TB Nurse Case Management
Lisle, Illinois
April 27-28, 2010

TB Medications and Adverse Reactions
Alisha Blair, LVN

April 27, 2010

TB Medications and Adverse Effects

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April 27th 2010
Lisle, Illinois
Objectives

- Describe the monitoring process for adverse drug events associated with anti-TB drugs.
  - Side effects versus drug toxicities
  - Recognizing the most common adverse effects of TB therapy

- Discuss the nursing interventions and medical management of the most common adverse drug events seen in patients on first- and second-line anti-tuberculosis therapy.
  - Case studies
  - Management and monitoring adverse reactions in special patients
  - Pediatrics

Adverse Drug Reaction Definitions

- “An undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both.”

- “An unintended harmful reaction to a drug administered at normal dosage”
Side effects

Usually *predictable* or dose dependent effect of drug (that is not the principle effect) for which the drug was chosen

- Desirable
- Undesirable

Serious Adverse Reactions
Anti-TB Therapy Toxicities

- Hepatotoxicity
- Ophthalmic toxicity
- CNS toxicity
- Neurotoxicity
- Ototoxicity
- Renal toxicity
Common Side Effects
Anti – TB Drug

- Gas
- Bloating
- Mild nausea
- Discoloration of body fluids
- Irritability
- Difficulty sleeping
- Photosensitivity

Drug Management Goals

- Recognize adverse drug events
- Assess appropriately
- Intervene rapidly
  - Prevent further morbidity/mortality
  - Minimize treatment interruptions
  - Reduce opportunities for “medical mismanagement”
  - Avoid development of psychological intolerance
  - Support adherence and the therapeutic relationship
First-line Drug Reactions

- Isoniazid (INH)
- Rifampin (RIF)
  - Rifabutin
- Ethambutol (EMB)
- Pyrazinamide (PZA)

Isoniazid (INH)

Common Reactions
- Epigastric discomfort
- Elevated liver transaminases, mild
- Hypersensitivity rxn, mild
- Nausea / vomiting
- Paresthesias, mild
  - Peripheral neuropathy
- Pyridoxine deficiency

Serious Reactions
- Agranulocytosis
- Aplastic anemia
- Hepatotoxicity, incl. fatal
- Hypersensitivity rxn
- Optic neuritis
- Peripheral neuropathy
- Seizures
- Thrombocytopenia
- Toxic psychosis
Managing & Monitoring of INH

• Avoid alcohol

• Monitor seizure disorders, especially if taking Phenytoin

• Avoid foods containing **Tyramine**, may cause hypertensive crisis
  – If flushing occurs instruct patients to decrease intake monoamines
  – 10 to 25 mg of tyramine required for a severe reaction

Tyramine Containing Foods

• Aged cheese
• Aged or cured meats (e.g., air-dried sausage)
• Any potentially spoiled meat, poultry, or fish
• Broad (fava) bean pods
• Marmite concentrated yeast extract
• Sauerkraut
• Soy sauce and soy bean condiments
• Tap beer, Chianti wine and vermouth
• Liquid and powdered PROTEIN DIETARY SUPPLEMENTS
Rifampin

Common Reactions
- Abdominal pain
- Anorexia
- Diarrhea
- Dizziness / Ataxia
- Dyspnea
- Elevated liver transaminases
- Fatigue / Drowsiness
- Headache
- Hypersensitivity rxn, mild
- Nausea / Vomiting
- Visual changes

Serious Reactions
- Agranulocytosis / Leukopenia
- Anaphylaxis
- Hemolytic anemia
- Hemorrhage / DIC
- Hepatitis
- Interstitial nephritis / Renal failure
- Porphyria exacerbation
- Pseudomembranous colitis
- Psychosis
- Shock
- Thrombocytopenia

Managing & Monitoring Rifampin

- Monitor CBC monthly
- Advise women using hormonal contraceptive to use another form of control
- Reduction of methadone almost to an ineffective level
- Cannot use with some Antiretroviral drugs
Rifabutin
Same as Rifampin +

**Common Reactions**
- Asthenia
- Chest pain
- Diarrhea
- Dyspepsia
- Eructation
- Fever
- Flatulence
- Insomnia
- Myalgias
- Pain
- Rash
- Taste changes
- Yellow skin

**Serious Reactions**
- Clostridium difficile associated diarrhea
- Neutropenia (agranulocytosis)
- Uveitis

Ethambutol (EMB)

