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Review Article

Ozenoxacin: A novel topical quinolone

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ABSTRACT

The burden of dermatological conditions is huge on the global health accounting for 44.1 million DALYs worldwide. Impetigo is a highly contagious bacterial infection with 2.5 time's greater likelihood in pediatrics (12.3%) than in adults (4.9%). Micro-organisms causing impetigo include bacteria like *staphylococcus aureus, group A beta-haemolytic streptococcus* or both. The management of Impetigo is with topical and systemic antimicrobial agents. Topical antimicrobial resistance is on the rise in patients with Impetigo. Therefore, there is clearly a need for newer antimicrobials having different mode of action and showing good activity against non-responding strains in the management of impetigo. Ozenoxacin is a novel, topical quinolone with a good safety and tolerability profile in the management of Impetigo. The authorizing bodies namely USFDA, European Medical Agency, and DCGI have approved the use of Ozenoxacin 1% cream for the topical treatment of impetigo due to *Staphylococcus aureus or Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older.

1. Background

Dermatological conditions have a huge impact on global context of health. About 1.9 billion people are affected at any given time with these conditions. There are substantial disabilities secondary to dermatological conditions. They are amongst the top 25 leading causes of Disability Adjusted Life Years (DALYs). They account for 44.1 million DALYs worldwide.[1]

2. Impetigo

Impetigo is a bacterial skin infection which is highly contagious.[2] It is common in children in the age group of twenty four months to five years.[3] The estimated burden globally was more than 140 million cases in 2010.[4] In general population the worldwide median prevalence is around 11.2%. It is 2.5 times greater in pediatric (12.3%) than adults (4.9%).[1,3]

Micro-organisms causing impetigo include bacteria like *staphylococcus aureus, group A beta-haemolytic streptococcus* or both. *Staphylococcus* infection is common in tropical regions and *streptococcal* in temperate climates.[1] Overcrowding, hot and humid surroundings, socioeconomic deprivation, malnutrition, and close-contact sports activities are the major predisposing factors.[2]

3. Morbidity Related to Impetigo

The local and systemic spread of infection can cause complications like cellulitis, lymphangitis, or septicaemia especially due to staphylococcal infection. Other potential complications which can occur are pneumonia, osteomyelitis, toxic shock syndrome, endocarditis and staphylococcal scalded skin syndrome. A very serious complication, acute post-*streptococcal* glomerulonephritis,

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can affect 1-5% patients.[5]

4. Management of Impetigo

Non-bullous and bullous impetigo can be treated with oral or topical antimicrobials.[6] Topical therapy seem to be better for patients with a fewer lesions with the advantage of fewer side effects (especially gastrointestinal) and less chance of bacterial resistance.[6,7] Oral therapy is recommended by the Infectious Diseases Society of America (IDSA) if multiple lesions are present or in conditions of outbreaks in more number of people to help to reduce the transmission.

5. Antimicrobial Resistance

In clinical practice, it has been observed that gram positive organisms especially *S. aureus* have become resistant to the commonly used topical antimicrobial agents. A major concern worldwide of antimicrobial resistance, is the methicillin-resistant *S. aureus* (MRSA) isolates. The spread of resistant isolates is due mainly to emergence of community-acquired MRSA infections. The overall efficacy of Fusidic Acid has reduced due to emerging resistant strains of *S. aureus*.[8–12] *S. aureus* has also developed resistance to commonly-used topical agent Mupirocin.[13–16] Around 31.3% of skin and soft tissue infection samples for S. aureus isolates (n = 358) from outpatient pediatric population were resistant to Mupirocin as per data from a large study.[17]

The empirically-managed conditions such as impetigo[18] have a potential threat due to increasing antimicrobial resistance which are a major concern to the patients. This is because these patients are treated without the benefits of susceptibility testing and microbial culture. Therefore, there is clearly a need for newer antimicrobials having different mode of action and also showing good effect against resistant and non-responding strains in the management of impetigo.[19]

6. Ozenoxacin: A Novel Topical Quinolone

Ozenoxacin is a novel, topical quinolone with molecular formula C21H21N3O3 and chemical name 1-cyclopropyl-8-methyl-7-[5-methyl-6-(methylamino)- pyridin-3-yl]-4-oxoquinoline-3-carboxylic acid. It has a non-fluorinated quinolone, with pyridinyl group at C7.

