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Azithromycin

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Continuing Education Activity

Azithromycin is a macrolide primarily prescribed to treat bacterial infections, including community-acquired pneumonia and sexually transmitted infections. This activity addresses the indications, mechanism of action, and contraindications of azithromycin, emphasizing critical factors such as administration, adverse event profile, toxicity, monitoring, and drug interactions. This review provides healthcare professionals with essential insights for optimizing azithromycin therapy by tailoring treatment to patient-specific needs, minimizing adverse effects, and ensuring safety in diverse populations.

A deeper understanding of azithromycin's pharmacological properties enables informed prescribing decisions and appropriate dosing strategies. This program underscores the role of interprofessional collaboration, clarifying roles, and enhancing coordination within the healthcare team to support effective management of azithromycin therapy for bacterial infections. By equipping healthcare professionals with evidence-based knowledge, this activity fosters improved patient outcomes through personalized and effective treatment plans, advancing standards in care related to azithromycin administration.

Objectives:

- Identify the mechanism of action and appropriate administration methods of azithromycin.
- Assess the adverse effects and contraindications associated with azithromycin therapy.
- Evaluate the appropriate monitoring strategies for patients receiving azithromycin therapy.
- Implement effective collaboration and communication among interprofessional team members to improve outcomes and treatment efficacy for patients who might benefit from azithromycin therapy.

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Indications

Azithromycin is a broad-spectrum macrolide antimicrobial and one of the most frequently prescribed antimicrobial drugs in the United States. Azithromycin is an erythromycin derivative with greatly enhanced activity against gram-negative bacteria (including *Enterobacteriaceae*) that also provides coverage against many gram-positive organisms.[1][2] As an inhibitor of bacterial protein synthesis, azithromycin is effective against many "atypical" bacteria such as chlamydiae (eg, *Chlamydia trachomatis* and *Chlamydophila psittaci*), legionella (eg, *Legionella pneumophila*), mycoplasma (eg, *Mycoplasma pneumoniae*), and mycobacteria (eg, *Mycobacterium avium*).[3]

FDA-Approved Indications

- Community-acquired pneumonia (CAP) caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis* [4]
- Other upper respiratory infectious processes, including acute otitis media and acute exacerbation of chronic obstructive pulmonary disease (COPD) [5]
- Pharyngitis caused by *Streptococcus pyogenes* (as an alternative to a β-lactam agent)
- Skin infection due to *S pyogenes*, *Streptococcus agalactiae*, or *Staphylococcus aureus*
- *M avium* complex (MAC) infection treatment and prophylaxis for patients with advanced AIDS
- Sexually transmitted infections, including chlamydia, gonococcal disease, chancroid (*Haemophilus ducreyi*), and *Mycoplasma genitalium* [6][7][8][9][10]
- Urethritis and cervicitis caused by *C trachomatis* or *Neisseria gonorrhoeae*. However, the CDC guidelines recommended azithromycin only in combination with gentamicin for uncomplicated gonococcal infections of the cervix or urethra, particularly for patients with a cephalosporin allergy.[11]

Off-Label Uses

- *Salmonella typhi* infection (enteric fever) [12]
- Long-term prophylaxis for bronchiolitis obliterans (BO) in patients who have undergone lung transplantation [13]

One study examined whether adding azithromycin to standard therapy could induce remission in patients with persistent uncontrolled asthma compared to placebo. Data from 335 participants over 12 months included increased rates of clinical remission and remission with lung function criteria, with some achieving complete remission. Factors such as better asthma-related quality of life predicted clinical remission. These findings suggest that azithromycin may help achieve asthma remission, highlighting its therapeutic potential. However, antimicrobial resistance should be considered.[14]

A systematic review and meta-analysis suggest that azithromycin may reduce hospitalization duration in children with acute bronchiolitis who are younger than 2 years, but it does not prevent the recurrence of wheezing. Further studies with larger sample sizes and clinically relevant outcomes are necessary.[15]

For patients 6 years and older with cystic fibrosis and persistent *Pseudomonas aeruginosa* infection, the Cystic Fibrosis Foundation recommends the long-term administration of azithromycin to improve lung function and reduce exacerbations. However, due to potential resistance in patients with nontuberculous mycobacterial infections, screening for nontuberculous mycobacteria is advised before initiating azithromycin and every 6 to 12 months thereafter. The committee has determined the benefit of long-term azithromycin therapy to be high for patients with *P aeruginosa* infection and moderate in those without, with the estimated net benefit deemed small. Meta-analyses indicates that azithromycin therapy for patients with cystic fibrosis yields modest improvements in respiratory function and reduces exacerbation risk, though long-term efficacy is uncertain. Concerns about macrolide resistance highlight the need for further research, especially for patients receiving cystic fibrosis transmembrane conductance regulator modulator therapies.[16][17]

