

## Drug Corner

# Open-label, Prospective, Interventional Clinical Study to Evaluate the Efficacy and Safety of Oral Lincomycin in the Treatment of Upper Respiratory Tract Infection

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**Background** : Respiratory diseases constitute the leading cause of mortality globally. Lincomycin, a lincosamide antibiotic, has proven effective in treating respiratory infections. This study aims to evaluate the efficacy of 1000 mg of lincomycin once daily in the treatment of Upper Respiratory Tract Infections (URTIs).

**Methods** : The study was an open-label, prospective, interventional clinical study conducted on 40 patients who were diagnosed with URTIs and received oral lincomycin 1000 mg once daily for five days.

**Results** : The results showed that lincomycin significantly reduced the mean symptom scores for headache, throat pain, odynophagia (difficulty swallowing), and sinus tenderness. Additionally, the mean scores for nasal and tonsillar congestion were completely reduced post-lincomycin treatment ( $p < 0.05$ ). Lincomycin also shown to be safe and tolerated by all patients.

**Conclusion** : In this clinical study, 1000mg of lincomycin once daily has been shown to be effective and safe in treating URTI.

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**Key words** : Upper Respiratory Tract Infections (URTIs), Lincomycin.

Respiratory Tract Infections (RTIs) are one of the top ten reasons for patient visits to Primary Health Care (PHC). Infections of the respiratory tract cause 9-28% of appointments and are the most frequent among acute illnesses. In India, Upper Respiratory Tract Infections (URTIs) are among the most frequently diagnosed conditions in PHCs. These infections encompass a range of ailments, including rhinosinusitis, Acute Otitis Media (AOM), pharyngotonsillitis and laryngitis<sup>1</sup>.

Respiratory diseases constitute the leading cause of mortality in China and globally, impacting over one billion individuals worldwide. Among children aged 0-18 years, URTI accounts for 81% of emergency room hospital visits for respiratory issues. Li YR, *et al* conducted a cross-sectional study on morbidity in Hong Kong, revealing that 26.4% of hospital outpatient cases were linked to URTI<sup>2</sup>. As one of the prevalent diseases, the global burden of URTI was estimated to be 17.2 billion in 2019<sup>3</sup>.

According to the 2019-2020 National Family Health Survey, Maharashtra recorded 2.4% and 3.8% prevalence of Acute Respiratory Infections (ARIs) in urban and rural areas that would ensue in the following 2 weeks. In the Indian slum areas, ARI constitutes more than two-thirds of all childhood illnesses<sup>4</sup>. However, diverse microbial agents target different viruses and bacteria that are implicated in URTIs. This broad category of infections contributes to the development of diseases in patients, such as acute bronchitis, common cold, influenza and respiratory distress syndromes. Defining most of these patient diseases is challenging because the symptoms associated with URTIs often overlap and their causes are similar<sup>5</sup>.

Due to the diverse pathogenic mechanisms triggered by numerous virus types, no universally effective treatment is currently available for URTIs. Despite their widespread use in treating uncomplicated viral URTIs, antibiotics are ineffective against viruses.

Lincomycin is a lincosamide antibiotic derived as a natural fermentation product from *Streptomyces lincolnensis*<sup>7</sup>. It received approval from the Food and Drug Administration on December 29, 1964. Lincomycin has proven effective in treating acute URTIs and ear, nose, and throat infections, such as tonsillitis, pharyngitis, sinusitis and AOM, along with pneumococcal pneumonia and paediatric

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streptococcal infections. In the context of RTIs, lincomycin can be a valuable choice when there is awareness of local susceptibility trends and epidemiology and when culture data is accessible.<sup>8</sup> This antibiotic exhibits activity against Gram-positive cocci, bacilli, Gram-negative cocci, and certain other microorganisms, including *Haemophilus* species. It inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the bacterial ribosome. Lincomycin has demonstrated activity against the majority of bacterial strains<sup>9</sup>.

The increased frequency of antibiotic usage in URTIs is a global issue, consistently ranking high among the conditions associated with antibiotic prescriptions. According to the current review of literature, before prescribing an antibiotic for these infections, a precise diagnosis must precede; such diagnosis shall establish its bacterial origin to prevent the null clinical utility of the drug and the potential risk of increasing bacterial resistance. Suttajit S, *et al.* explored the patterns and evaluated the appropriateness and predictors of antibiotic prescriptions for bacterial and viral URTIs. The study showed that irrespective of the diagnosis, amoxicillin, macrolides and lincomycin injections were most frequently prescribed for bacterial infections versus those for viral infections<sup>6</sup>. With the help of a drug prescription database, a retrospective observational study showed that lincomycin was in the list of top 25 antibiotics that were frequently prescribed in children under 16 years of age with URTIs at private ambulatory healthcare practices<sup>10</sup>.