**Common Reactions**
- Abdominal pain / Dyspepsia
- Anorexia
- **Blurred vision** / Dizziness
- Disorientation / Hallucinations
- Elevated LFTs
- Fever
- Headache
- Hyperuricemia
- Joint pain
- Malaise
- Nausea / Vomiting
- Rash / Pruritus

**Serious Reactions**
- Anaphylaxis
- **Blindness**, irreversible
- Erythema multiforme
- Hepatotoxicity, incl. fatal
- Hypersensitivity syndrome
- Leukopenia
- Neutropenia
- Optic neuritis
- Peripheral neuropathy
- Thrombocytopenia
Managing & Monitoring EMB

- Baseline & monthly visual acuity test (Snellen chart)
- Baseline & monthly color discrimination test (Ishihara tests)
- Question pt regarding possible visual disturbances including blurred vision & scotomata
  - Observe children for eye rubbing, excessive blinking, sitting close TV, difficulty with accurate grasping
  - Hold Rx
  - Refer for Ophthalmologic evaluation
  - Permanent vision impairment if Rx continued

Pyrazinamide (PZA)

**Common Reactions**
- Anorexia
- Arthralgia
- Elevated LFTs
- Gout
- Hyperuricemia
- Malaise
- Nausea / Vomiting
- Photosensitivity
- Rash / Urticaria

**Serious Reactions**
- Anemia
- Hepatotoxicity
- Interstitial nephritis
- Porphyria
- Thrombocytopenia
Managing & Monitoring of PZA

• Little info about the safety of PZA in pregnancy

• Serum uric acid measurements are not recommended as a routine but may serve as a surrogate marker for compliance.

Second-line Drugs

• Cycloserine
• Ethionamide
• Levofloxacin
• Moxifloxacin

• PAS
• Streptomycin
• Amikacin
• Kanamycin
• Capreomycin
Cycloserine

Common Reactions
- Allergic rxn
- Behavior changes / Aggressive behavior / Irritability
- Confusion
- Dysarthria
- Elevated liver transaminases
- Headache
- Hyperreflexia / Tremors
- Impaired memory
- Paresthesias
- Rash
- Somnolence
- Vertigo

Serious Reactions
- Anemia
- CHF, acute
- Coma
- Psychosis
- Seizures
- Suicidal ideation

Ethionamide

Common Reactions
- Anorexia
- Diarrhea
- Dizziness
- Drowsiness
- Dyspepsia
- Elevated liver transaminases
- Excessive salivation
- Gynecomastia
- Headache
- Hypoglycemia
- Hypothyroidism
- Impotence
- Metallic taste
- Nausea / Vomiting
- Orthostatic hypotension

Serious Reactions
- Hepatitis
- Hypothyroidism
- Optic neuritis
- Peripheral neuritis
- Psychosis
- Thrombocytopenia
Levofloxacin

Common Reactions
- Abdominal pain
- Constipation / Diarrhea
- Dizziness
- Dyspepsia
- Headache
- Insomnia
- Nausea / Vomiting
- Tendonitis

Levofloxacin Continued

Serious Reactions
- Anaphylaxis
- Arthralgia / Myalgia
- Arthropathy (animal studies)
- Blood dyscrasias
- C. diff associated diarrhea
- Depression / Suicidal ideation
- Hepatotoxicity, incl. fatal
- Hypersensitivity rxn
- ICP increase / Seizures
- Myelosuppression
- Nephrotoxicity
- Peripheral neuropathy
- Phototoxicity / Photosensitivity
- Pneumonitis, allergic
- QT prolongation / Torsades de pointes
- Serum sickness
- Skin rxns, severe
- Tendon rupture
- Superinfection
- Toxic psychosis
- Vasculitis
Monitoring & Managing Levo.