Azithromycin also has efficacy against some protozoal organisms such as *Babesia* spp. (eg, *B microti*), *Plasmodium* spp. (eg, malaria), and *Toxoplasma gondii.* This medication is sometimes used off-label for the treatment of these parasitic diseases in combination with antiprotozoal drugs such as atovaquone.[18][19][20] According to the Infectious Diseases Society of America (IDSA), atovaquone combined with azithromycin is the preferred antimicrobial regimen for babesiosis.[21][22]

Azithromycin's role in managing viral infections, including respiratory syncytial virus and SARS-CoV-2 has not been determined.[23][24][25][26][27]

Mechanism of Action

Like other macrolide antimicrobials, azithromycin binds to the 23S portion of the 50S bacterial ribosomal subunit. The drug inhibits bacterial protein synthesis by preventing the transit of aminoacyl-tRNA and the growing protein through the ribosome. Azithromycin is less prone to disassociation from the gram-negative ribosome than erythromycin, which may explain its greater efficacy against gram-negative pathogens.[28] Like other macrolides and protein-synthesis inhibitors, azithromycin is primarily bacteriostatic, inhibiting bacterial growth rather than directly killing organisms. However, higher doses of azithromycin have a bactericidal effect against certain bacteria, such as streptococci and *H influenzae*.[29][30]

Azithromycin rapidly moves from the bloodstream into tissues and, once there, readily crosses cellular membranes, making it effective against intracellular pathogens.[28][30] In nonbacterial organisms (ie, apicomplexan parasites such as *Babesia spp.*, *Plasmodium spp.*, and *Toxoplasma spp.*), azithromycin inhibits the 50S ribosome found in the parasite apicoplast, an endosymbiosis-derived organelle with bacteria-like protein-synthesis machinery that performs critical metabolic functions.[31][32]

In addition to azithromycin’s antimicrobial activity, it is a potent immunomodulator that markedly reduces airway neutrophilia, IL-8 gene expression, and C-reactive protein levels in lung transplant recipients and cystic fibrosis.[33][34] Azithromycin has in vitro antiviral properties, which has created interest in the experimental treatment of SARS-CoV-2. By inducing the expression of retinoic acid-inducible gene I (*RIG-I*) like helicases, azithromycin enhanced the rhinovirus-induced expression of interferons in cultured cells of COPD patients but not in cultured cells of healthy patients in vitro.[35]

Azithromycin resistance mechanisms are primarily linked to mutations in the 23S ribosomal subunit across various bacterial species, including *N gonorrhoeae*, *P aeruginosa*, and *C trachomatis*. In *Enterobacteriaceae*, resistance is associated with 23S rRNA mutations and ribosomal protein alterations, often coupled with methylation by erm-like genes. Efflux pump overexpression is a common resistance mechanism observed in *P aeruginosa*, *E coli*, and *S aureus*, contributing to reduced drug accumulation.[36]

Pharmacokinetics

Absorption: The absolute bioavailability of a 250 mg dose of azithromycin is approximately 38%. When administered as an oral suspension with food, the peak plasma concentration increases by 56%, while the area under the curve (AUC) remains unchanged.

Distribution: Azithromycin demonstrates excellent tissue penetration and intracellular accumulation. Azithromycin exhibits variable serum protein binding, decreasing from 51% at a concentration of 0.02 µg/mL to 7% at 2 µg/mL. Azithromycin penetrates various human tissues, including the skin, bones, lungs, tonsils, cervix, prostate, ovaries, uterus, stomach, liver, and gallbladder. Azithromycin is highly concentrated in phagocytes, with an intracellular-to-extracellular concentration ratio exceeding 30 after 1 hour. This accumulation in phagocytes likely enhances drug distribution to inflamed tissues.

Metabolism: Azithromycin is metabolized primarily in the liver. After administering single 500 mg oral or intravenous doses of azithromycin, plasma concentrations decrease in a polyphasic manner, leading to an average terminal half-life of about 68 hours.[37] The long half-life and extensive tissue and intracellular distribution permit once-daily dosing and a shorter course of treatment than other antimicrobials. For example, a chlamydia infection may be treated with a single 1 g dose of azithromycin versus 100 mg of doxycycline twice daily for 7 days.

