever and leukocytosis

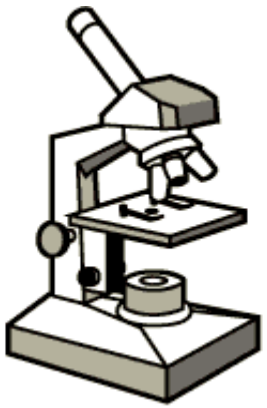


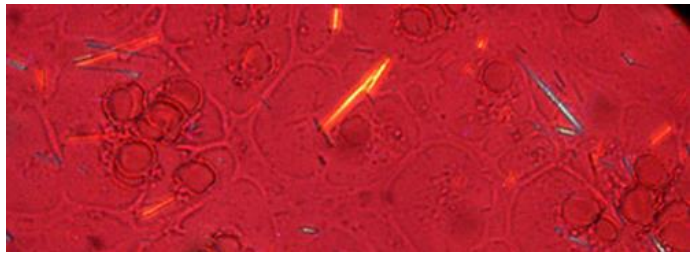
ARTHROCENTESIS (JOINT ASPIRATION)

Remove fluid from space around a joint using a needle and syringe



Painful!





Urate Crystals

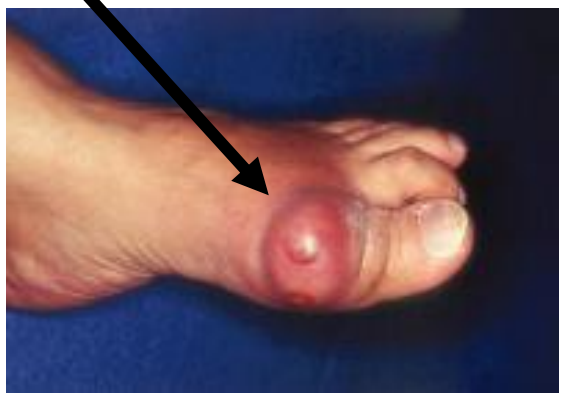
ACUTE GOUTY ARTHRITIS

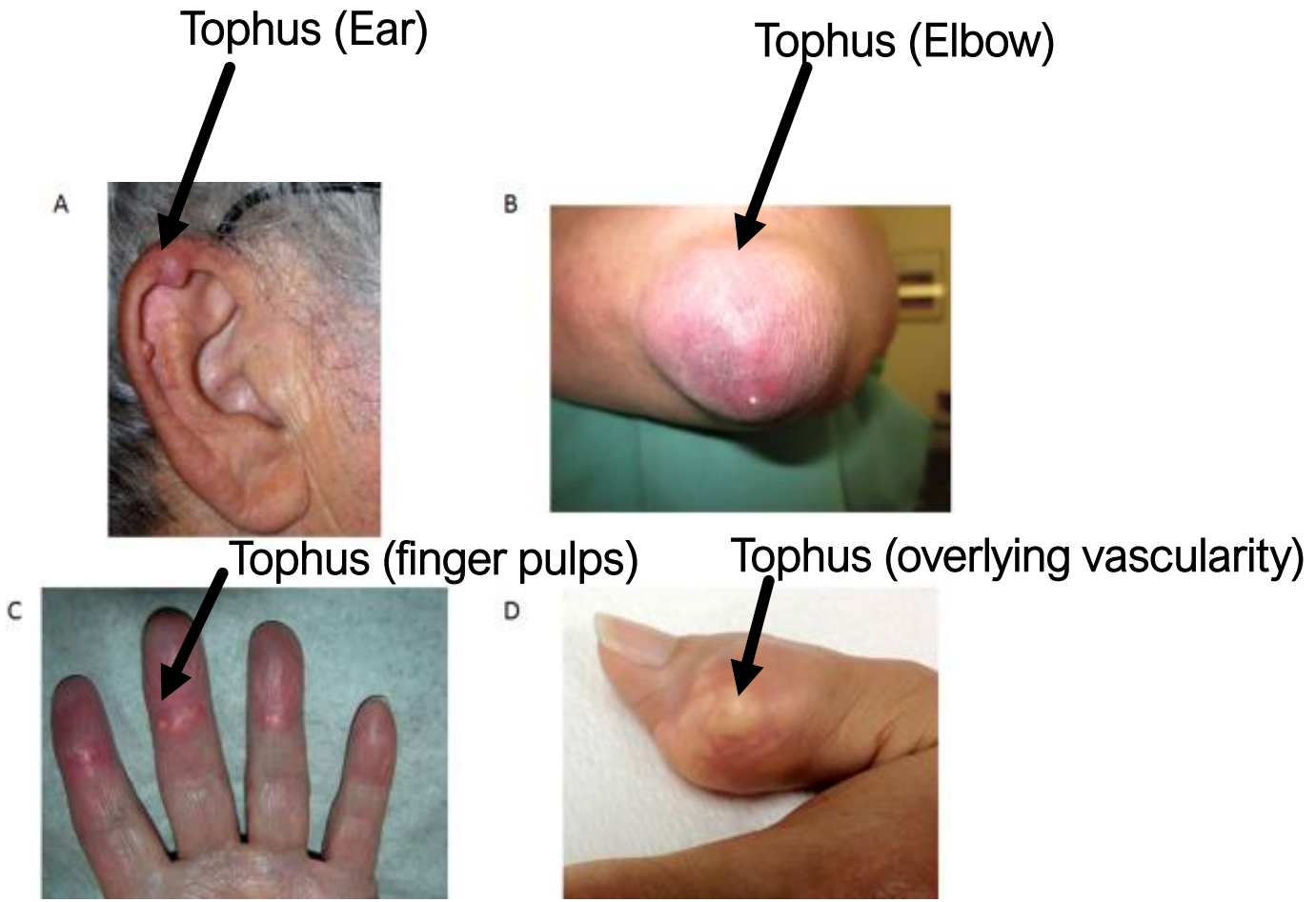
- Attacks may be idiopathic or induced by:
  - Stress, local trauma, alcohol, infection, surgery
  - Rapid decrease in serum uric acid with urate-lowering drugs
  - Drugs known to raise serum uric acid

SEVERE & PROGRESSIVE FORMS OF GOUT

- Uric acid nephrolithiasis
- Gouty nephropathy
- Tophaceous gout

Tophus (big toe)





