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Review

Pharmacological Management of Otitis Media and Externa

Mohammed A M Imbarak[a*]

[a] Faculty of Medicine, University of Benghazi, Benghazi- Libya

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ABSTRACT

Otitis media and otitis externa are among the most frequently encountered ear infections in clinical practice, particularly affecting children and individuals exposed to humid environments or water. Despite differing in anatomical site and causative organisms, both conditions require prompt and tailored pharmacological intervention to alleviate symptoms, resolve infection, and prevent complications. Acute otitis media (AOM) is primarily managed with analgesics and selective antibiotic use, following evidence-based guidelines that emphasize judicious antimicrobial therapy to reduce resistance. Otitis media with effusion (OME) and recurrent AOM often necessitate non-pharmacological strategies, including tympanostomy tubes, rather than routine antibiotics. In contrast, otitis externa is best treated with topical antimicrobials—particularly fluoroquinolone-steroid combinations—with systemic antibiotics reserved for severe or necrotizing cases. This review synthesizes the current evidence on the pharmacological approaches to otitis media and externa, emphasizing pathogen-specific treatment, age-based recommendations, and antibiotic stewardship

1. Introduction

Otitis media (OM) and otitis externa (OE) are among the most common ear conditions encountered in clinical and primary care settings. These disorders affect individuals across all age groups and are associated with significant healthcare costs and morbidity, particularly in pediatric and elderly populations (Schilder et al., 2016). While both conditions involve inflammation of ear structures, their anatomical location, pathophysiology, and management strategies differ substantially. Understanding the pharmacological approaches to these conditions is essential for optimal treatment and for minimizing complications and antimicrobial resistance.

Otitis media, particularly acute otitis media (AOM), is highly prevalent in young children, with estimates suggesting that approximately 80% of children will experience at least one episode by the age of 3 (Lieberthal et al., 2013). The condition is characterized by the rapid onset of middle ear effusion accompanied by signs of inflammation and often follows viral upper respiratory infections. These infections predispose to Eustachian tube dysfunction, allowing pathogens to colonize the middle ear. The most commonly implicated bacteria include *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis* (Casey & Pichichero, 2004). Viral pathogens, such as respiratory syncytial virus, also play a role, either as primary agents or by facilitating secondary bacterial infection (Heikkinen & Chonmaitree, 2003).

In contrast, otitis externa (OE) involves infection and inflammation of the external auditory canal and is commonly referred to as “swimmer’s ear.” OE is often caused by repeated exposure to moisture, trauma from cotton swabs, or preexisting dermatologic conditions that disrupt the skin barrier (Roland & Stroman, 2002). The predominant bacterial pathogens include *Pseudomonas aeruginosa* and *Staphylococcus*

*Corresponding author e-mail adress: mahm.ali284@gmail.com

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aureus, though fungal infections (e.g., *Aspergillus* and *Candida*) are more frequent in chronic or immunocompromised patients (Rosenfeld et al., 2014). Symptoms include otalgia, pruritus, canal edema, and otorrhea, and the condition can progress to necrotizing or malignant OE in at-risk populations, such as individuals with diabetes.

Pharmacological treatment is central to the management of both OM and OE. In AOM, pain control using acetaminophen or ibuprofen is universally recommended, regardless of antibiotic use (McCormick et al., 2005). Given the self-limiting nature of many cases, especially in older children, guidelines now support watchful waiting or delayed antibiotic prescribing in select patients to reduce unnecessary antibiotic exposure and combat resistance (Venekamp et al., 2015). When antibiotics are indicated, high-dose amoxicillin is the first-line agent due to its efficacy, safety profile, and narrow-spectrum activity (Lieberthal et al., 2013).

Otitis externa, in contrast, is best managed with topical agents. Topical antibiotic drops, such as ciprofloxacin or ofloxacin, are considered the cornerstone of treatment due to their direct delivery and high local concentration (Kaushik et al., 2010). When inflammation is prominent, combination products that include corticosteroids—such as ciprofloxacin-dexamethasone—have demonstrated superior outcomes in reducing pain and swelling (Raymond et al., 2009). Systemic antibiotics are generally reserved for severe or complicated cases, including necrotizing OE, which may require hospitalization and intravenous therapy, particularly in immunocompromised patients (Di Lullo et al., 2020).

This review aims to synthesize current evidence regarding the pharmacological management of OM and OE, highlighting the pathophysiology, antimicrobial selection, and treatment strategies tailored to disease severity and patient risk factors. Through an evidence-based approach, clinicians can ensure optimal outcomes while minimizing unnecessary antimicrobial use and its associated risks.

