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An Overview of Levonadifloxacin in Tertiary Care Hospital: A Systematic Review of Observational Retrospective Study

[1] Dr Sadia Naseem, [2] A Rakesh Reddy, [3] Samreddy Bhavani, [4] Kota Naga Poornima, [5] Raheemunnisa, [6] Dr. Are Anusha Joel

[1] Assistant Professor, St Pauls College of Pharmacy, Hyderabad, Telangana - 501510.
[2] Pharm D 6th year, St Pauls College of Pharmacy, Hyderabad, Telangana - 501510.
[3] Pharm D 6th year, St Pauls College of Pharmacy, Hyderabad, Telangana - 501510.
[4] Pharm D 6th year, St Pauls College of Pharmacy, Hyderabad, Telangana - 501510.
[5] Pharm D 6th year, St Pauls College of Pharmacy, Hyderabad, Telangana - 501510.
[6] Associate Professor, St Pauls College of Pharmacy, Hyderabad, Telangana - 501510.

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Abstract:

Background: Antibiotic resistance poses a global health challenge, imposing the development of novel antibiotics. Levonadifloxacin, a third-generation fluoroquinolone, exhibits potent antibacterial activity against diverse pathogens, including drug-resistant strains.

Methods: An observational retrospective study was conducted at KIMS multispeciality hospital, Hyderabad, from October 2022 to June 2023. A total of 36 patients aged above 18 years were included, with diagnoses of severe bacterial infections. Data was collected on demographics, treatment details, unwanted effects, and analyse the results using chi-square test.

Results: Levonadifloxacin exhibited a broad spectrum of efficacy against respiratory pathogens. Common unwanted effects included constipation, cough, and decreased haemoglobin levels. Significant associations were found between the prescribed dose of levonadifloxacin and decreased haemoglobin levels ($p = 0.02$), as well as between treatment duration and increased random blood glucose levels ($p = 0.03$). Furthermore, levonadifloxacin was correlated with decreased white blood cell levels ($p < 0.001$).

Conclusion: Levonadifloxacin demonstrated promising efficacy against bacterial infections, with manageable unwanted effects. Significant associations between dose, duration, and specific unwanted effects highlight the need for cautious prescribing and monitoring. These findings underscore the potential of levonadifloxacin as an effective therapeutic option while emphasizing the importance of personalized treatment and careful patient management.

Keywords: Levonadifloxacin, respiratory infections, Antibiotic resistance, haemoglobin, blood glucose levels.

1. INTRODUCTION:

Antibiotic resistance has become a significant global health concern, leading to a rise in infections that are increasingly challenging to treat effectively [1]. In this context, the development and evaluation of novel antibiotics have become imperative to combat emerging microbial threats [2]. Levonadifloxacin, a promising fluoroquinolone antibiotic, has demonstrated potent antibacterial activity against a broad spectrum of pathogens, including Gram-positive and Gram-negative bacteria [8]. The drug's unique structural modifications have

improved its pharmacokinetic and pharmacodynamic properties, enhancing its efficacy and safety profile compared to earlier fluoroquinolones [4].

Levonadifloxacin, a third-generation fluoroquinolone antibiotic, has demonstrated promising activity against a wide range of respiratory pathogens, including Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, and atypical pathogens like Mycoplasma pneumoniae and Chlamydia pneumoniae [7]. This broad spectrum of antimicrobial activity positions levonadifloxacin as a potential therapeutic option for the management of respiratory infections [3].

The primary mechanism of action of levonadifloxacin involves inhibiting bacterial DNA gyrase and topoisomerase IV, essential enzymes involved in DNA replication and repair [11]. This action results in the disruption of bacterial DNA synthesis and subsequent bacterial cell death [3,8]. Additionally, levonadifloxacin's unique structural modifications contribute to improved binding affinity to these enzymes, enhancing its antimicrobial potency and reducing the likelihood of resistance development [12].

The pharmacokinetic properties of levonadifloxacin further support its utility in respiratory infections [3]. High oral bioavailability and excellent tissue penetration enable the achievement of therapeutic drug concentrations in lung tissues, facilitating effective eradication of pathogens at the site of infection [13]. Additionally, its extended half-life allows for convenient once-daily dosing, improving patient compliance and treatment outcomes [9].

Preclinical studies and early-phase clinical trials have shown promising results, establishing levonadifloxacin's safety and efficacy in the management of both community-acquired and hospital-acquired infections [4,8]. Furthermore, its activity against drug-resistant strains, including methicillin-resistant Staphylococcus aureus (MRSA) and fluoroquinolone-resistant Enterobacteriaceae, underscores its potential role as a therapeutic option in challenging clinical scenarios [5,9].