ASSESSMENT OF ACUTE GOUT ATTACK

- Characterized by severity, onset, and extent
  - Severity determined by self-reported pain score on scale of 1 to 10
  - Onset determined by time elapsed from symptoms of attack
  - Extent determined by number of affected joints

Severity:
• Mild: ≤ 4 • Moderate: 5 to 6 • Severe: ≥ 7
Onset:
• Early: < 12 hours after attack onset • Well-Established: 13 to 36 hours after attack onset • Late: >36 hours after attack onset
Extent:

• One or a few small joints
• 1 or 2 large joints (ankle, knee, wrist, elbow, hip, shoulder)
• Polyarticular
  • 4 or more joints with arthritis involving more than 1 region (regions: forefoot, midfoot, ankle/hindfoot, hip, fingers, wrist, elbow, shoulder, others)
  • Acute attack involving 3 separate large joints

PATIENT CASE

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GOALS OF TREATMENT

- Terminate acute attacks
- Prevent recurrent attacks
- Prevent complications

MANAGEMENT OF GOUT

LEARNING OBJECTIVES #5-11

TREATMENT INVOLVES ACUTE AND CHRONIC MANAGEMENT

Acute Gout Attack

Treat with full-dose anti-inflammatory:

- Colchicine
- NSAIDs
- Corticosteroid

Consider lifestyle modifications for all

Prevent Future Attack
(in patients who are indicated)

Treat with urate-lowering therapy (ULT)

- Allopurinol
- Febuxostat
- Probenecid
- Pegloticase

+

Treat with anti-inflammatory acute gout prophylaxis (when ULT is initiated)

- Low-dose colchicine
- Low-dose NSAIDs
- Low-dose prednisone

NONPHARMACOLOGIC RECOMMENDATIONS

- Regardless of disease activity:
  - Limit alcohol intake
  - Limit purine intake
    - Organ meats (sweetbreads, liver, kidney), sardines, shellfish, beef, lamb, pork
  - Limit high-fructose corn syrup
  - Weight loss

TREATMENT INVOLVES ACUTE AND CHRONIC MANAGEMENT

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MANAGEMENT OF ACUTE GOUT

INITIAL THERAPY

- Acute gouty arthritis attacks should be treated with pharmacologic therapy
- To provide optimal care, pharmacologic treatment should be initiated within 24 hours of acute gout attack onset
  - Can supplement with topical ice as needed
- Ongoing pharmacologic urate-lowering therapy (ULT) should not be interrupted during an acute gout attack

PHARMACOLOGIC TREATMENT

- First-line:
  - Colchicine
  - NSAIDs
  - Oral corticosteroids
- Patients who are unable to take oral medications (NPO)
  - Intramuscular, intravenous, or intraarticular corticosteroids
- Last line:
  - IL-1 inhibitors

Treatment selection should be driven by patient factors (comorbidities, access, past experience)

COLCHICINE

- Mechanism: inhibit β-tubulin polymerization in microtubules which inhibits neutrophils → reduce inflammation
- Ideally use within 36 hours of symptom onset (best within 24 hours)
- Dosing:
  - Acute attack: 1.2 mg PO initially, followed by 0.6 mg in 1 hour, followed by 0.6 mg once or twice daily beginning 12 hours later until attack resolution
  - *See next slide for dose adjustments
- Common side effects: diarrhea
- Rare, but serious side effects: bone marrow suppression, neuropathy, hepatotoxicity
- Most expensive first-line option (about ~$100-200 for 30 tablets without insurance)

COLCHICINE DOSING CONSIDERATIONS

- Needs to be adjusted for renal impairment:

  If CrCl < 30 ml/min, consider alternative therapy if possible

  - Acute attack:
    - CrCl < 30 ml/min: 1.2 mg at first sign of flare, followed in 1 hour with a single dose of 0.6 mg; do not repeat more frequently than every 14 days.
    - Hemodialysis: 0.6 mg as single dose; do not repeat more frequently than every 14 days.
  - Prophylaxis:
    - CrCl < 30 ml/min: 0.3 mg once daily (or 0.6 mg every other day)
    - Hemodialysis: 0.3 mg twice weekly

COLCHICINE INTERACTIONS

- Drug-drug interactions:
  - Interacts with moderate to strong CYP3A4 and p-gp inhibitors
  - Concomitant use of a p-gp or strong CYP3A4 inhibitor in presence of renal or hepatic impairment is *contraindicated*
- Drug-food interactions:
  - Grapefruit juice – may increase colchicine serum concentration

NSAIDS

- FDA approved NSAIDs for gout: naproxen, indomethacin, sulindac
- All NSAIDs are equally effective when dosed correctly
- Use the full dose (typically max dose) until the acute attack is completely resolved
- Avoid using in combination with systemic corticosteroids
- Recall NSAID considerations from osteoarthritis lecture – they apply here too!
- What about aspirin?

CORTICOSTEROIDS

- Oral corticosteroids:
  - Prednisone 0.5 mg/kg/day for 5 to 10 days
    - Depending on patient specific factors, could consider taper after burst dosing (for example: prednisone 0.5 mg/kg/day for 2 to 5 days, followed by 5-to-10-day taper)
- Other options:
  - Could consider intra-articular corticosteroid for 1-2 large joints
  - Intramuscular triamcinolone acetonide 60 mg as bolus first dose, followed by oral prednisone to complete the course
  - Intravenous corticosteroids for hospitalized patients

CORTICOSTEROIDS ADVERSE EFFECTS

- Adverse effects of corticosteroids:
  - Irritability, insomnia, mania/hypomania
  - Increased blood glucose
  - Weight gain
  - Increase risk for osteoporosis
  - Delayed wound healing
  - Immune system suppression
  - GI bleeding