Tendonitis/Tendon Rupture

- Tendon rupture (usually Achilles) is rare
- If tendon inflammation mild:
  • Rest the joint/NSAID’s
  • Evaluate dose and reduce if possible
  • If symptoms progress, stop the fluoroquinolone
  • Evaluate risks and benefits of continuing drug in regimen

Moxifloxacin

Common Reactions

- Diarrhea
- Dizziness
- Nausea
Moxifloxacin

Serious Reactions

- Anaphylaxis
- Arthropathy (animal studies)
- Blood dyscrasias
- Depression / Suicidal ideation
- Hepatotoxicity, incl. fatal
- Hypersensitivity rxn
- ICP increase / Seizures
- Myelosuppression
- Nephrotoxicity
- Peripheral neuropathy
- Phototoxicity
- Pneumonitis, allergic
- Pseudomembranous colitis
- QT prolongation / Torsades de pointes
- Serum sickness
- Skin rxns, severe
- Superinfection
- Tendon rupture
- Toxic psychosis
- Vasculitis

p-Aminosalicylic acid (PAS)

Common Reactions

- Abdominal pain
- Diarrhea
- Hepatitis
- Nausea / Vomiting

Serious Reactions

- Hypothyroidism
- Hypokalemia
- thrombocytopenia
Monitoring and Management

PAS

• Monitor abdominal pain diarrhea
  – Diarrhea improves with time (self limiting)
• Management
  – Mix with acidic juice or apple sauce
• Monitor Thyroid function

Streptomycin

Common Reactions

• Amblyopia
• Vertigo
• Nausea / Vomiting
• Rash / Urticaria
• Fever
• Injection site rxn

Serious Reactions

• Anaphylaxis
• Angioneurotic edema
• Azotemia
• Hemolytic anemia
• Deafness
• Eosinophilia
• Exfoliative dermatitis
• Leukopenia
• Muscle weakness
• Pancytopenia
• Paresthesias, facial
• Thrombocytopenia
Amikacin

**Common Reactions**
- Dizziness
- Elevated BUN & Creatinine
- Mild Hearing loss
- Injection site rxn
- Tinnitus
- Vertigo

**Serious Reactions**
- **Auditory ototoxicity**
- Hypersensitivity rxn
- Nephrotoxicity
- Neuromuscular blockade
- Neurotoxicity
- Superinfection
- Vestibular ototoxicity

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**Auditory Toxicity**

Perform audiometry at baseline and repeat monthly

- Identify pre-existing hearing loss
- Refer for evaluation if any decrease from baseline

- Fullness, ringing, roaring, hissing, or “buzzing” in ears
- Generally reversible
### Kanamycin

#### Common Reactions
- Elevated BUN & Creatinine
- Hearing loss
- Injection site rxn
- Tinnitus
- Vertigo

#### Serious Reactions
- Anaphylaxis
- Auditory ototoxicity
- Hypersensitivity rxn
- Nephrotoxicity
- Neuromuscular blockade
- Neurotoxicity
- Superinfection
- Vestibular ototoxicity

### Capreomycin

- Abnormal liver function tests
- Eosinophilia
- Hearing loss
- Hypersensitivity (febrile reactions, urticaria, maculopapular rash)
- Induration and excessive bleeding at injection site
- Leukocytosis / Leukopenia
- Nephrotoxicity
- Ototoxicity
- Pain
- Sterile abscesses
- Thrombocytopenia
Monitoring for Toxicity in High Risk Patients

• Patients with HIV Taking Protease Inhibitors Should not take Rifampin
  – Interacts with HIV meds: NNRTI’s (Sustiva) and PI’s (Kaletra, ritonavir, Reyataz)
  – Rifabutin in reduced dose is good option
  – Ensure Patients are taking PI’s

• Monitor for IRIS Reaction
  – Worsening CXR
  – Enlarging Lymph Nodes
  – Worsening TB Symptoms

• Educate Patient

Case Studies
Hepatotoxicity

38 y.o. male diagnosed with PTB during incarceration

- Mar. 13: started standard RIPE regimen
  - Baseline laboratory values: ALT 42, AST 63

- April 15: changed to BIW dosing; EMB d/c'd when susceptibility results showed isolate to be susceptible to INH/RIF

- June 4: F/U laboratory values: ALT 304, AST 97
  - Asymptomatic for hepatitis

Hepatotoxicity Cont.

What is the appropriate response?

- Hold TB medications!
  ALT \geq 5\times \text{ULN} in asymptomatic patient, or \geq 3\times \text{ULN} in patient with signs/symptoms consistent with hepatitis
Hepatotoxicity

When can therapy be safely restarted?

Once ALT is < 2X ULN

Hepatotoxicity Cont.

Should other TB therapy be started?

If it is likely there will be a delay of > 2-3 wks consideration can be given to starting a “liver friendly” regimen (EMB, fluoroquinolone, aminoglycoside) while waiting for LFT’s to normalize
Hepatotoxicity Cont.