Elimination: Biliary excretion is the primary route for eliminating unchanged medication following oral administration.[38]

Administration

Available Dosage Forms and Strengths

- Oral formulations include tablets (250 mg, 500 mg), packets (1 gram dissolved in ¼ cup or 60 mL of water), and suspension for reconstitution (100 mg/5 mL, 200 mg/5 mL). These formulations can be administered with or without food.
- Intravenous (IV) azithromycin is available in a 500 mg preservative-free solution for reconstitution. IV azithromycin should be infused over at least 60 minutes. Azithromycin should not be administered via intramuscular injection or IV bolus.
- Ophthalmic azithromycin solution (1%) for bacterial conjunctivitis is available in a 2.5 mL bottle.
- The extended-release formulation of azithromycin has been discontinued.

Adult Dosage

The standard dose is 250 or 500 mg, once daily, for 3 to 5 days. Higher doses are typically reserved for severe infections. A single 1 g dose may be given for adults with chlamydia.

Acute otitis media: For patients 6 months and older, azithromycin may be given in a single 30 mg/kg dose, or 10 mg/kg once daily for 3 days, or 10 mg/kg on Day 1, followed by 5 mg/kg/d for the next 4 days.

Community-acquired pneumonia: For patients 6 months and older with an infection due to *C pneumoniae*, *H influenzae*, *M pneumoniae*, or *S pneumoniae*, the recommended dosage is 10 mg/kg orally as a single dose on Day 1, followed by 5 mg/kg/d orally for the next 4 days. Azithromycin is usually combined with third-generation cephalosporins, such as ceftriaxone.[39]

Acute bacterial sinusitis: The azithromycin dosage is 10 mg/kg orally once daily for 3 days.

Pharyngitis/tonsillitis: For patients 2 years and older with pharyngitis or tonsillitis caused by *S pyogenes*, azithromycin is given at 12 mg/kg orally once daily for 5 days, with a maximum daily dose of 500 mg.

Specific Patient Populations

Hepatic impairment: The pharmacokinetics of azithromycin in hepatic impairment have not been determined, so it should be prescribed cautiously in this population.

Renal impairment: Azithromycin may be administered to patients with renal disease or failure without regard for creatinine clearance. Dose adjustments are usually not necessary.[37]

Pregnancy considerations: According to the American College of Obstetricians and Gynecologists guidelines, azithromycin may be included in a combination regimen for managing preterm rupture of membranes and can serve as an adjunctive prophylactic antibiotic for patients undergoing emergent cesarean delivery. Additionally, azithromycin may be indicated in specific scenarios before vaginal delivery for patients at high risk of endocarditis.[40][41][42]

Breastfeeding considerations: Azithromycin is concentrated minimally in breast milk, making adverse effects in breastfed infants unlikely; monitoring for gastrointestinal effects, including vomiting, diarrhea, and candidiasis, is recommended. One study demonstrated that a single dose of azithromycin administered to women who were nasal carriers of pathogenic *Staphylococcus* and *Streptococcus* during labor reduced bacterial counts in breast milk but

increased the prevalence of azithromycin-resistant *E coli* and *K pneumoniae*. The use of azithromycin eye drops by breastfeeding mothers poses negligible risk to the infant, and applying pressure over the tear duct for 1 minute after administration can further reduce drug transfer to breast milk.[43]

Pediatric patients: Azithromycin is indicated for patients 6 months or older with community-acquired pneumonia due to *C pneumoniae*, *H influenzae*, *M pneumoniae*, or *S pneumoniae.* Azithromycin is also FDA-approved for patients 6 months or older with acute otitis media caused by *H influenzae*, *M catarrhalis*, or *S pneumoniae*. Azithromycin is also indicated for patients 6 months or older with acute bacterial sinusitis caused by *H influenzae*, *M catarrhalis*, or *S pneumoniae.* For patients 2 years or older with pharyngitis or tonsillitis caused by *S pyogenes*, azithromycin is an alternative therapy for individuals who cannot tolerate first-line treatment.

Older patients: No significant differences in safety or effectiveness have been observed between older and younger patients. However, greater sensitivity among some older patients cannot be ruled out based on reported clinical experiences.

Adverse Effects

Azithromycin is considered a safe antimicrobial agent, and only a few patients discontinue it due to adverse effects.[44] This medication is also associated with fewer adverse cardiac effects than other macrolides (eg, erythromycin, clarithromycin).