The good safety and tolerability profile is attributed to the absence of a fluorine atom in the molecular structure. Due to this unique molecular structure it lacks quinolone-induced chondrotoxicity and phototoxicity.[5,20]

7. Mechanism of Action

Ozenoxacin inhibit the enzymes DNA gyrase and topoisomerase IV, involved in the DNA synthesis in bacteria. This occurs by inhibition of supercoiling activity of DNA gyrase and topoisomerase IV decatenation. This prevents the bacterial DNA replication.[3]

It has been observed that, Ozenoxacin at lowest concentrations as against various quinolones inhibit decatenation of topoisomerase IV and supercoiling of DNA gyrase in SA113 strain of *S. aureus*.[21] Ozenoxacin penetrates the bacterial cell wall of *S. aureus* and *S pyogenes* very rapidly and attains maximum concentration in the bacterial cell within a minute of application, as against various other quinolones.[3] The reason being that, Ozenoxacin is a not a substrate whereas other quinolones are a substrate for efflux pumps like MepA and NorA, commonly found in Gram-positive bacteria.[22]

8. Pharmacokinetics

Ozenoxacin exhibits negligible systemic absorption after topical application. After topical application, high concentration are seen in the stratum corneum, with lower concentration in epidermis and negligible in the dermis. No data is available on distribution, metabolism and elimination as they have not been investigated in humans.[3]

9. Indications and Usage

Topical Ozenoxacin is indicated in the management of impetigo caused by microorganisms namely *Staphylococcus* aureus or *Streptococcus pyogenes* in adult and pediatric patients aged 2 months and older.[23]

10. Dosage and Administration

A thin layer is applied topically over the affected area two times a day for five days. In children 12 years and above and in adults the area affected may be around 100 cm^2 or total body surface area (TBSA) of 2% and not more than 100 cm^2 in children younger than 12 years.[23]

11. In vitro Antibacterial Activity

In a surveillance study, 1031 Gram-positive isolates from infections of soft tissue areas and the skin, Ozenoxacin and other antimicrobial agents were compared. Around 49% of isolates were *Staphylococcus aureus* isolates. Minimum inhibitory concentration (MIC) values of various 11 antimicrobial agents were assessed. Data summary for most relevant antimicrobial are shown inTables 1 and 2.[24]

Ozenoxacin had a MIC of ≤0.05 mg/L with 99.4% inhibition of *S. aureus* isolates and 94.8% inhibition of *S. epidermidis* isolates. 98.3% and 95.5% of *S. pyogenes* and *S. agalactiae* isolates respectively were inhibited by Ozenoxacin with MIC of ≤0.03 mg/L. Thus, Ozenoxacin is a potent against *staphylococci* and *streptococci*.[24]

Table 1: MIC50 (mg/L) values for various antimicrobials[24]

	Ozenoxacin	**Mupirocin**	**Fusidic Acid**	**Retapamulin**	**Levofloxacin**	**Ciprofloxacin**
S. aureus (all)	0.002	0.25	0.12	0.12	0.25	0.25
MSSA	0.002	0.25	0.12	0.12	0.12	0.25
MRSA	0.004	0.25	0.12	0.12	0.25	0.5
Levofloxacin-susceptible *S. aureus*	0.002	0.25	0.12	0.12	0.12	0.25
Levofloxacin-non-susceptible *S. aureus*	0.06	0.25	0.12	0.12	8	>16
S. epidermidis (all)	0.008	0.25	0.12	0.06	0.25	0.5
Methicillin-susceptible *S. epidermidis*	0.004	0.25	0.12	0.06	0.25	0.25
Methicillin-resistant *S. epidermidis*	0.06	0.25	0.12	0.06	4	8
Levofloxacin-susceptible *S. epidermidis*	0.004	0.25	0.12	0.06	0.25	0.25
Levofloxacin-non-susceptible *S. epidermidis*	0.06	0.25	0.12	0.06	8	>16
Streptococcus pyogenes	0.008	0.06	4	0.03	0.5	0.5
Streptococcus agalactiae	0.015	1	8	0.06	0.5	0.5