2. Microbiology & Pathophysiology

2.1. Otitis Media

Otitis media, particularly AOM, is primarily an infection of the middle ear that occurs following viral upper respiratory tract infections (URTIs). Viral infections contribute to eustachian tube dysfunction, leading to negative middle ear pressure and transudation of fluid into the middle ear space. This creates a nutrient-rich environment that facilitates bacterial colonization and proliferation (Heikkinen & Chonmaitree, 2003). The viral contribution is especially significant in infants and toddlers, where the anatomy and function of the eustachian tube are immature and more prone to obstruction (Wiertsema & Leach, 2009).

The most frequently isolated bacterial pathogens in AOM are *Streptococcus pneumoniae*, *non-typeable Haemophilus influenzae* (NTHi), and *Moraxella catarrhalis*. These organisms are responsible for more than 95% of culture-positive middle ear fluid in children with AOM (Casey & Pichichero, 2004). Notably, the prevalence of these pathogens has shifted in the post-pneumococcal conjugate vaccine (PCV) era. While vaccine-serotype *S. pneumoniae* has declined, non-vaccine serotypes and *H. influenzae* have become more prominent (Marom et al., 2014). Some of these bacteria produce β-lactamase, contributing to antibiotic resistance, which influences empirical treatment choices.

In otitis media with effusion (OME), the underlying pathophysiology is not always associated with active bacterial infection. Instead, OME is characterized by the persistence of fluid in the middle ear without signs of acute infection. The pathogenesis involves chronic inflammation, biofilm formation, and eustachian tube dysfunction (Hall-Stoodley et al., 2006). Biofilms formed by bacteria like *S. pneumoniae* and *H. influenzae* within the middle ear mucosa are particularly problematic because they confer resistance to antibiotics and host immune responses, contributing to recurrent or chronic OM (Post, 2001).

2.2. Otitis Externa (OE)

OE, or "swimmer's ear," is primarily an infection of the external auditory canal and differs significantly from OM in its microbiology and pathogenesis. The skin of the ear canal is normally acidic (pH ~5) and protected by cerumen, which provides both physical and antimicrobial defense. Disruption of this barrier—due to moisture, trauma (e.g., cotton swabs), or dermatologic conditions—creates a favorable environment for microbial invasion (Roland & Stroman, 2002). This leads to inflammation and overgrowth of pathogens within the canal epithelium.

The most common organisms associated with acute OE are *Pseudomonas aeruginosa* and *Staphylococcus aureus*, with *P. aeruginosa* being isolated in approximately 38–50% of cases (Wiegand et al., 2019). These pathogens thrive in moist environments and can form biofilms, especially in chronic OE. In rare cases, OE may involve polymicrobial infections or gram-negative rods, and fungal infections with *Aspergillus* or *Candida* may occur in immunocompromised hosts or following prolonged topical antibiotic use (Vennewald & Klemm, 2010). Chronic or necrotizing OE is especially concerning in elderly or diabetic patients, where *P. aeruginosa* can invade soft tissue and bone, leading to osteomyelitis of the skull base (Di Lullo et al., 2020).

In malignant otitis externa (MOE), *P. aeruginosa* is nearly always the

causative agent, accounting for over 90% of cases. The infection spreads from the external auditory canal to the temporal bone and adjacent tissues, leading to severe pain, granulation tissue, cranial nerve involvement, and potentially life-threatening complications. The pathophysiology involves bacterial invasion of the cartilage and bone facilitated by compromised host immunity, particularly in diabetic patients where neutrophil function is impaired (Di Lullo et al., 2020).

3. Pharmacological Strategies in the Management of Otitis Media

3.1. Pain Management

Pain management is the cornerstone of AOM treatment, regardless of the decision to use antibiotics. Otalgia is often the most distressing symptom, especially in young children, and adequate pain control improves quality of life and reduces emergency room visits. First-line treatment includes paracetamol or non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, which have been shown to be effective in reducing fever and discomfort (McCormick et al., 2005).

A Cochrane review found that NSAIDs significantly reduce pain at 6 and 12 hours post-treatment, although their benefit at later time points is less consistent (Foxlee et al., 2006). Additionally, topical analgesics, such as antipyrine and benzocaine otic drops, may provide local pain relief for children with intact tympanic membranes. However, these drops are not widely available in all countries and should not be used if there is tympanic membrane perforation or tympanostomy tubes (Foxlee et al., 2006).

Despite common practice, the use of decongestants and antihistamines is not recommended, as studies have shown no significant benefit in symptom relief or prevention of complications (Griffin et al., 2011).