What treatment should be considered when ALT returns to < 2X normal?

• RIF/EMB X 3-7 day
  Monitor LFT’s twice weekly

• If LFT’s stable after 3-7 days, add INH
  Continue to monitor LFT’s twice weekly

• If LFT’s stable, EMB can be discontinued and pt. returned to BIW dosing and tx. completed with INH/RIF

Immune Reactions

77 y.o. contact to daughter, PTB suspect

• Jan. 31: initial clinic visit
  • TST + (15 mm)
  • C/O several weeks of productive cough, now asymptomatic
  • CXR: blunting of CPA
  • Sputum AFB smear + (<1/HPF); culture pending
  • PMH: arthritis, 71 yr tobacco hx, hospitalized 1 mo prior for pneumonia/bronchitis

• Feb.4: started RIPE standard regimen
  • Baseline LFT’s WNL
Immune Reactions

Feb. 13: ER visit; c/o generalized rash, swelling of lower lip

- RX: injection (?) plus prednisone 20 mg. BID
- TB medications held
- Local TB physician consulted
- Reinitiate one drug at a time to identify offending agent
- Request consult from State TB expert physician consultant

Immune Reactions Cont.

Feb. 17: Received dose of INH 300mg in TB clinic

- Prior to dose, c/o itching of scalp, no visible rash or swelling
- Clinic RN requested consult from State TB physician consultant that day

What concerns might you have in rechallenging this patient with TB medications?
Immune Reactions Cont.

Follow up:

• Provider given rechallenge protocol, but elected to hold TB medications pending further evaluation
• All sputum cultures eventually reported negative for AFB
• CXR: minimal abnormality, not suggestive of TB
• Patient remained asymptomatic
• + TST may be from recent exposure to daughter or may represent old infection in a 77 y/o ♀ living along the US/Mexico border

Consider risks vs. benefits of treatment

Evaluate The Rash

• When did it start?
• Where is it?
• What does it look like now? Is that different?
• Has it spread?
• What makes it better or worse?
• Does it itch?
• Have you had an insect bite?
• New Soaps or Perfumes?
Stevens-Johnson Syndrome
Mild, maculopapular rashes and/or itching

Maculopapular Drug Eruption
Maculopapular Drug Eruption

Petechial rash
Petechial Rash

Urticaria/Hives
Ophthalmic Toxicity

21 yo male diagnosed with PTB in October

- **February-May**: Incarcerated in county jail
  - May: onset of illness (fever, chills, productive cough, chest pain, night sweats, wt. loss)

- **October 7**: Initial Clinic Visit
  - CXR: LUL cavitary infiltrate
  - AFB smear + (1-10/HPF), sent for culture

- **October 12**: Started RIPE standard regimen

- **November 9**: Isolate reported INH/SM resistant

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Ophthalmic Toxicity

What do we do next?

- Pt. improving: afebrile, 6 lb wt. gain, night sweats resolved, cough improving

- INH discontinued; continued on RIF, PZA, **EMB** to complete 9 mo. treatment
Ophthalmic Toxicity

- **March**: pt. c/o difficulty driving, reading road signs

  **What do we do?**

  - Advised by LHD nurse to see “eye doctor”
    - **March 21**: seen by optometrist and given RX for corrective lenses (3/30)
    - EMB continued

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Ophthalmic Toxicity

- **May 3**: Pt. c/o worsening vision
    - Visual acuity: 20/200 both eyes
      - Baseline visual acuity (October): 20/20 both eyes

  **What would you do?**

- **May 5**: EMB discontinued; continued on RIF, PZA and Levo added to regimen to complete 9 mo of tx.

- Referred to retinal specialist
Ophthalmic Toxicity

Follow-up

- Seen by retinal specialist in May and June
  - DX: EMB optic neuropathy
  - Central scotoma on right and parascotoma on left
  - Vision uncorrected: 20/200
  - Vision best corrected: 20/60

- Nurse admitted not performing visual acuity screening (Snellen chart), only color discrimination testing (Ishihara plates)

Optic Neuritis
Uveitis

Central Nervous System

48 y.o. female with drug susceptible PTB

- PMH significant for treatment for depression 1992-1996

- Jan. 15: started RIPE standard regimen

- Jan. 24: reported to ER with c/o insomnia, loss of energy, fatigue, anorexia, difficulty concentrating, unable to work, uncontrollable crying spells, suicidal ideation
Central Nervous System

What do we do?