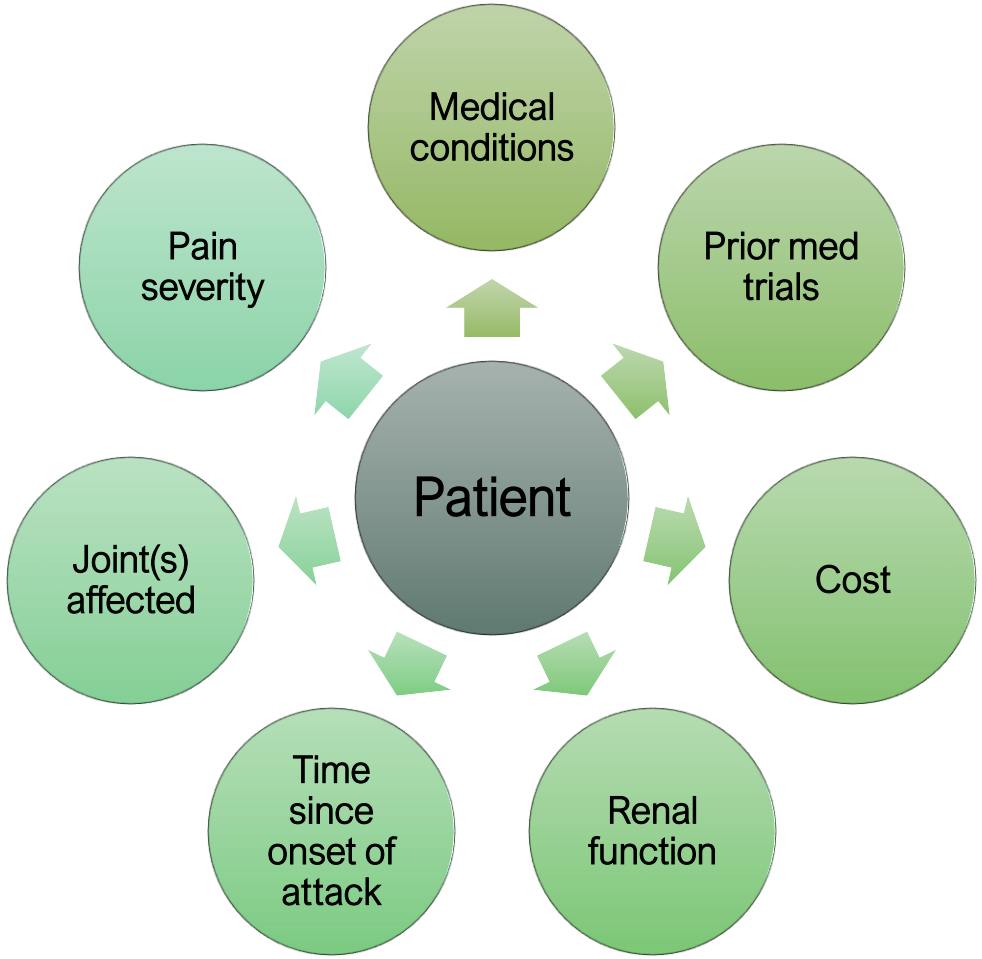
IL-1 BLOCKERS

- IL-1 secretion plays key role in acute gout
- Inhibiting IL-1 binding may alleviate the acute gout attack
- Drugs (all administered subcutaneously; all are off-label)
  - Anakinra (Kineret®) – 100 mg once daily until symptom improvement (usually 3 to 5 days)
  - Canakinumab (Ilaris®) – 150 mg once as single dose
  - Rilonacept (Arcalyst®) – 320 mg loading dose, followed by 160 mg weekly (for acute gout prophylaxis)

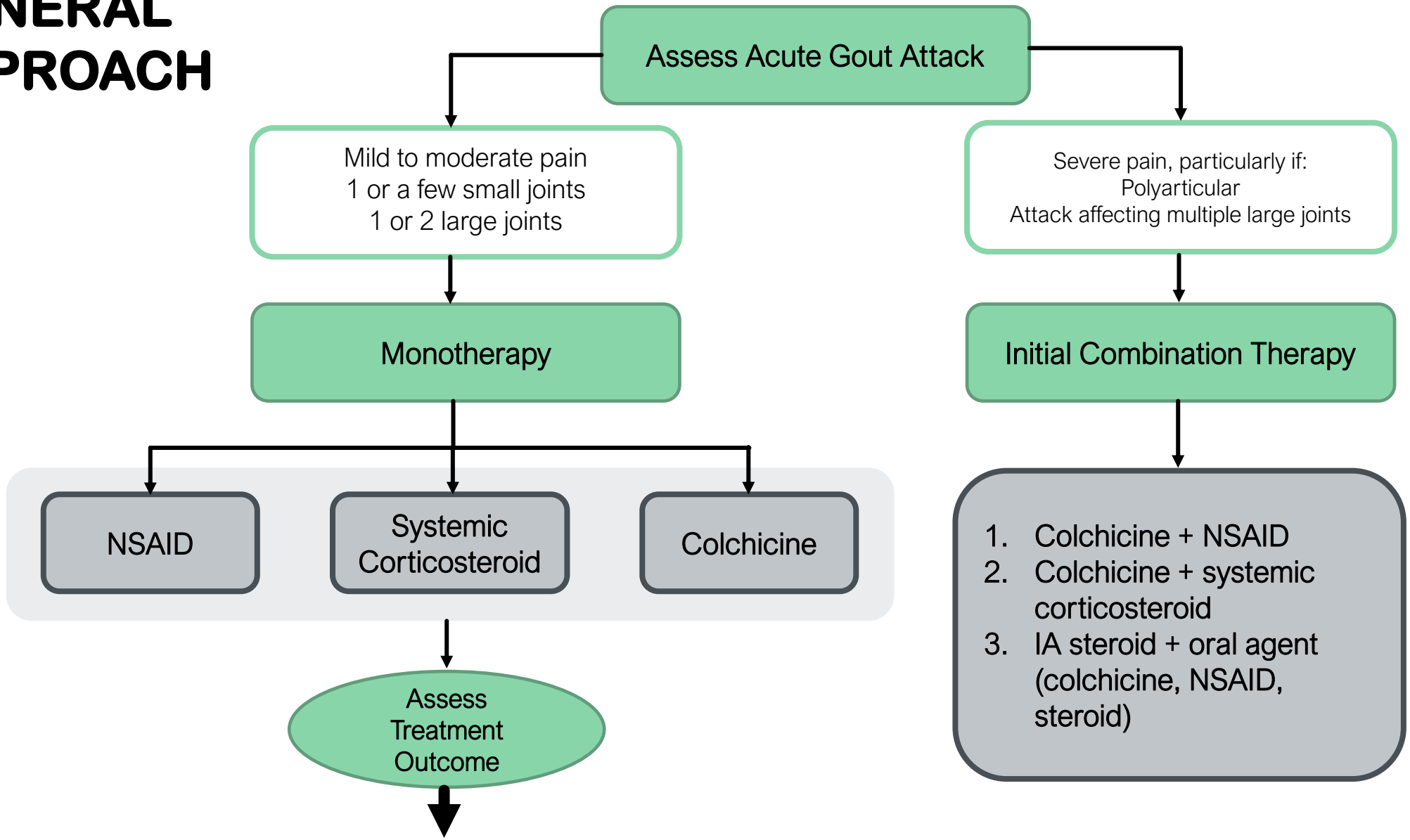
KNOWLEDGE CHECK

- When should colchicine be initiated in relation to onset of acute gout attack?