3.2. Antibiotic Use in AOM

Antibiotics are frequently prescribed in AOM, but current guidelines recommend a more selective approach. Not all cases require immediate antimicrobial therapy. The American Academy of Pediatrics (AAP) recommends “watchful waiting” in children aged ≥6 months with non-severe unilateral AOM, provided that follow-up is ensured and symptoms are mild (Lieberthal et al., 2013). This approach aims to reduce unnecessary antibiotic use and combat the rise in antibiotic-resistant organisms.

When antibiotics are indicated, high-dose amoxicillin (80–90 mg/kg/day) is the first-line agent due to its efficacy against *Streptococcus pneumoniae*, its low cost, and favorable safety profile (Venekamp et al., 2015). In cases with recent beta-lactam exposure, purulent conjunctivitis (suggestive of *H. influenzae*), or recurrent AOM, amoxicillin-clavulanate is preferred to overcome beta-lactamase-producing strains (Casey & Pichichero, 2004).

For penicillin-allergic patients, alternatives include cefdinir, cefuroxime, clindamycin, or azithromycin. However, macrolide resistance is increasing, and these agents may be less effective against *S. pneumoniae* (Pichichero & Casey, 2007). Treatment duration is age-dependent: 10 days for children under 2 years or with severe symptoms, and 5–7 days for older children with mild to moderate symptoms (Rosenfeld et al., 2016).

3.3. OME Recurrent AOM

OME is characterized by the presence of middle ear effusion without signs of acute infection. It frequently follows an episode of AOM or occurs independently due to Eustachian tube dysfunction. OME is common in children aged 2 to 5 and is often asymptomatic, but may present with hearing difficulties, speech delays, or balance problems (Rosenfeld et al., 2016). Antibiotics, corticosteroids, antihistamines, and decongestants are not recommended for OME, as meta-analyses have shown limited efficacy and potential harm (Williamson et al., 2006).

Recurrent AOM, defined as ≥3 episodes in 6 months or ≥4 in 12 months, is a common indication for further intervention. Factors associated with recurrence include early onset of first AOM episode, exposure to tobacco smoke, day-care attendance, and lack of breastfeeding (Pichichero, 2000). While prolonged antibiotic prophylaxis was once common, it is no longer routinely recommended due to concerns about resistance and marginal efficacy.

In cases of recurrent AOM or persistent OME lasting >3 months with documented hearing loss, tympanostomy tube insertion is the preferred intervention. Tubes help ventilate the middle ear and reduce effusion and infection frequency. However, their benefit on long-term speech and language outcomes is modest (Browning et al., 2010). Adenoidectomy may also be considered in selected children with persistent symptoms despite tube placement.

4. Pharmacological Management of Otitis Externa (OE)

4.1. Topical Therapy

Topical therapy is the cornerstone of treatment for uncomplicated acute OE. It delivers high local concentrations of antimicrobial agents directly to the site of infection while minimizing systemic exposure. Initial treatment aims to reduce inflammation, eradicate infection, and restore the acidic environment of the external canal (Rosenfeld et al., 2014).

Acidifying and drying agents, such as acetic acid (2%) or Burow's solution (aluminum acetate), are effective in mild cases without significant swelling or otorrhea. These agents reduce pH and inhibit bacterial and fungal growth, although their efficacy is less than antibiotic-steroid combinations in moderate-to-severe OE (Kaushik et al., 2010).

For bacterial OE, topical antibiotics are the primary treatment. Fluoroquinolone drops such as ciprofloxacin (0.3%) and ofloxacin (0.3%) are preferred due to their broad-spectrum activity, effectiveness against *P. aeruginosa*, and low risk of ototoxicity, making them safe even in patients with tympanic membrane perforation (Raymond et al., 2009). Neomycin–polymyxin B–hydrocortisone is another effective combination but should be used with caution in patients with ruptured tympanic membranes due to potential ototoxicity (van Balen et al., 2003).

Combination products containing antibiotics and corticosteroids, such as ciprofloxacin–dexamethasone (Ciprodex) or hydrocortisone–ciprofloxacin, provide both antimicrobial and anti-inflammatory effects. Studies have shown that these combinations reduce pain and edema more rapidly than antibiotic monotherapy (Roland et al., 2004). Corticosteroids help reduce inflammation and canal edema, improving comfort and facilitating drop penetration.

Proper application technique is critical. Ear canal cleaning (aural toilet) may be required before starting drops, especially in cases of heavy debris or discharge. Patients should be instructed to lie with the affected ear upward for at least 5 minutes after drop instillation and may be advised to use a wick if canal edema prevents drop penetration (Rosenfeld et al., 2014).

