Drug Corner

Effectiveness and Safety of Lincomycin in Dental Practice

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Aims and Objectives : The retrospective observational study aimed to assess the safety and effectiveness of a 1000 mg lincomycin hydrochloride in managing odontogenic conditions caused by susceptible pathogens.

Materials and Methods : The study included 253 participants aged 11 to 80 years diagnosed with dental conditions such as periodontitis, dental abscess, and gingivitis. Lincomycin hydrochloride 1000 mg was administered once daily for 5 days. Outcome measures included adverse events, Total Symptom Severity (TSS) Score, Physician's Global Assessment Scale (PGA) and Causality Assessment.

Results : After lincomycin treatment, a significant reduction in TSS score was observed (p=0.0000027108), indicating effectiveness in alleviating symptoms. Adverse events were rare (5%), primarily gastrointestinal disturbances, vomiting, headache, diarrhoea, skin rashes or mouth ulcers.

Conclusion : Lincomycin demonstrated effectiveness in reducing symptom severity in the treatment of odontogenic conditions. The study suggests a favourable safety profile for lincomycin, making it a potentially well-tolerated intervention for odontogenic infections. Further research, including comparative studies and extended follow-ups, is warranted for a comprehensive evaluation.

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Key words **: Lincomycin, Effectiveness, Safety, Dental infections.**

Oral health significantly influences overall systemic well-being. The mouth is often regarded as a gateway to general health, with certain oral signs and symptoms potentially indicating conditions such as osteoporosis, diabetes, Human Immunodeficiency Virus (HIV) and specific endocrine issues. The repercussions of inadequate oral health extend beyond the mouth, impacting our daily wellness and overall quality of life[1]. One such factor that significantly impacts poor oral health is dental infection.

Dental infections typically stem from the tooth or its supportive structures and can potentially extend to neighbouring tissues. In situations where facial structures are compromised, the infection commonly arises from factors such as necrotic pulp, periodontal pockets, or pericoronitis[2]. Dental caries and periodontal diseases have long been recognized as predominant challenges to oral health, impacting populations in both developed and developing nations, affecting approximately 20-50% of the global population and serving as a leading cause of tooth loss. In India, particularly among individuals aged 30 and above, periodontal disease has been identified as the primary factor, contributing to nearly 80% of tooth loss.

Antibiotics find extensive use in the management of dental caries and other related dental issues, serving both therapeutic and prophylactic purposes. Dental practitioners often prescribe antibiotics with the awareness that the oral cavity naturally harbours a substantial number of microorganisms as part of its normal flora, potentially leading to infections in patients. Inappropriate utilization of antimicrobials fosters the development of antibiotic-resistant microbial strains, heightens the risk of antibiotic-related adverse reactions and represents a misuse of healthcare resources. Past studies have highlighted instances where dental practitioners frequently prescribed inappropriate antibiotics, contributing to the escalation of antimicrobial resistance[3]. The systematic review by Bhuvaraghan, *et al,* 2021 highlighted that antibiotics are being misused extensively in the context of dental diseases. Additionally, there was a prevalent trend of self-medication among the general population too. Addressing this issue requires the immediate implementation of focused stewardship programs in the dental care domain[4].

The World Health Organization reports that numerous bacterial microorganisms linked to dental

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and oral-maxillofacial infections exhibit antibiotic resistance. Although these infections are clinically significant and prevalent, recent information is lacking regarding the range of clinical pathogens and the corresponding antimicrobial resistance. Up-to-date data is essential for formulating clinical recommendations and guidelines for the treatment of dental and oral-maxillofacial infections[5].