Table 2: MIC90 (mg/L) values for various antimicrobials[24]

	Ozenoxacin	**Mupirocin**	**Fusidic Acid**	**Retapamulin**	**Levofloxacin**	**Ciprofloxacin**
S. aureus (all)	0.06	0.5	0.25	0.12	16	>16
MSSA	0.004	0.5	0.25	0.25	0.25	1
MRSA	0.12	0.5	0.25	0.12	>16	>16
Levofloxacin-susceptible *S. aureus*	0.002	0.25	0.25	0.25	0.25	0.5
Levofloxacin-non-susceptible *S. aureus*	0.5	2	0.25	0.12	>16	>16
S. epidermidis (all)	0.25	>256	8	0.25	>16	>16
Methicillin-susceptible *S. epidermidis*	0.03	256	8	0.25	4	4
Methicillin-resistant *S. epidermidis*	0.5	>256	16	0.12	>16	>16
Levofloxacin-susceptible *S. epidermidis*	0.008	>256	4	0.25	0.25	0.5
Levofloxacin-non-susceptible *S. epidermidis*	1	>256	16	0.12	>16	>16
Streptococcus pyogenes	0.015	0.25	4	0.06	1	1
Streptococcus agalactiae	0.03	1	16	0.12	1	0.5

12. Therapeutic Efficacy: Clinical Data

Two pivotal studies demonstrated the efficacy and safety of Ozenoxacin 1% cream in patients with impetigo.[25,26]

Ozenoxacin 1% cream (n = 155) was compared with placebo (vehicle) cream (n = 156) in paediatric patients aged > 2 years and adults with impetigo in randomized, double-blind, multicenter phase III study. Study drug was applied for 5 days in twice daily basis. The follow-up period was 2 weeks after which clinical, microbiological and laboratory evaluations were done. The primary efficacy endpoint was the clinical success rate (i.e. clinical cure) at day 6-7 (end of therapy). In the intention-to-treat (ITT) population, Ozenoxacin showed significant superiority as compared to vehicle (34.8 vs. 19.2%, p = 0.003). Ozenoxacin was superior to placebo (85.2 vs. 73.7%; p = 0.028) in the post hoc analysis with respect to the clinical success based on Skin Infection Rating Scale (SIRS).[25]

In another randomized, double-blind, phase III study, 512 impetigo patients of aged 2 months and above were randomized to Ozenoxacin (n = 206) or placebo (vehicle). Drugs were applied two times a day for 5 days. The primary efficacy endpoint was the clinical success rate (i.e. clinical cure) at day 5 (end of therapy). In the intention-to-treat (ITT) population, Ozenoxacin showed significant superiority as compared to vehicle (54.4 vs. 37.9%, p = 0.001). Ozenoxacin was superior to placebo (88.8 vs. 78.2%; p = 0.003) with respect to secondary outcome i.e., clinical success including clinical cure and improvement at the end of therapy.[26]

A pooled analysis from both phase III trials, confirmed the superiority of Ozenoxacin (n = 361) versus placebo (n = 362). The clinical success rates favoured Ozenoxacin (p < 0.001) in the ITT population at the end of therapy. Good number of patients achieved clinical success including clinical cure and improvement at the end of therapy, favouring Ozenoxacin (p < 0.0001).[27]

13. Therapeutic Efficacy : Microbiological Data

In a phase III trial, Ozenoxacin had a significantly higher microbiological clearance as compared to placebo [70.8% and 38.2% (p < 0.0001) at day 2−3, and 79.2% and 56.6% (p < 0.0001) at day 6-7 (end of therapy) respectively] in patients aged 2 years and above. Ozenoxacin also had a higher microbiological clearance rates as compared to Retapamulin [70.8% and 56.9% (p = 0.0087) after 2−3 days, and comparable i.e., 79.2% and 81.7% (p = 1.000) after 5-6 days respectively].[25]