4.2. Systemic Therapy & Severe Cases

In most cases of acute OE, systemic antibiotics are not required and may even contribute to antimicrobial resistance and unnecessary side effects. However, oral or intravenous antibiotics may be indicated in certain severe or complicated cases, including:

- Infection extending beyond the ear canal (periauricular cellulitis)
- Immunocompromised patients (e.g., diabetes, chemotherapy)
- Fever, lymphadenopathy, or systemic toxicity
- Necrotizing (malignant) otitis externa

Malignant otitis externa (MOE) is a potentially life-threatening complication of OE, most often caused by *Pseudomonas aeruginosa*. It typically occurs in elderly diabetic or immunocompromised patients and presents with severe otalgia, granulation tissue at the bony-cartilaginous junction, and sometimes cranial nerve involvement (Di Lullo et al., 2020). Diagnosis is confirmed by imaging (e.g., CT or MRI) and bone scans, along with cultures.

Initial treatment of MOE involves hospital admission and intravenous antipseudomonal therapy, typically with agents such as ceftazidime, cefepime, or piperacillin-tazobactam. Once clinical improvement is noted, therapy may be transitioned to oral ciprofloxacin, often for 6 to 8 weeks, guided by clinical response and inflammatory markers (Di Lullo et al., 2020).

Surgical intervention is generally limited to biopsy to exclude malignancy or to drain abscesses in refractory cases. Hyperbaric oxygen therapy has been used as adjunctive therapy in some centers, though evidence remains limited.

5. Conclusion

Effective pharmacological management of OM and OE is critical to optimizing patient outcomes while minimizing the risks of antimicrobial resistance, adverse drug reactions, and disease recurrence. Although both conditions affect the ear, they differ significantly in their pathophysiology, causative organisms, and preferred therapeutic modalities. As such, treatment must be individualized based on the clinical subtype, patient demographics, and disease severity.

In the case of AOM, the widespread use of antibiotics has historically led to overprescription, which in turn has contributed to the rise of resistant bacterial strains such as β-lactamase–producing Haemophilus influenzae and Moraxella catarrhalis (Casey & Pichichero, 2004). Contemporary guidelines, such as those from the American Academy of Pediatrics, now endorse delayed prescribing and "watchful waiting" in selected cases, especially in children over 2 years with mild, unilateral symptoms (Lieberthal et al., 2013). This approach is both safe and effective, and it reinforces the principles of antibiotic stewardship. Pain management with acetaminophen or NSAIDs remains the foundation of therapy and should not be overlooked, as it improves comfort and quality of life regardless of etiology or antibiotic use (McCormick et al., 2005).

The management of recurrent AOM and OMErequires a shift away from antibiotics. Numerous clinical trials and meta-analyses have confirmed that neither antibiotics nor corticosteroids significantly improve long-term outcomes in OME (Williamson et al., 2006). Instead, tympanostomy tube placement remains the gold standard in cases of persistent effusion associated with hearing loss. Moreover,

risk factor modification—such as reducing tobacco smoke exposure and promoting breastfeeding—can help prevent recurrence in susceptible pediatric populations (Pichichero, 2000).

In contrast, OE is primarily a localized infection of the external auditory canal and is most effectively treated with topical agents. Fluoroquinolone-based ear drops, often combined with corticosteroids, offer high local concentrations, excellent antimicrobial coverage (especially against Pseudomonas aeruginosa), and a low risk of systemic side effects (Raymond et al., 2009). The addition of corticosteroids accelerates symptom resolution and reduces canal edema. Systemic therapy, however, should be reserved for complicated or severe cases such as MOE, which typically occurs in immunocompromised patients and can be life-threatening if not treated with prolonged intravenous antibiotics.

An important but often underappreciated element in both OM and OE management is patient and caregiver education. Emphasizing adherence to dosing schedules, correct administration of topical agents, and the appropriate indications for antibiotic use can significantly enhance therapeutic success and prevent recurrence or complications.

Ultimately, best practices in otitis management lie at the intersection of clinical experience, patient-centered care, and guideline-based decision-making. Continuous medical education, patient engagement, and ongoing research are key to evolving treatment paradigms and maintaining the efficacy of existing pharmacological tools. By integrating antimicrobial stewardship principles with evidence-based therapy, clinicians can ensure optimal care for patients while preserving therapeutic efficacy for future generations.

Despite advances in understanding the microbiology and pharmacodynamics of these conditions, gaps remain. For example, increasing resistance to first-line antibiotics, limitations in vaccine coverage for emerging otopathogens, and challenges in treating biofilm-associated infections warrant further investigation. Future research should also evaluate novel anti-biofilm strategies, host-targeted therapies, and vaccine optimization to reduce the incidence of otitis-related morbidity.

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