Lincomycin, an antibiotic derived from Streptomyces lincolnensis. Lincomycin is a primary therapeutic option for bacterial infections affecting the respiratory system, soft tissues, bones, joints and oral health[6]. Lincomycin's spectrum includes Gram-positive bacteria such as *Staphylococcus* and *Streptococcus* (*pyogenes, viridans, pneumoniae*), *Corynebacterium diphtheriae* and anaerobes like *Clostridium tetani, Clostridium perfringens* and *Propionibacterium*. It has demonstrated efficacy in treating orodental and circumoral infections caused by *Staphylococcus* and anaerobes. Its chemical composition is distinct from all other antibiotics available for clinical use. Hnatko's, *et al* research, particularly in the treatment of osteomyelitis and soft-tissue infections, carries significant implications for dentistry. The study demonstrated that prolonged use of Lincomycin over 1 to 3 months was effective and relatively safe in patients with osteomyelitis and soft tissue infections[7]. Lincomycin's mode of action is believed to stem from its ability to inhibit protein synthesis rather than interfering with cell wall formation. Lincomycin effectiveness may well be ascribed to its capacity to penetrate diseased bone and severely infected soft tissue[7].

Based on a study by Khosla, *et al*, lincomycin hydrochloride 500mg capsules is a traditional antibiotic proven effective for alleviating dental infections associated with gingivitis, periodontitis, and pre/post-surgical dental procedures[7]. A placebo-controlled study by Ariaudo AA, highlighted that Lincomycin is an effective adjunct in post-periodontal surgery. The study also favours prophylactic use of Lincomycin before and after periodontal surgery[8].

Although there is research that validates the effectiveness of Lincomycin in dental infections, studies focussing on the safety perspective of Lincomycin in dental procedures remain obscure. This study was conducted to evaluate the safety and effectiveness of Lincomycin in the management of dental infections.

Materials and Methods

Study Design :

This was an open-label, single arm, retrospective, observational study. The study aimed to evaluate the safety and effectiveness of a 1000 mg sustained-release tablet of lincomycin hydrochloride for managing odontogenic conditions caused by susceptible pathogens. Patients willing to follow the procedures as per the study protocol voluntarily signed an informed consent form.

Patient Criteria :

The study included participants aged between 11 and 80 years who had been diagnosed with odontogenic conditions like periodontitis, dental abscess, gingivitis, etc. The participants who had not been a part of a similar investigation within the preceding four weeks were included in the study.

Participants who were pregnant, lactating, allergic to lincomycin antibiotics, had pre-existing renal, liver, or cardiac conditions, or other conditions as determined by the investigator (such as uncontrolled diabetes, uncontrolled hypertension, etc), or who were already on antibiotic treatment or unable to follow the study procedures and protocol were excluded from the study.

Study Intervention :

Lincomycin hydrochloride 1000 mg sustained release tablet was administered once daily for 5 days.

Outcome Measures :

The primary outcome measures involved adverse events and causality assessment. The secondary outcomes involved the Total Symptom Severity (TSS) score and the Physician's Global Assessment (PGA) scale. The TSS scale evaluated the effectiveness of Lincomycin treatment, while the PGA was used to assess the successful treatment outcome at the end of the lincomycin treatment. The TSS score and PGA scale are widely used tools to assess disease severity and treatment response. The TSS score quantifies overall symptom severity by summing ratings of multiple symptoms, providing a composite measure that tracks changes over time. It has been validated and shown to be reliable in clinical trials. The PGA scale, a clinician-reported outcome, evaluates the overall severity of a patient's condition based on clinical judgment. Both tools are considered reliable and valid, with the TSS showing strong inter-rater reliability and responsiveness, and the PGA consistently used across various diseases to track disease progression or improvement.

Data Analysis :

A sample size of 253 patients was studied. Categorical data were expressed in numbers and percentages. The effectiveness was tested using the

Wilcoxon signed rank test. All adverse events were recorded and evaluated using the causality assessment tool; causality was categorized as definite, probably, possible or unlikely.

Results

Demographic Details :

A total of 253 patients, comprising 156 (61.66%) males and 97 (38.34%) females, were enrolled in the study. The patients belonged to an age group ranging from 11 to 80 years old who had been diagnosed with dental conditions like periodontitis, dental abscess, gingivitis, etc. Although there were no potential biases in patient selection, the study participants mostly belonged to 31-40 years age group (Table 1).

Indications for Lincomycin :

The study included 18 dental conditions for which Lincomycin was recommended. Patients in each group with dental abscess, dental infection, gingivitis, pain and periodontitis accounted for more than 10% of these indications (Fig 1). The remaining indications are summarized in Table 2.