While in vitro and preclinical studies have demonstrated levonadifloxacin's efficacy against respiratory pathogens, clinical data on its safety and effectiveness in real-world settings are essential to guide evidence-based treatment decisions [10]. Therefore, this research article aims to evaluate the clinical outcomes and safety profile of levonadifloxacin in a well-defined patient population diagnosed with respiratory infections [3]. The study will assess various clinical parameters, including treatment response rates, incidence of adverse events, and overall patient satisfaction with levonadifloxacin therapy [10].

Despite its potential benefits, the clinical use of levonadifloxacin has raised concerns regarding certain unwanted effects, such as gastrointestinal disturbances, haematological abnormalities, and increased blood glucose levels [8]. As healthcare professionals increasingly prescribe levonadifloxacin, a comprehensive understanding of its safety and tolerability is crucial to optimize patient outcomes and minimize adverse reaction [1].

2. AIMS AND OBJECTIVES

AIM-

Aim of the study is to determine the profile of IV and oral levonadifloxacin in management of severe bacterial infections.

Objective –

- To assess the patient's safety on levonadifloxacin.
- To assess the effectiveness of levonadifloxacin in bacterial infection
- To find out the adverse drug reactions to levonadifloxacin.

3. Material and Methods

Study design –

Retrospective Observational Study

Study site –

The study was conducted in KIMS multispecialty hospital, Kondapur, Hyderabad for a period of 6 months i.e. From October 2022-june 2023

Need of study- To determine the profile the of novel antibiotic levonadifloxacin in management to determine severe bacterial infections.

Inclusion criteria –

- All the patients above 18 years were included in the study
- Patients who are receiving other antibiotics
- Patients with other comorbidities.

Exclusion criteria-

- Pregnant women
- Below 18 years
- Known hypersensitivity to antibiotics.

Source of data and material –

- Patient data collection forms
- Patient case sheets

Designing of the data collection forms –

A suitable data collection form was designed to collect, document, and analyze the data. The data collection forms include the provision for collection of information related to demographic details of patients like patient's age, gender, weight, date of admission, date of discharge, reason for admission, diagnosis, and medication used like (Antibiotics): generic name of the drug, dose, route of administration and frequency.

Computerization of collected data:

All the collected data was entered into the Microsoft Excel 2010 for easy accessibility, retrieval, and analysis of data. The Microsoft Excel format is enclosed as an appendix. The data was analysed using chi-square test in SPSS.

Results:

During the study period total of 36 patients were enrolled for the study depending on inclusion criteria and the remaining were excluded according to the study's exclusion criteria.

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Table 1: Patients were distributed according to Age group

AGE GROUP	NO OF PATIENTS	PERCENTAGE
20 – 29 YEARS	2	6%
30 – 39 YEARS	2	6%
40 – 49 YEARS	3	8%
50 – 59 YEARS	16	44%
ABOVE 60 YEARS	13	36%
TOTAL	36	100%

The majority of patients are aged 50 and above, constituting 80% of the total, with the highest representation in the 50-59 age group (44%) followed by those above 60 (36%).

During the study period total of 36 patients were reviewed and enrolled in the study according to the inclusion criteria and exclusion criteria 36 patients were distributed according to gender.

Table 2: Patients distributed according to Gender

GENDER	NO OF PATIENTS	PERCENTAGE
MALE	25	69%
FEMALE	11	31%

Among 36 patients the majority of patients were male (25) constitutes about 69% followed by the female patients (11) constitutes about 31%.

In this study the common unwanted effects which we discovered in the study by prescribing levonadifloxacin are **constipation, cough, nausea, decreased haemoglobin levels, decreased RBC levels, thrombocytopenia, increased random blood glucose levels, irregular heartbeat, and drowsy.**

TABLE 3: Relationship between the prescribed dose of levonadifloxacin and Adverse effects

Dose	Constipation	Cough	Nausea	Decreased Hemoglobin	Decreased rbc	Thrombocytopenia	Increased rbs	Tachycardia	Drowsiness
500mg	5	3	0	3	1	3	6	1	1
800mg	9	6	4	17	7	3	13	3	1

The effects of two different doses, 500mg and 800mg, were observed in a study**.** The majority of patients were experienced decreased haemoglobin.

Table 4: Cross tabulation between the prescribed dose of levonadifloxacin and Decreased Haemoglobin

Levonadifloxacin (DOSE)	DECREASED Hb	
	prescribed	Not prescribed
500 mg	3	8

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800 mg	17	8

From the cross-tabulation and chi-square test we conclude that a decreased Hb is the more common unwanted effect in both doses. More patients i.e(17) experienced Decaresed HB with the prescribed dose of 800mg with a significant p-value of 0.02.