- Like other macrolides, azithromycin can cause QTc prolongation, which can result in torsades de pointes or polymorphic ventricular tachycardia. In a large retrospective cohort study, azithromycin use correlated with a small but significant absolute increase in cardiovascular death as well as an increased risk of cardiovascular death relative to amoxicillin. These results were most pronounced among patients with the highest baseline cardiovascular risk.[45] However, another large cohort study failed to detect an increased risk of death from cardiovascular causes in young and middle-aged adults.[46]
- Azithromycin is rarely associated with hepatotoxicity, which primarily manifests as hepatocellular injury within 3 weeks of initiating therapy. Clinical features of hepatotoxicity include cholestatic jaundice and elevated transaminase concentrations.[47]
- Like other macrolides, azithromycin is associated with gastrointestinal adverse effects such as nausea and diarrhea. All macrolides exhibit dose-dependent activation of intestinal motilin receptors, stimulating gastric motility. Clinicians widely prescribe erythromycin for treating gastroparesis due to this mechanism.[48]
- Life-threatening hypersensitivity reactions to azithromycin, such as anaphylaxis and Stevens-Johnson syndrome (SJS), are rare.[49][50]
- Macrolides are also associated with the development of *Clostridioides difficile* infection but to a lesser degree than other common antimicrobial classes (eg, clindamycin, fluoroquinolones, and cephalosporins).[51][52][53]
- A retrospective cohort study found that outpatient azithromycin use was associated with a higher risk of cardiovascular and noncardiovascular death. However, causality cannot be established due to potential residual confounding.[54]

Drug-Drug Interactions

- Azithromycin should be avoided in patients taking the first-generation antipsychotic pimozide. Macrolide antimicrobials inhibit CYP3A4, the same cytochrome that metabolizes pimozide; concomitant use of azithromycin with pimozide can cause dangerous plasma concentrations of pimozide, leading to QTc prolongation and, potentially, lethal arrhythmias. While azithromycin is a poor inhibitor of CYP3A4 relative to other macrolides, avoiding this interaction is still advisable.[55][56]

- Azithromycin is an inhibitor of p-glycoprotein/ABCB1, a cell membrane glycoprotein transporter. Drugs that are substrates of P-glycoprotein, particularly those that are also substrates of CYP3A4, represent a relative contraindication to azithromycin administration. Examples include colchicine and small-molecule calcitonin gene-related peptide (CGRP) antagonists.[57][58]
- Intravesical Bacillus Calmette-Guérin (BCG) instillations are prescribed as a treatment for bladder cancer. While product labeling advises suspending BCG therapy during antibiotic treatment due to potential interference with clinical response, antibiotics may still be necessary during this interval. A recent study of 126 patients found no significant impact of antibiotics on recurrence-free or progression-free survival during BCG induction. Prolonged antibiotic treatment did extend the duration of BCG therapy, but overall, antibiotics did not adversely affect oncological outcomes or adverse effects; a thorough risk-benefit evaluation is required.[59]

Contraindications

Azithromycin is contraindicated for patients with a history of severe hypersensitivity (eg, anaphylaxis or SJS) to azithromycin or another macrolide antimicrobial. Azithromycin is also contraindicated for patients with a history of cholestatic jaundice or hepatic dysfunction related to prior use of the drug.

Warning and Precautions

- Azithromycin effectively preserves FEV and ameliorates bronchiolitis obliterans (BO) with no effect on overall survival in lung transplant patients; however, a study comparing azithromycin with placebo for the prevention of BO in hematopoietic stem cell transplant (HSCT) recipients demonstrated decreased BO-free and overall survival with azithromycin.[60] Hence, long-term azithromycin prophylaxis in HSCT recipients is inadvisable.
- Clinicians should be cautious regarding the concomitant use of azithromycin and other medications that prolong the QTc interval, such as antipsychotics.
- According to the KIDs list (Key Potentially Inappropriate Drugs in Pediatrics), azithromycin should be avoided in neonates due to the risk of hypertrophic pyloric stenosis.[61]

Monitoring

Most courses of treatment with azithromycin are short, and adverse effects requiring therapy adjustment or discontinuation of azithromycin are rare.[44] Azithromycin should be immediately discontinued if signs of hepatotoxicity develop (eg, jaundice or elevated transaminases). For patients receiving long-term azithromycin prophylaxis (eg, AIDS patients for MAC prophylaxis or lung transplant recipients for BO prophylaxis), many patients experience gastrointestinal adverse effects, especially at higher doses (ie, 600 or 1200 mg). Reducing the dose or twice-daily dosing may be considered for these patients.[62][63]