Effectiveness of Lincomycin based on Symptom Severity Score :

The effectiveness of Lincomycin was evaluated using the TSS score. The symptoms assessed were acute pain, gum pain, gingivitis, periodontitis, bleeding gum, and tooth mobility. At baseline, 83(32.81%) and 163(64.43%) patients suffered from moderate and severe symptoms, respectively (Fig 2). After 5 days of lincomycin treatment, the number of patients with moderate and severe symptoms was substantially less (Fig 2), with a significant reduction in the TSS score (p=0.0000027108) (Table 3). There was a substantial decrease in the average TSS score at day 5 versus baseline (Fig 3).

Table 1 — *Age distribution of patients involved in the study*

Age Group	No of Patients	Percentage
11-20 Years	9	3.56%
21-30 Years	47	18.58%
31-40 Years	57	22.53%
41-50 Years	50	19.76%
51-60 Years	50	19.76%
61-70 Years	32	12.65%
71-80 Years	7	2.77%
> 80 Years	1	0.40%
TOTAL	253	100.00%

Table 2 — *Indications for lincomycin use in the study population accounting for less than 10% of the dental conditions*

Indication	No of Patients (N=47)	Percentage
Pericoronitis	7	2.76%
Root canal	7	2.76%
Acute Pulpitis	5	1.97%
Inflammation	4	1.58%
Teeth Extraction	4	1.58%
Periapical Abscess	4	1.58%
Periapical Infection	3	1.18%
Gum bleeding	3	1.18%
Molar Extraction	3	1.18%
Ulcerative Gingivitis	3	1.18%
Acute Pain	2	0.79%
Broken Teeth	1	0.39%
Wisdom Extraction	1	0.39%

Overall Treatment Outcome of Lincomycin :

The overall treatment outcome of Lincomycin was assessed using the PGA scale. A total of 164 (87.70%) patients recovered from their clinical conditions (Fig 4). Notably, no fatal outcomes were recorded throughout the study.

Safety Outcomes of Lincomycin Treatment :

A total of 240 (95%) patients did not experience any adverse reactions post-lincomycin treatment. However, 13 (5%) of patients experienced adverse drug reactions primarily related to Gastrointestinal (GI)

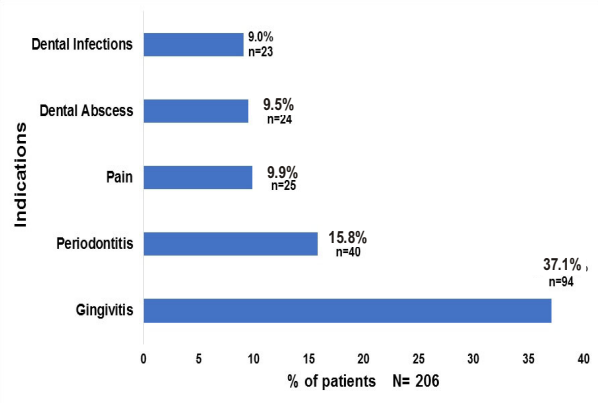

Fig 1 — Indications for lincomycin use in the study population accounting for more than 10% of the dental conditions

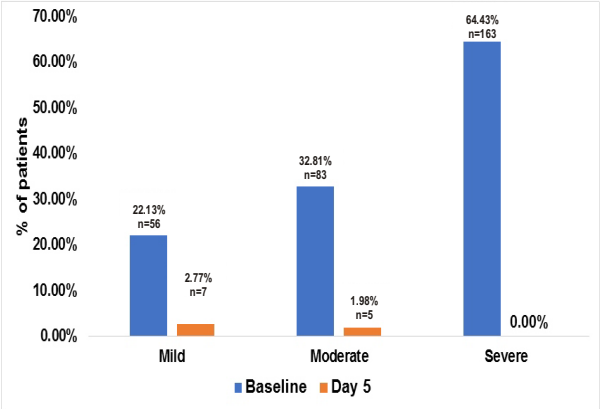

Fig 2 — Total symptom severity score of patients at baseline versus day 5 of lincomycin treatment