Relationship between the duration of therapy (levonadifloxacin) and all Adverse effects

Table 5: Duration of therapy(levonadifloxacin) with all Adverse effects

No Of Days Used	Constipation	Cough	Nausea	Decreased Hb	Decreased RBC	Thrombocytopenia	Increased RBS	Tachycardia	Drowsiness
0-3	3	2	0	4	1	2	2	0	0
4-6	2	3	3	7	4	1	6	1	0
7-10	9	4	1	9	3	3	11	3	2

Across different usage durations, adverse effects were observed. In the 0-3 days range, decreased hemoglobin and thrombocytopenia were notable, while in the 4-6 days range, increased occurrences of cough, decreased hemoglobin, and thrombocytopenia were observed. In the 7-10 days range, constipation and decreased hemoglobin were prominent, along with instances of increased blood sugar and tachycardia.

Table 6: Cross Tabulation Between Duration of therapy(levonadifloxacin) with Increased Random Blood Glucose Levels

Duration of therapy	Increased Random Blood Glucose Level	
	Not Increased	Increased
0-3 days	5	2
4-6 days	8	6
7-10 days	4	11

The association between therapy duration and increased random blood glucose levels was evident. The majority of patients stayed between 7-10days have experienced increased random blood glucose levels when compared to 0-3days or 4-6days. From the cross-tabulation and the square test, we conclude that patients have increased random blood glucose levels with more duration of therapy because of the occurrence of a significant p-value of 0.03

Table 7: Relationship between levonadifloxacin and WBC levels in the body

WBC levels	levonadifloxacin
Increased	10
Decreased	26

Levonadifloxacin use showed a notable impact on WBC levels, out of 36 patients primarily causing a decrease in 26(72%) instances while leading to an increase in 10 cases.

Discussion:

The research article investigates the Drug profile of IV&Oral levonadifloxacin, an antibiotic drug, in the treatment of various infections. The study involved 36 patients who were enrolled based on inclusion criteria and were distributed across different age groups, genders, and departments. The study aims to assess the drug's efficacy and safety by analysing its impact on various health parameters. The statistical analysis was performed using IBM SPSS, and a significance level of $p < 0.05$ was considered statistically significant.

The study population was predominantly male (69%), female (31%) and distributed across different age groups, with a majority of patients being 50-59 years old (44%). The patients were admitted to various departments, with pulmonology being the most common (41.6%).

The researchers observed common unwanted effects associated with levonadifloxacin, including constipation, cough, nausea, decreased haemoglobin (Hb) levels, decreased red blood cell (RBC) levels, thrombocytopenia, increased random blood glucose levels, irregular heartbeat, and drowsiness. No significant association was found between gender and unwanted effects, past medical history, and unwanted effects, or department and unwanted effects.

However, a significant association was found between the prescribed dose of levonadifloxacin and decreased Hb levels. Patients prescribed 800 mg of levonadifloxacin showed a higher incidence (96%) of decreased Hb levels compared to those prescribed 500 mg (63%).

Additionally, the duration of levonadifloxacin therapy appeared to have an impact on patients' blood glucose levels. Patients with a longer duration of therapy (7-10 days) had a higher incidence of increased random blood glucose levels compared to shorter durations (0-3 days and 4-6 days).

The study also highlighted a potential correlation between levonadifloxacin and decreased white blood cell (WBC) levels. The majority of patients (72%) responded positively to the treatment, with a clinical success rate observed in terms of microbial activity and reduced WBC levels after receiving levonadifloxacin.

Overall, the study provides valuable observations into the effects of levonadifloxacin on different health parameters and suggests the need for careful monitoring of patients, especially regarding Hb levels, blood glucose levels, and WBC counts during the course of treatment.

Conclusion:

The study demonstrated that levonadifloxacin emerges as a novel antibiotic with potential clinical benefits in treating a range of infections. The drug's safety profile was generally favourable, with common unwanted effects being manageable. The antibiotic's potency in decreasing WBC levels highlights its efficacy in combating infections effectively.Significant associations were observed between levonadifloxacin use and specific unwanted effects, such as decreased haemoglobin levels, increased random blood glucose levels, and decreased WBC levels. However, Close monitoring of patients during therapy,

along with appropriate intervention if unwanted effects arise, is crucial to ensuring patient safety and optimizing treatment outcomes. Despite the observed unwanted effects, levonadifloxacin's overall clinical success rate was favourable, providing an effective option for managing severe bacterial infections.

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