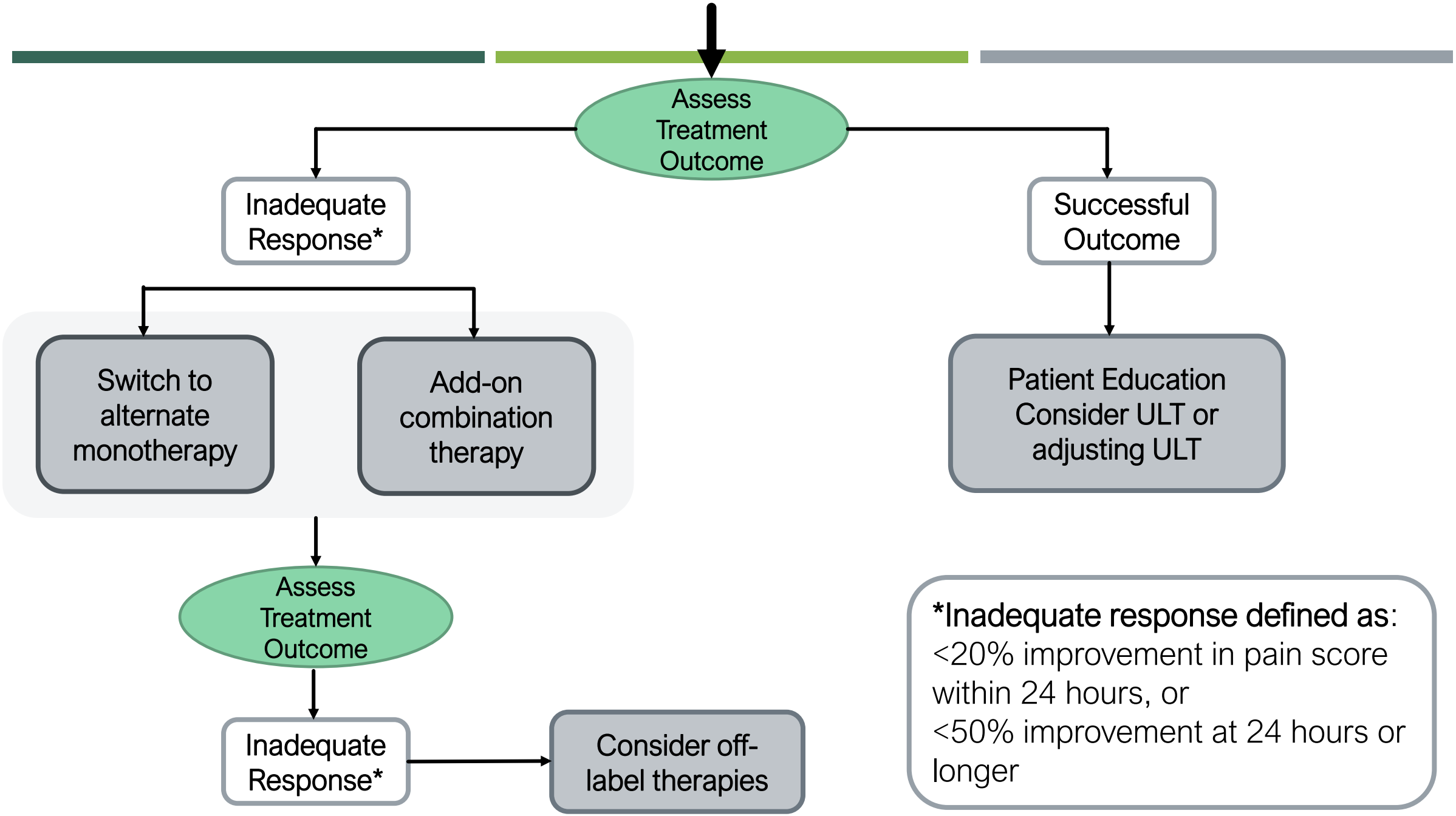
HOW DO WE CHOOSE WHICH DRUG(S) TO USE FOR TREATMENT OF ACUTE GOUT ATTACK?



GENERAL APPROACH



Adapted from 2012 ACR guidelines



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MORE EXAMPLES:

- 44 yo male with A1c of 11.5%
- 65 yo female with stage 4 CKD (eGFR 22 ml/min)
- 57 yo male with no insurance
- 74 yo female with atrial fibrillation on apixaban

TREATMENT INVOLVES ACUTE AND CHRONIC MANAGEMENT

Acute Gout Attack

Treat with full-dose anti-inflammatory:

- Colchicine
- NSAIDs
- Corticosteroid

Consider lifestyle modifications for all

Prevent Future Attack
(in patients who are indicated)

Treat with urate-lowering therapy (ULT)

- Allopurinol
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- Probenecid
- Pegloticase

+

Treat with anti-inflammatory acute gout prophylaxis (when ULT is initiated)

- Low-dose colchicine
- Low-dose NSAIDs
- Low-dose prednisone

PREVENTION OF RECURRENT GOUT

OVERALL APPROACH

- Provide patient education regarding diet/lifestyle modifications
- Consider elimination of drugs that raise serum uric acid if possible
- Assess whether there is an indication for urate lowering therapy (ULT)
  - If indicated, treat to serum urate target
    - Minimum serum urate goal is < 6 mg/dL
  - Initiate concomitant "acute gout prophylaxis" with anti-inflammatory drug when starting ULT
- ULT is usually considered lifelong therapy