Table 3 — *Summary of total symptom score of patients at baseline versus day 5 of lincomycin treatment*

TSS	Mean	N	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Baseline	2.62	253	3.00	0.54	0.0340	-14.124[b]	0.0000027108	90.03	Sig
Day 5	0.26	253	0.00	0.48	0.0304				

TSS : Total Symptom Score; N : number of patients; SD : Standard Deviation; SE : Standard Error; Sig: Significant; P : Probability value

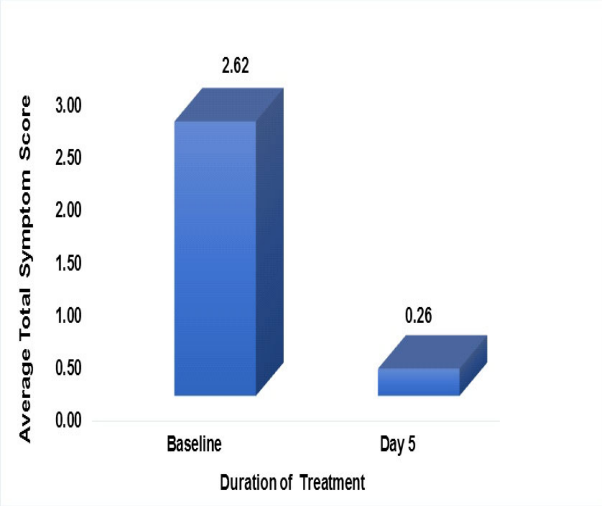

Fig 3 — Average total symptom score of patients at baseline versus day 5 of lincomycin treatment

system like GI disturbance (n=3, 23.08%), vomiting or headache (n=3, 23.08%), diarrhoea (n=3, 23.08%), abdominal pain (n=1, 7.69%) and skin rashes or mouth ulcers (n=3, 23.08%)(Figs 5,6) (Table 4). All adverse events were mild in nature and did not require medications. All 13 adverse events were completely resolved.

Causality Assessment of Lincomycin Treatment :

Table 4 — *System-Wise Adverse Events*

System / Event	n	%
Total Patients with No Adverse Events	240	95.00%
Total Patients with Adverse Events	13	5.00%
Gastrointestinal		
Gastrointestinal Disturbance	3	23.08%
Vomiting	3	23.08%
Diarrhoea	3	23.08%
Abdominal Pain	1	7.69%
Dermatological		
Skin Rashes or Mouth Ulcers	3	23.08%

The causality assessment scale used in this study aimed to determine the probability of an adverse event being linked to Lincomycin treatment. Six (50%) patients out of a total of 12 individuals with adverse reactions reported a possible causal relationship between Lincomycin and adverse reactions, whereas only one patient (8.33%) reported no possible causal relationship between Lincomycin and drug reactions.

Confounding Factors :

Potential confounding factors that may influence the outcomes of this study on lincomycin use in dental infections warrant careful consideration. Patient adherence to the prescribed treatment regimen is a significant variable, as inconsistent medication use could lead to suboptimal outcomes or skewed efficacy assessments. Variability in dental hygiene practices among participants is another critical factor; individuals with better oral hygiene may experience faster resolution of infections, independent of the antibiotic therapy. Additionally, the use of concomitant treatments, such as pain relievers, anti-inflammatory medications, or adjunctive dental procedures like drainage or debridement, may influence the perceived effectiveness of Lincomycin. These factors, if not adequately controlled or accounted for, could confound the results and limit the ability to draw definitive conclusions about the efficacy of Lincomycin.