In another phase III trial, Ozenoxacin had a significantly greater microbiological clearance as compared to placebo [87.2% and 63.9% (p = 0.002) after 2−3 days, and 92.0% and 73.1% (p = 0.005) after day 5 respectively] in patients aged 2 years and above.[26]

A pooled analysis from both phase III trials, confirmed the superiority of Ozenoxacin (n=279) versus placebo (n=271). Ozenoxacin had a significantly higher microbiological success rates as compared to placebo at day 2−3 and at the end of therapy (both p < 0.0001).[27]

Ozenoxacin had a greater eradication and presumed eradication rates of *S. aureus* as compared to placebo (86.6% and 50%, respectively, at day 2−3, and 75.8% and 39.5% at the end of therapy). Ozenoxacin also had a greater eradication and presumed eradication rates of *S. pyogenes* as compared to placebo (75.8% and 39.5%, respectively, at day 2−3, and 87.9% and 60.4% at the end of therapy).[3]

14. Therapeutic Efficacy: Activity against Resistant Strains

In a data from a pooled analysis of phase III trials, patients with resistant infection to antimicrobial agents like Retapamulin, Fusidic Acid, Mupirocin, Methicillin (Oxacillin), and ciprofloxacin achieved clinical cure or improvement at the end of therapy with Ozenoxacin (n=37). These included 10 of 10 patients with methicillin-resistant *S. aureus* and 11 of 11 patients with Mupirocin-resistant *S. aureus*. Clinical improvement was seen in 23 patient with ciprofloxacin-resistant *S. aureus* strain when they were treated with Ozenoxacin. At the end of treatment, all patients achieved clinical improvement or cure treated with Ozenoxacin.[27]

15. Safety Profile

In a series of randomized placebo controlled phase I studies, Ozenoxacin showed excellent dermal tolerability in healthy adult volunteers under occlusive patch conditions. There was minimal to no evidence of phototoxicity, photoallergy, cumulative irritation or sensitizing potential. Ozenoxacin application was not related to the adverse events reported across eight repeated-doses studies.[28]

In phase III clinical trials, out of the 875 patients treated with Ozenoxacin, only one adult patient (0.1%) reported two treatment related adverse events namely worsening of pre-existing rosacea and seborrheic dermatitis. Patient treated with placebo reported events of dermatitis and skin tightness. No safety signals were identified, as treatment-related adverse event occurred in not more than a single subject.[27]

16. Guidelines on Impetigo

Patients with involvement <2% of total body surface area should be managed with topical agents (e.g., Fusidic Acid, Mupirocin, Ozenoxacin). Patients with poor response to topical therapy, multiple/extensive lesions, relapses and/or systemic involvement and children should be managed with systemic antibiotics (e.g., penicillins such as Flucloxacillin or a cephalosporin such as Cephalexin or Cefadroxil or

Amoxacillin/Clavulanic acid).[29]

17. Authorization

The USFDA (December 2017) approved Ozenoxacin 1% cream (10 mg/g) for impetigo due to *Staphylococcus aureus* or *Streptococcus pyogene*s in adult and children aged 2 months and above.[23]

Ozenoxacin 1% cream has been approved in Europe (May 2019) for non-bullous impetigo in patients aged 6 months and older.[30]

The Indian Regulatory Authority [CDSCO/DCGI-April 2021], approved Ozenoxacin bulk and Ozenoxacin cream 1% w/w for impetigo due to *staphylococcus aureus* or *streptococcus pyogenes* in adult and children aged 2 months and above.[31]

18. Conclusion

Skin and soft tissue infections are very common in developing countries. Ozenoxacin looks to be a promising option available for treatment of SSTI like impetigo with established efficacy and safety profile. Ozenoxacin is approved in US, Europe as well as in India. Ozenoxacin belongs to quinolone group acts by inhibiting DNA replication and causes rapid bacterial cell death. In animal model, it showed more rapid microbiological clearance and lower MIC as compared to other quinolones. It causes rapid penetration inside the bacterial cell within first minute after application and high intra-bacterial concentration. Twice a day application for 5 days will surely help to improve patient compliance.

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21. Conflicts of Interest

Dr. Amar Shirsat & Dr. Abhijit Trailokya are associated with Indoco Remedies Limited Mumbai.

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