Lincomycin has a relatively narrow activity spectrum, which primarily targets specific bacteria. Avoiding broad-spectrum antibiotics that could contribute to further antibiotic resistance can be advantageous<sup>11</sup>. Lincomycin can substitute for patients with penicillin allergies who need treatment for bacterial URTIs caused by susceptible organisms<sup>12</sup>. Despite numerous clinical and microbiological studies assessing the efficacy of lincomycin in common infections encountered in clinical settings, the existing evidence has not been extensively reviewed or propagated over the past few decades.<sup>8</sup> The objective of this study was to evaluate the efficacy of oral lincomycin for treating URTI.

#### MATERIALS AND METHODS

This is an open-label, prospective, interventional clinical study that evaluated the efficacy of lincomycin 1000 mg once daily in the treatment of URTI. A total of 40 patients were included in the study.

## RESULTS

A total of 40 patients were included in the study, including 28 (70%) male and 12 (30%) female patients, respectively. The mean age of the male and female patients was 42.68 and 41.42 years respectively. All patients received oral lincomycin 1000 mg once daily until day 5. The different co-morbidities of the patients are mentioned in Table 1. Patients diagnosed with tonsillitis contributed to the highest percentage of the population.

Table 1 — Demographic details of patients		
<b>Co-morbidity wise distribution :</b>		
Other Co-morbidity	Frequency	Percentage
Diabetes Mellitus	9	22.50%
Hypertension	6	15.00%
Cardiovascular	1	2.50%
Obesity	1	2.50%
<b>Diagnosis wise distribution :</b>		
Diagnosis	Frequency	Percentage
Tonsillitis	12	30.00%
Pharyngitis	10	25.00%
Tonsillo Pharyngitis	9	22.50%
Bacterial Rhinosinusitis	8	20.00%
Laryngo Pharyngitis	1	2.50%

#### Effectiveness of Oral Lincomycin :

Oral lincomycin 1000mg once daily for 5 days significantly reduced the mean symptom scores for headache ( $p < 0.05$ ), throat pain ( $p < 0.05$ ), odynophagia ( $p < 0.05$ ) and sinus tenderness ( $p < 0.05$ ). Further, the mean scores for nasal ( $p < 0.05$ ) and tonsillar congestion ( $p < 0.05$ ) formation were completely reduced post-lincomycin treatment (Fig 1).

#### Safety :

Lincomycin was shown to be safe and tolerated by all patients. Readmission was not observed in any patients and no adverse events such as diarrhoea, CDI or anaphylaxis were reported.

## DISCUSSION

In this study, there was a significant reduction in the mean scores for various symptoms that included headache, throat pain, odynophagia (difficult swallowing) and sinus tenderness. Mean scores for manifestations such as nasal congestion and tonsillar congestion were completely reduced after the lincomycin treatment, indicating a reduction in infection and overall improvement in the patient's condition. These findings demonstrate the efficacy of oral lincomycin 1000mg in treating URTI.

The effectiveness of lincomycin has been established in previous studies. A clinical study by