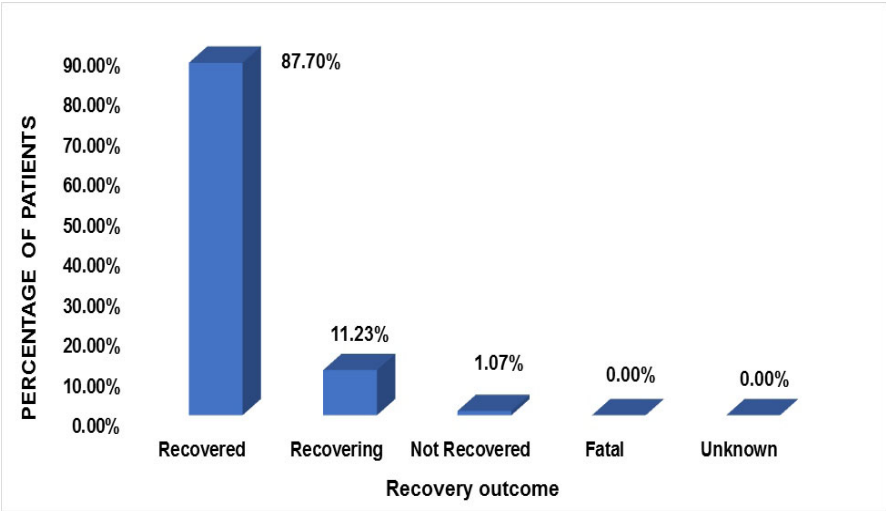

Fig 4 — Patient recovery rate after 5 days of lincomycin treatment

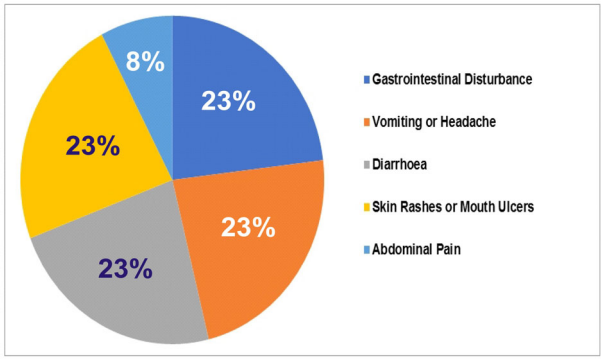

Fig 5 — Adverse events Distribution

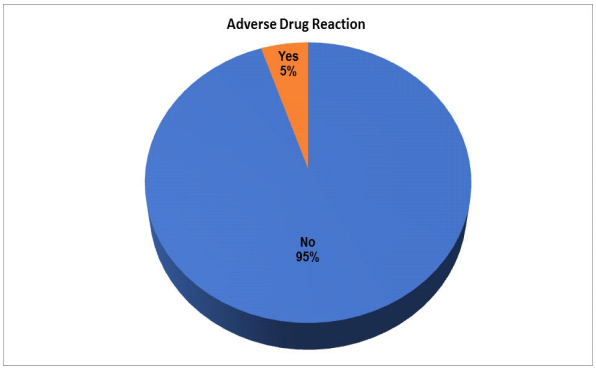

Fig 6 — Incidence of Adverse Drug Reaction with Lincomycin Treatment

Discussion

Antibiotic therapy in the management of dental infections becomes essential in cases involving systemic symptoms, fascial space infections, and the spread of infections to the bony cortex and surrounding soft tissue. Dental infections commonly involve Gram-negative organisms, facultative anaerobes, and strict anaerobes, with anaerobes surpassing aerobic bacteria by a factor of three[2]. This study was carried out to evaluate the safety and effectiveness of Lincomycin in dental infections. The study demonstrated a significant decrease in symptom severity on Day 5 versus baseline levels, suggesting its potential as an effective intervention for addressing dental infections. The significant improvement in symptom severity underscores the positive impact of Lincomycin on dental treatment outcomes.

In the private sector, dentists prescribe antibiotics in approximately 10% of cases, making them the primary prescribers among various specialties. Although standardized metrics like antibiotic days are beneficial for guiding stewardship efforts, there is a lack of reported data on antibiotic consumption in dentistry. In 2013, a cross-sectional study Suda KJ, *et al* showed that more than one antibiotic dose per day was prescribed to 16.2% of the Veteran dental patients from the Veteran Affairs dental care in the United States, totaling 476,451 patients. Aminopenicillins were the most commonly prescribed class (69.4%), followed by Lincomycin (21.9%)[9].