Toxicity

Signs and Symptoms of Overdose

Azithromycin, like other macrolides, is associated with QTc prolongation. Azithromycin administration can result in potentially lethal arrhythmias such as torsades de pointes. This is particularly true for patients with a history of QTc interval perturbation, cardiac arrhythmia, or concomitant use of other medications associated with QTc prolongation. In animal studies, although azithromycin was associated with similar QTc prolongation compared to other macrolides, it seemed to have a negligible proarrhythmic effect.[64] While significant hepatoxicity resulting from azithromycin is relatively rare, macrolides are known to cause mixed hepatocellular/cholestatic drug-induced liver injury. With prompt discontinuation of azithromycin, liver injury is almost always reversible with minimal residual impairment. Often, azithromycin-induced hepatotoxicity has associated immunoallergenic features such as rash, fever,

and eosinophilia. Severe reactions, such as anaphylaxis, SJS, and drug reaction with eosinophilia and systemic symptoms (DRESS), are rare.[65] Gastrointestinal toxicity is common but typically mild, and most patients can complete the prescribed course of azithromycin. This toxicity is the result of azithromycin's activation of pro-motility receptors in the gastrointestinal tract.

Management of Overdose

There is no antidote for azithromycin overdose. General symptomatic and supportive measures should be instituted as necessary.

Enhancing Healthcare Team Outcomes

Although azithromycin is a well-tolerated and effective antimicrobial agent with many clinical indications, it is often inappropriately prescribed, particularly in the primary care setting. Several large retrospective cohort studies involving high levels of inappropriate antimicrobial prescribing overall singled out azithromycin as the most frequently misused drug.[66][67][68][69] Azithromycin is frequently prescribed when there is no clinical indication for antimicrobials, and in many instances, azithromycin is not first-line therapy (e.g., acute otitis media).[66][70] Azithromycin is frequently prescribed when a narrow-spectrum β-lactam (eg, amoxicillin) is the indicated first-line therapy.[66] Increasing resistance to azithromycin, particularly among *S pneumoniae* isolates, makes the widespread use of azithromycin for upper respiratory illness particularly concerning.[71][72] Broad-spectrum antimicrobial therapy for upper respiratory infection is also associated with increased rates of adverse effects compared with narrow-spectrum agents.[73][74]

One possible association with high rates of azithromycin prescription is patient-reported penicillin allergy.[75] Macrolides, particularly azithromycin, are preferred to β-lactam drugs for many clinical indications. Researchers found 12.8% of patients in an extensive electronic medical records database have a penicillin allergy listed in 1 large cohort.[76] Patients with a reported penicillin allergy are as much as 4 times more likely to be prescribed a macrolide antimicrobial.[75] However, a detailed history of a patient's adverse reactions to penicillin, paying close attention to features suggestive of IgE-mediated hypersensitivity (eg, urticaria, anaphylaxis), is often sufficient to clarify and possibly remove a listing of penicillin allergy.[77] Patients with more concerning histories may be administered allergy testing or referred to an allergy specialist. Lastly, providers should know the low cross-reactivity rates with cephalosporins (especially third and later-generation agents) and other β-lactams in penicillin allergy.[78]

Through antimicrobial stewardship, healthcare professionals can ensure appropriate antimicrobial administration, including azithromycin. Adhering to evidence-based guidelines and educating patients reduce resistance and optimize treatment outcomes. Clinicians should prescribe azithromycin judiciously and adhere to IDSA guidelines. Clinicians working with or supervising non-physician prescribers should ensure that all prescriptions accord with evidence and guideline-based practice.[68] Additionally, patients requesting antimicrobial therapy when it is not necessary or sharing concerns about drug allergies should be provided with education and appropriate follow-up. Nurses can address patient questions and facilitate continuity of care. Pharmacists are an invaluable resource for helping providers select the most appropriate antimicrobial agent, dosing, and duration of treatment. They can also help providers and patients avoid interactions between azithromycin and other drugs that affect the QTc interval. While azithromycin is a safe and effective antimicrobial drug, practitioners must prescribe it appropriately. The appropriate choice of antibiotic enhances treatment, supports public health, and avoids placing patients at unnecessary risk of adverse effects. An interprofessional team approach and communication among clinicians, pharmacists, and nurses are crucial to decreasing potential adverse effects, improving disease course, and improving outcomes for patients receiving azithromycin.

Review Questions

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