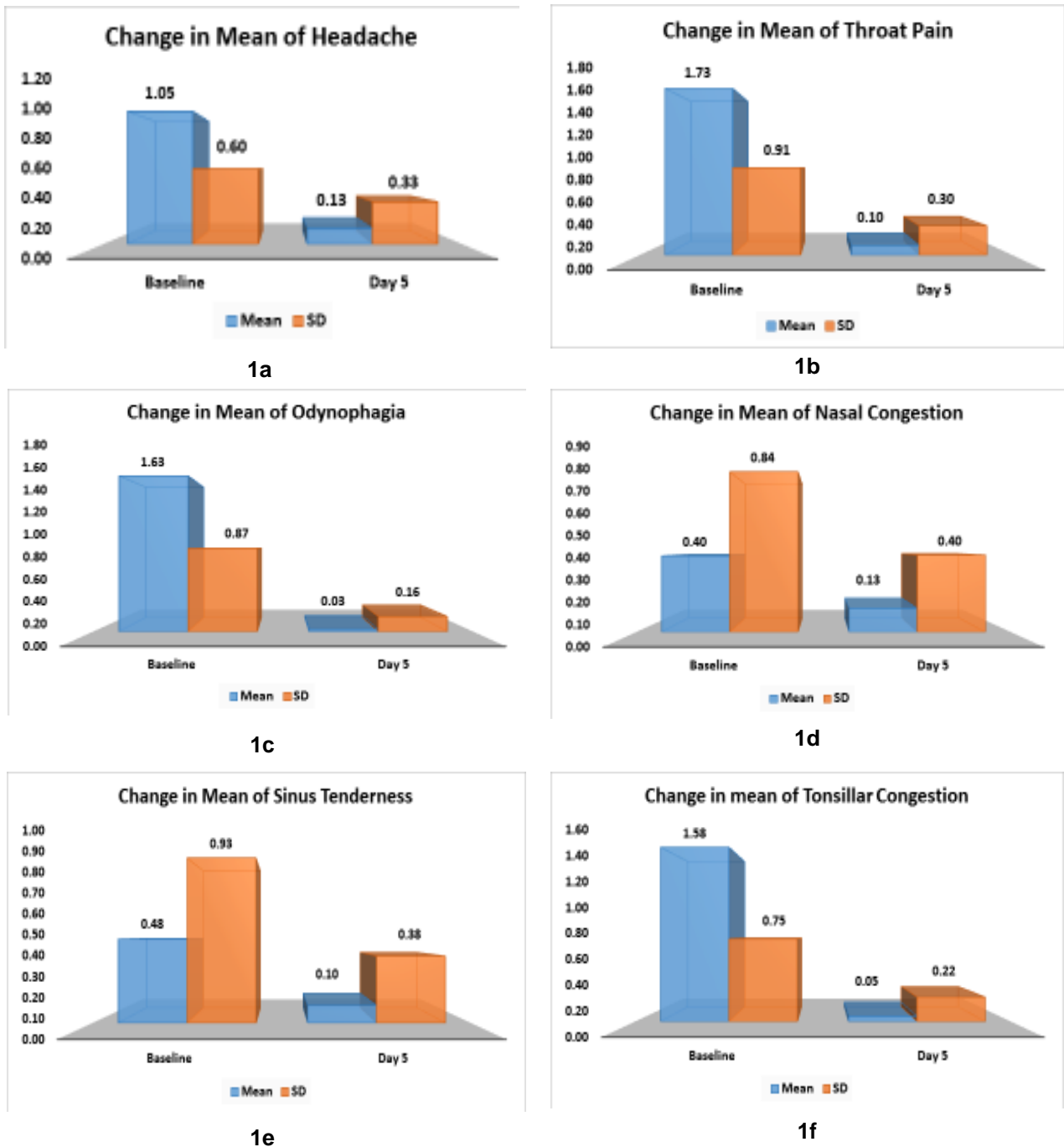


Fig 1 — Mean symptom scores post lincomycin administration for (a) Headache (b) Throat pain (c) Odynophagia (d) Nasal congestion, (e) Sinus tenderness (f) Tonsillar congestion

Breese BB, *et al* reported that 100 patients (paediatric) with haemolytic streptococcal infection were randomly administered with ampicillin, penicillin and lincomycin. All three drugs were given orally for ten days: lincomycin and ampicillin in capsule form and potassium penicillin G in pill form. The ampicillin and potassium penicillin G dosage was approximately 5

to 10 mg per pound of body weight (10 to 20 mg per kilogram); lincomycin was just twice as large. The study demonstrated that approximately 82% of patients showed improvement with lincomycin. Within three weeks of therapy, failure rates were 12.0% for lincomycin, 17.8% for ampicillin and 25.4% for penicillin, with the penicillin-lincomycin difference

(13.4%) being significant ( $p < 0.02$ ). Randomly selected groups and consistent failure criteria ensure therapy effectiveness differences are shown by failure rate differences, including recurrences and carriers. The study concluded that ampicillin and lincomycin might be added to the list of drugs effective against haemolytic streptococcal disease<sup>13</sup>.

In another Indian study involving 40 adult patients diagnosed with tonsillitis or sinusitis, the efficacy of oral lincomycin at a dose of 500mg and cefpodoxime at 200mg, administered twice daily for a duration of 5 days, was investigated. Following the study period, all participants underwent re-evaluation and their response rates were examined. The prevalent clinical symptoms included body temperature, headache, throat pain, postnasal discharge, mucopus, odynophagia (difficult swallowing), sinus tenderness, nasal congestion, pharyngeal congestion and tonsillar congestion. Overall, lincomycin hydrochloride demonstrated higher efficacy in alleviating all symptoms, except for headache, versus cefpodoxime proxetil. Out of a total of 100% patients in each group, 67.89% of those treated with lincomycin and 52.27% of those treated with cefpodoxime experienced complete relief across all clinical symptoms<sup>14</sup>. In our study, administration of lincomycin 1000mg once daily also significantly reduced the clinical manifestations of URTI presented by the patients.

However, this present study has limitations, such as a restricted assessment period of 5 days to evaluate the efficacy of lincomycin. The short duration may not fully capture potential long-term effects or complications associated with prolonged use. Hence, it is recommended that future research should engage in comparative studies involving other antibiotics and the inclusion of extended follow-up studies becomes crucial for a thorough assessment of safety considerations.

### CONCLUSION

In this clinical study, lincomycin 1000 mg once daily has been shown to be effective in treating URTI.

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

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**Conflict of Interest :** No

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