URATE-LOWERING THERAPY (ULT)

STRONGLY recommended in any patient with established diagnosis of gouty arthritis and:

- ≥ 1 subcutaneous tophi
- Evidence of radiographic damage attributable to gout
- Frequent gout flares (≥ 2 attacks/year)

CONDITIONALLY recommended for patients who:

- Have previously experienced >1 flare but have infrequent flares (<2/year)
- Have a first gout flare AND one or more of the following:
  - CKD stage 3-5
  - Serum uric acid >9 mg/dL
  - Urolithiasis

CONDITIONALLY recommended against in patients who:

- Have a first gout flare with “uncomplicated” gout
- Have asymptomatic hyperuricemia (uric acid >6.8 mg/dL with no prior flares or tophi)

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ULT DRUGS

Xanthine Oxidase Inhibitors	• Allopurinol • Febuxostat (Uloric®)
Uricosuric	• Probenecid • Losartan, Fenofibrate
Uric Acid Transporter 1 (URAT1) Inhibitor	• Lesinurad (Zurampic®)
Recombinant urate-oxidase enzyme	• Pegloticase (Krystexxa®)

XANTHINE OXIDASE INHIBITOR: ALLOPURINOL

- First line drug in most patients requiring ULT
- Dosing:
  - *Initial:* 100 mg daily (50 mg daily in CKD stage 4 or 5)
  - Titrate to serum urate target as tolerated. Max dose = 800 mg/day
  - Split daily dosing when using >300 mg/day
- Generally, well tolerated
  - Some side effects include GI distress, elevated LFTs

ALLOPURINOL – POTENTIAL TOXICITIES

- Drug-induced rash
  - Dose-dependent
  - Discontinue if rash develops
- Allopurinol Hypersensitivity Syndrome
  - Rare, but potentially fatal (20-25% mortality rate)
  - Genetic testing of HLA-B*5801 allele recommending in following populations: Koreans with CKD stage 3 or worse, Han Chinese patients, or Thai patients
    - If positive → avoid allopurinol
  - Manifests at hypertension, severe rash, leukocytosis, eosinophilia, acute kidney dysfunction, hepatotoxicity

XANTHINE OXIDASE INHIBITOR: FEBUXOSTAT (ULORIC®)

- Greater urate-lowering effect compared to allopurinol, but considered second line to allopurinol
- Dosing:
  - *Initial*: 40 mg PO once daily
  - Titrate to serum urate target as tolerated (Max dose = 80 mg/day FDA; 120 mg/day ACR)
  - Max dose = 40 mg/day when CrCl <30 ml/min
- Need to periodically monitor LFTs
- Box warning: higher rate of cardiovascular death compared to allopurinol