The impact of systemic antibiotics on oral microbiota composition remains relatively unexplored, with a predominant research focus on the gut microbiota despite the oral cavity serving as the initial segment of the gastrointestinal tract. A study conducted by Kopra, *et al* aimed to investigate potential associations between prescribed antibiotics, periodontal status, and oral microbiota, among other objectives. Out of 505 participants, 261 individuals (51.7%) had received antibiotics. The breakdown of prescriptions included 29.4% cephalosporins, 25.7% penicillin, 14.3% quinolones, 12.7% macrolides or Lincomycin, 12.0% tetracycline, and 5.8% trimethoprim or sulphonamide. Notably, the use of Lincomycin correlated with lower levels of specific bacterial groups, suggesting potential benefits in reducing periodontal inflammation. Individual analysis revealed that changes in bacterial levels were most consistently associated with cephalosporins, macrolides/ Lincomycin, or quinolones, while penicillin and trimethoprim showed no significant impact on bacterial phyla[10].

Prioritizing safety is crucial in any medical intervention, and our study suggests a reassuring safety profile for Lincomycin. Among the total study population, only 5% suffered from adverse reactions using Lincomycin. The adverse drug reactions were primarily related to GI disturbance, vomiting or headache, diarrhoea, and skin rashes or mouth ulcers. Our findings were similar to the findings reported by Khosla VM, *et al*, where adverse reactions reported were found to be rare with Lincomycin administration and were in the form of either diarrhoea, skin rashes, or mouth ulcers[7].

The paucity of available data on lincomycin has limited the scope of an elaborate discussion in this manuscript. Nevertheless, the current study contributes valuable evidence to the existing body of knowledge on lincomycin, paving the way for further research in this area.This study has certain limitations, including its single-center design, which may affect the generalizability of the findings. The retrospective design and short follow-up period limit the ability to assess long-term outcomes. The single-arm approach which lacks a comparator group, limits the ability of the study to assess the true treatment effect and control for biases, such as the placebo effect.

While this study supports Lincomycin's effectiveness, its relative efficacy in comparison to other antibiotics used for similar infections remains unexplored. The retrospective design and short follow-up period limit the ability to assess long-term outcomes, such as recurrence or sustained effectiveness. Lastly, the study primarily represents patients aged 31-40, which might limit the generalizability to other age groups. Future research should include comparative studies with other antibiotics and incorporate longer follow-up periods to evaluate safety and effectiveness comprehensively. The limited data on lincomycin restricts an in-depth analysis, yet the study offers significant contributions to the existing literature, warranting further investigation. The long-term impact of antibiotic use in dental infections requires further investigation, particularly concerning antibiotic resistance and effects on the oral microbiota[3]. Prolonged use of antibiotics may contribute to the emergence of resistant bacterial strains, complicating future treatment options[11]. Additionally, antibiotics could disrupt the balance of oral microbiota, potentially causing dysbiosis, secondary infections, or other oral health issues[12]. Longitudinal studies with extended follow-up, including microbial and resistance profiling, are needed to assess these risks and inform safe, effective clinical use and antimicrobial stewardship.

Conclusion

In summary, this study confirms the effectiveness of Lincomycin in the treatment of odontogenic conditions and highlights its generally positive treatment outcomes. The favorable safety profile indicates the potential of Lincomycin as a well-tolerated intervention for odontogenic infections, suggesting its consideration as a viable treatment option in managing such conditions.

Declaration : Article is not published / submitted in any other journal.

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Conflict of Interest : The study was supported by Intellimed Healthcare Solutions, which collected data, provided writing support, and facilitated publication support. The healthcare company was engaged by Wallace Pharmaceuticals, which provided financial and publication assistance for the study. The authors have ensured transparency and the integrity of the research process by following rigorous protocols. To minimize investigator bias, independent data analysis was conducted by an external statistician, and a blinded peer review process was employed. All authors are employed by Intellimed Healthcare Solutions and have disclosed any potential conflicts of interest in accordance with institutional guideline.

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