• Prescribed Effexor-XR

• Discharged to her home under husband’s supervision with f/u appointment for psychiatric evaluation

Central Nervous System

• Jan. 26: initial evaluation by psychiatrist
  – Dx’ed with substance induced mood disorder
  – INH held; continued on RIF, PZA, EMB

• Feb. 1: CV for DOT

What do we assess for?

– Described as “like a different person”; reported feeling better, mood and affect brighter, make-up applied, neatly dressed, denied suicidal ideation
Central Nervous System

• **Feb. 10**: F/U with psychiatrist
  
  – No evidence of depressive signs/symptoms
  – Effexor-XR continued
Special Conditions

• HIV-TB Co-infected Patient
  – Patients not taking antiretroviral therapy are candidates for standard four drug TB treatment for 6-9 months
    • Rifampin, Isoniazid, Pyrazinamide, Ethambutol
  – Patients receiving anti-retroviral therapy
    • Monitor for interactions between rifamycins, protease inhibitors, and non-nucleoside reverse transcriptase inhibitors
      – Seek Consultation From Expert

Treatment Considerations in Coinfection

• Initiation of HAART and TB treatment
  – Initiation should not be simultaneous
    • Ideally treat TB first with initiation of HAART introduced at 4-8 weeks.
    • Possible exception, pts with CD4 < 50

• Management of TB Regimen
  – Similar to patients without HIV
    • 2 month initial phase
    • 4 month continuation phase
    • Pts with CD4 < 100, dosing daily or tri-weekly
Monitoring: Baseline

- LFT's
- Renal function
- CBC
- CMP
- Uric Acid with PZA
- Visual acuity with EMB
- CD4

TB IRIS

Emergence of new manifestations of TB or the worsening of existing symptoms of TB in the presence of appropriate anti-TB therapy

- Frequency of reaction varies from 11% to 45%
- Occurs more often in patients with:
  - lower CD4+ counts
  - extra-pulmonary disease
  - disseminated disease
  - shorter interval from TB diagnosis to antiretroviral initiation
- Reported most frequently within 6 weeks of TB treatment initiation in the presence of HAART
- Usually self limiting
Drug-Drug Interactions: Rifamycins & ARVs

**Goal is to manage complications, not avoid them**

- Preferred regimen: Rifampin and the NNRTIs
  - Rifampin → ↓Efavirenz concentrations
  - Can dose adjust Efavirenz: 600 → 800 mg q day

- Not all patients can tolerate NNRTIs
  - Alternative choice: PIs

- Rifampin contraindicated with all boosted PIs
  - Alternative choice: Rifabutin

Rifabutin

- Less Reactions with PI's
  - Preferred to Rifampin in treating HIV/TB co-infected patients
  - Effective for Tuberculosis Treatment

- Rifabutin
  - Similar efficacy to Rifampin in TB therapy

- Rifabutin and Protease Inhibitors (PIs)
  - Rifabutin does not affect serum concentration of PIs
  - PIs (especially ritonavir-boosted regimens) increase rifabutin levels → rifabutin toxicity (uveitis, eye pain, elevated LFTs, neutropenia)
Ongoing Monitoring

- HIV-TB co-infected patients receiving ART
  - Monitor
    - Concomitant Medications
    - Drug-Drug Interactions
- It is Essential to Monitor Labs
  - Hepatotoxicity
- Assess the need for dose adjustments for both TB/HIV Meds
- Clinical

Overlapping Side Effects

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Special Conditions Pregnancy

- Pregnant women confirmed or suspected of having TB
  - Treat without delay
    - RIF, INH, EMB, B6
    - No PZA
      - No data on risk for teratogenicity
  - Usually 9 months
- Low Concentrations of TB Meds in breast-milk does not cause toxicity
- Same Monitoring process

Reporting ADRs

- Form EF12-12274
  - [Link to form](http://www.dshs.state.tx.us/idcu/investigation/forms/TBEF12-12274AdverseDrugReaction.pdf)

- Information forwarded to CDC and/or FDA, if necessary
References

• TB at a Glance, "A guide for Practitioners on Basic Tuberculosis Information": revised Dec 2009.
• Centers for Disease Control, "Managing Drug Interactions in the Treatment of HIV-Related Tuberculosis": Dec 2007

Special Thanks
Sarah Hoffman, MSN, ACRN
Debbie Onofre, BSN