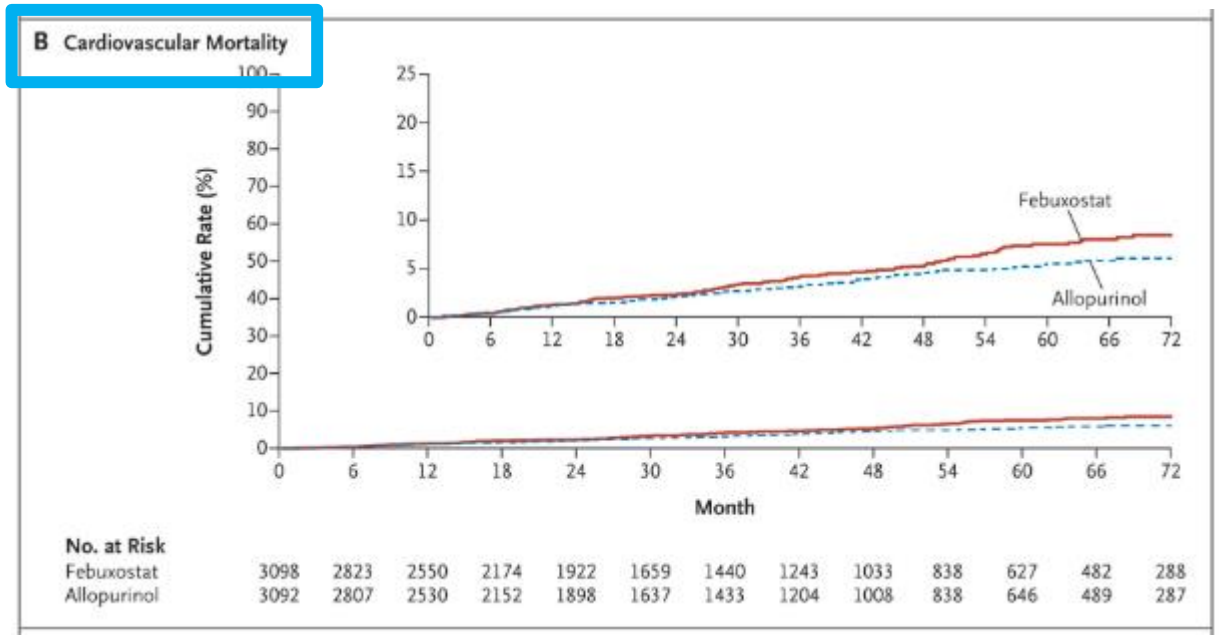
CARES TRIAL

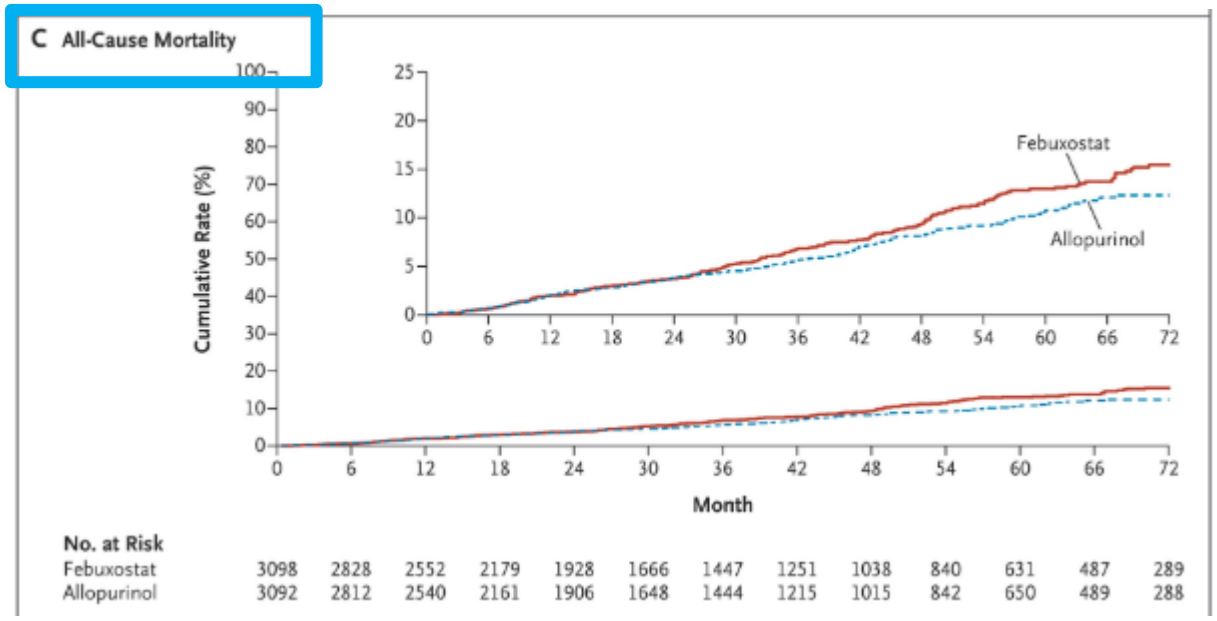
ORIGINAL ARTICLE

Cardiovascular Safety of Febuxostat or Allopurinol in Patients with Gout

William B. White, M.D., Kenneth G. Saag, M.D., Michael A. Becker, M.D., Jeffrey S. Borer, M.D., Philip B. Gorelick, M.D., Andrew Whelton, M.D., Barbara Hunt, M.S., Majin Castillo, M.D., and Lhanoo Gunawardhana, M.D., Ph.D. for the CARES Investigators*

- Patients with diagnosis of gout and history of major cardiovascular disease
- All-cause and cardiovascular mortality higher in febuxostat group than in allopurinol group





URICOSURIC: PROBENECID

- Can be used alone or in combination with xanthine oxidase inhibitor
- Inhibits renal tubule resorption of uric acid
- Not recommended in patients with CrCl < 50 ml/min (ACR)
- Contraindicated in patients with:
  - History of urolithiasis
  - Elevated urine uric acid

URICOSURICS: FENOFIBRATE, LOSARTAN

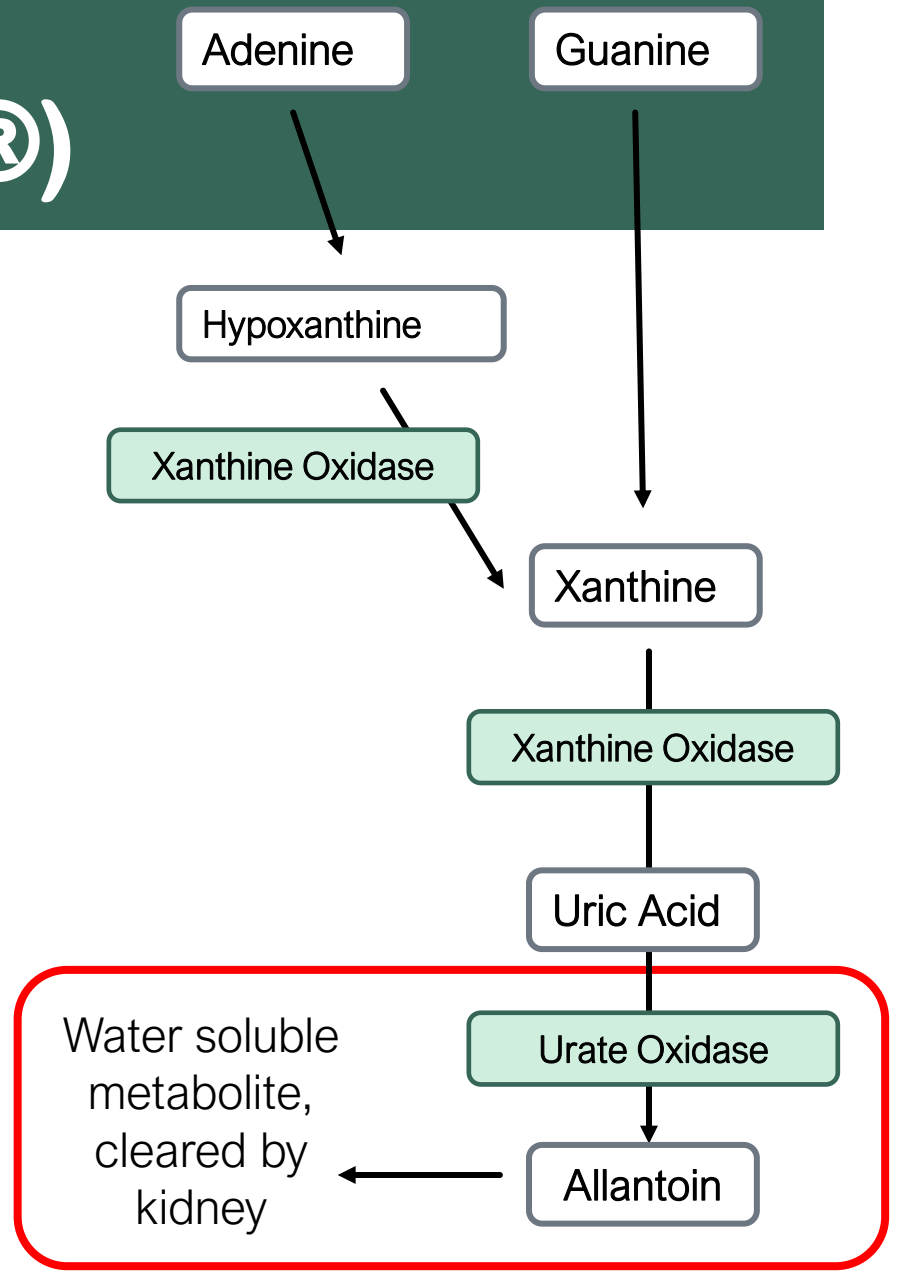
- These drugs have clinically significant uricosuric effects
- Do not have an FDA indication for gout
- Consider preferentially choosing losartan when patients have gout AND hypertension (and avoid diuretics when feasible)
- While fenofibrate has uricosuric effects, it is not recommended to add or switch cholesterol-lowering agents to fenofibrate as risks (e.g. side effects) outweigh benefit

LESINURAD (ZURAMPIC®) - FYI

- Inhibits function of transporter proteins (URAT1) involved in renal uric acid reabsorption → increases renal clearance of uric acid
- Approved December 2015
- Discontinued Feb 2019 by pharmaceutical company
  - "This is a business decision and is not related to efficacy, safety, or clinical concerns"

PEGLOTICASE (KRYSTEXXA®)

- Pegylated, recombinant urate oxidase
- Reserved for patients with severe gout disease burden and refractory to other ULT drugs
- Discontinue use of oral antihyperuricemic drugs prior to initiation
- Dosing: 8 mg IV q2 weeks
- Risk of anaphylaxis and infusion reactions



KNOWLEDGE CHECK

- What is a rare, but serious adverse effect of allopurinol?

ULT AND RISK OF ACUTE GOUT

- Even though we are using ULT for prevention of gout, there is an increased risk of acute gout attack upon initiation of ULT
- Initiation of ULT drugs lead to a disruption of pre-existing urate crystals → "mobilization gout"
- Incidence of ULT-induced acute flares decreases with time and tends to subside as serum urate levels decrease

ACUTE GOUT PROPHYLAXIS

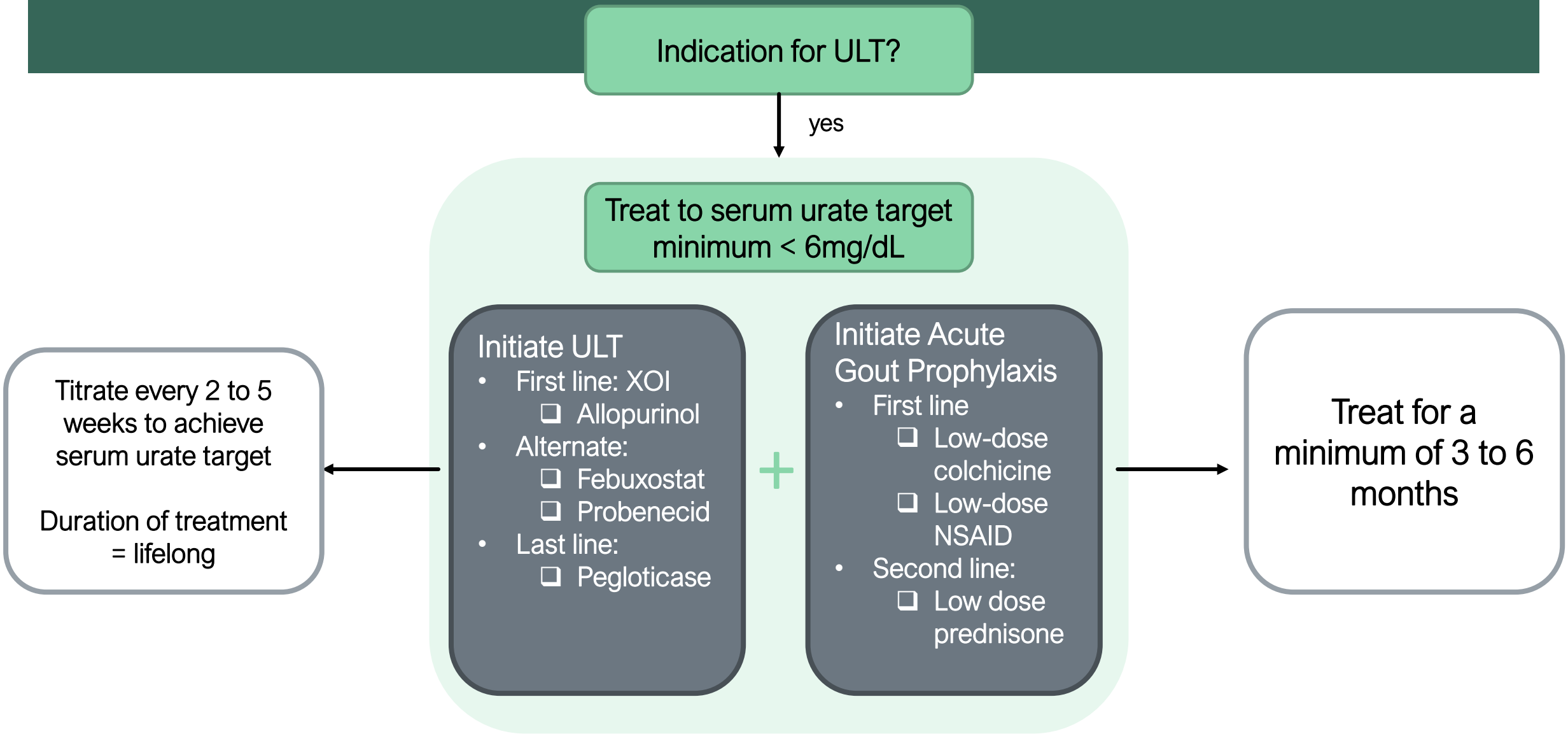
- When ULT is initiated, we also need to initiate concomitant pharmacologic anti-inflammatory acute gout prophylaxis with one of the following:
  - Low dose colchicine: 0.6 mg once or twice daily
  - Low dose NSAIDs: naproxen 250 mg PO twice daily
  - Low dose corticosteroid (prednisone ≤ 10 mg daily)

- Continue for at least 3 to 6 months with ongoing evaluation. Can continue for >6 months if needed (e.g., patient continues to experience gout flares)

INITIATION & TITRATION OF ULT

- If decision is made that ULT is indicated while patient is experiencing acute flare, ULT should be started during the flare (rather than waiting until the flare resolves)
- ULT should be titrated to achieve a serum urate target of <6 mg/dL
  - Xanthine oxidase inhibitors can be titrated every 2-5 weeks
- Guidelines recommend that nonphysician providers (specifically pharmacists or nurses) are involved in ULT management including patient education, shared-decision making, and dose titration
- Recommended to continue ULT indefinitely

PUTTING IT ALL TOGETHER: PREVENTION OF RECURRENT GOUT



PATIENT CASE

CC: "My toe is on fire"

HPI: RH is a 78-yo male who presents to the ED. RH states, "I think I'm paying the price for my fun at Oktoberfest." He reports having spent the weekend indulging on beer and sausage. Approximately 3 hours ago, he awoke to sudden excruciating pain in his right big toe. Over the past hour, his toe has become red, swollen, and so painful that he cannot walk. This is his first time experiencing these symptoms.

PMH: Hypertension, PUD, Obesity, CKD stage 3

Meds: Chlorthalidone 25 mg PO daily (started 1 month ago), omeprazole 20 mg PO daily

Vital signs/Labs:
BP 120/60 mm Hg
Weight 88 kg, Height 5'6", BMI 31.2
Uric acid = 9.3 mg/dL; CrCl = 42 ml/min

SH:
Patient typically drinks "a can of beer or two" daily but drank significantly over the past weekend

PATIENT CASE

Therapeutic Plan:

Acute attack:

Prevention:

Nonpharm:

Monitoring:

TREATMENT INVOLVES ACUTE AND CHRONIC MANAGEMENT

Acute Gout Attack

Treat with full-dose anti-inflammatory:

- Colchicine
- NSAIDs
- Corticosteroid

Consider lifestyle modifications for all

Prevent Future Attack
(in patients who are indicated)

Treat with urate-lowering therapy (ULT)

- Allopurinol
- Febuxostat
- Probenecid
- Pegloticase

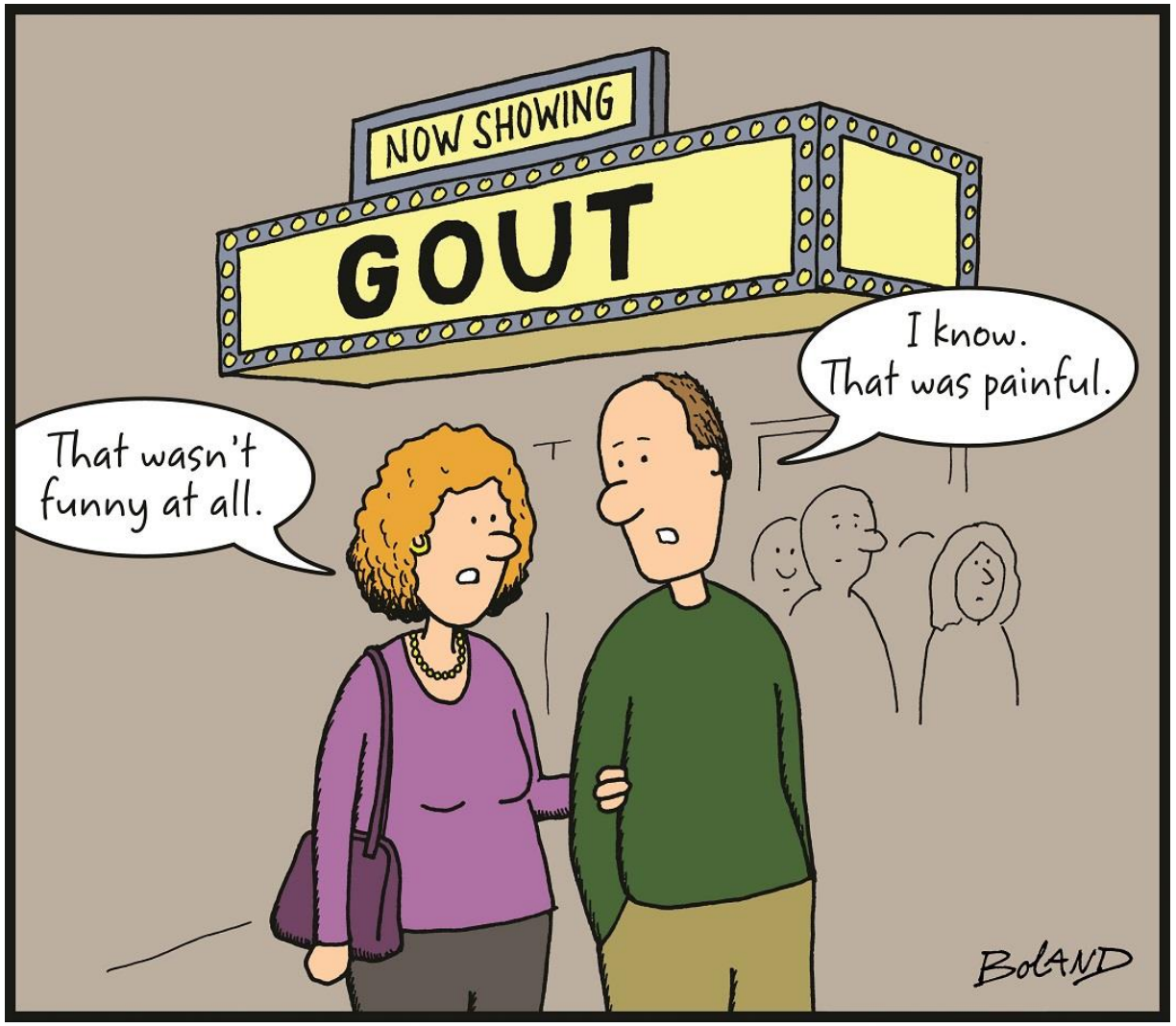
+

Treat with anti-inflammatory acute gout prophylaxis (when ULT is initiated)

- Low-dose colchicine
- Low-dose NSAIDs
- Low-dose prednisone

PHARMACIST ROLE

- Identify medications that could be contributing to risk of acute gout
- Ensure acute gout prophylaxis is concomitantly prescribed with new prescriptions for ULT
- Provide education to patients about why both ULT and acute gout prophylaxis are needed
- Use appropriate starting doses of ULT
- Titrate ULT to target
- Adjust drugs for renal function
- Monitor for drug-drug interactions



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GOUT

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