## Drug Corner

# Assessment of Effectiveness and Safety of Lincomycin in Surgical Site Infections

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**Background:** Surgical Site Infections (SSIs), often caused by *Staphylococcus*, pose a significant health challenge. Lincomycin, which is effective against gram-positive and anaerobic bacteria, lacks sufficient safety data in India, especially in SSIs. This study aimed to address this gap by investigating the effectiveness and safety of Lincomycin in various SSIs.

**Method:** This open-label, retrospective, observational, single arm study focused on evaluating the safety and effectiveness of a 1000 mg sustained-release Lincomycin hydrochloride tablet for treating SSIs caused by susceptible pathogens. Lincomycin was administered for 5 days and primary outcomes included adverse events and causality assessment, whereas secondary outcomes included Total Symptom Severity (TSS) and Physician's Global Assessment scale (PGA).

**Results:** A significant reduction in the TSS score (p=0.0000001256) was observed after 5 days of Lincomycin treatment compared to the baseline. Clinical success with Lincomycin was achieved in 89.86% of patients, and 65.38% of the patients successfully recovered from their clinical condition. Adverse drug reactions were reported by only 3.5% of the patients and were mainly associated with Gastrointestinal (GI) disturbances. Among these cases, 54.90% deemed the causal relationship between Lincomycin and GI disturbances unlikely.

**Conclusion:** This study confirms the effectiveness of Lincomycin hydrochloride (1000 mg) for the treatment of SSIs, with positive overall outcomes. Its favourable safety profile suggests that Lincomycin is a well-tolerated pharmacological intervention, making it a viable treatment option for managing SSIs in India.

[*J Indian Med Assoc* 2025; **123(1):** 79-83]

***Key words*** **: Lincomycin, Surgical Site Infection, Effectiveness, Tolerability.**

The most common organisms implicated as causes of Surgical Site Infections (SSIs) include *Staphylococcus aureus, Staphylococcus epidermidis, Aerobic streptococci, and Anaerobic cocci*[1]. The global pooled incidence of SSI was found to be 2.5% (95% CI: 1.6, 3.7). Based on the subgroup analysis by WHO region and survey period, the incidence of SSI was 2.7% (95% CI: 2.2, 3.3%) and 2.5% (95% CI: 1.8, 3.5%), respectively[2]. Surgical-site infections remain one of the foremost causes of morbidity and mortality in India. The SSI rate in India varies widely and ranges from 1.6% to 38%, depending on the setting[3]. The mortality associated with SSIs represents just the visible aspect of a more significant issue. Beneath lies additional challenges, including extended hospital stays, the necessity for repeat surgeries, readmission to the hospital, reduced Quality of Life, and the financial and social hardships endured by affected families due to loss of daily income[3].

Several patient-related factors, such as advanced age, malnutrition, low levels of serum albumin, obesity, smoking, pre-existing infections and immunosuppression (eg, due to Diabetes Mellitus or irradiation), elevate the risk of SSIs. On the surgical front, various factors, including contaminated surgical procedures, emergency surgeries, lengthy operations, suboptimal sterilization, improper instrument handling and inadequate antiseptic preparation of the surgical site, may contribute to the onset of infection. Certain physiological conditions like multiple traumas, hemodynamic instability, shock, extensive blood transfusions during surgery and postoperative occurrences of hypothermia, hypoxia, and hyperglycaemia can also predispose individuals to SSIs[4].

The choice of antibiotics for Surgical Antibiotic Prophylaxis (SAP) relies on local resistance patterns and institutional guidelines, although, in most cases, SAP regimens are selected based on the antibiotics' spectrum of activity in alignment with the surgical procedure performed[5]. The guidelines provided by the Centers for Disease Control and Prevention suggest

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***Received on : 14/01/2025***

***Accepted on : 14/01/2025***

the administration of the selected antibiotic approximately 60 minutes before making the surgical incision[6]. Addressing the challenges associated with SAP in today's era of antibiotic resistance is crucial for enhancing patient care and surgical outcomes. The growing problem of antibiotic-resistant bacteria and the strategies needed to ensure effective SAP pose escalating challenges for healthcare professionals within the surgical setting. Enhancing existing practices and integrating antibiotic stewardship programs through collaborative multidisciplinary teams are expected to continue playing a pivotal role in mitigating antibiotic resistance (AR) and reducing the incidence of SSIs caused by resistant pathogens[5]. The initial timing of drug administration, redosing of the drug, if required, the length of prophylactic therapy and dosage in obese patients are critical elements in avoiding SSIs and contributing to antibiotic stewardship. Reducing unnecessary antibiotic use is essential for minimizing adverse effects and preventing the development of AR. It is also essential to regularly review antibiotic selection to avoid contributing to emerging resistance patterns identified on the antibiogram[1].

Lincomycin is an antibiotic produced by actinomycete Streptomyces lincolnensis, belonging to the lincosamide group, initially discovered in 1964. It demonstrates a range of antibacterial properties, mainly targeting anaerobic bacteria such as Clostridium (including tetani and perfringens) and Propionibacterium, as well as gram-positive bacteria, including *Staphylococcus, Streptococcus* (such as Pyogenes, Viridans, and Pneumonia), and *Corynebacterium diphtheriae*[7,8]. Lincomycin serves as a treatment choice for bacterial infections affecting the respiratory system, soft tissues, bones, joints, and oral health[9]. The primary benefit of lincomycin lies in its ability to be utilized across a significantly broader range of clinically effective therapeutic doses[8].

Several studies have shown significant effectiveness in employing lincomycin to prevent SSIs[10-12]. Moreover, the safety aspect of lincomycin in several studies indicated no toxicity, with only mild adverse effects, such as allergic contact dermatitis, anaphylaxis, bowel upset, occasional diarrhea or other non-bothersome side effects[10,13]. A study involving both in-vivo and in-vitro assessments of Lincomycin's effectiveness against Staphylococcus aureus revealed no relapse and side effects, and the drug was well tolerated by 95 children with pyoderma[14]. Though Lincomycin has been on the market for many decades, there are few clinical studies on Lincomycin safety outcomes in India. This study has been undertaken to understand the use of Lincomycin and its safety outcomes in combating various SSIs.

## Materials and Methods

### Study design

This was an open-label, retrospective, observational, single arm study. The study aimed to evaluate the safety and effectiveness of a 1000mg sustained-release tablet of Lincomycin hydrochloride in the treatment of SSIs caused by susceptible pathogens. The patients willing to follow the procedures per the study protocol voluntarily signed an informed consent form.

### Patient criteria

The study included individuals aged between 11 and 80 years who had been diagnosed with SSIs, such as Skin and Soft Tissue Infections (SSTIs), postoperative infections, boils, furuncles, abscesses, cellulitis, etc. The participants who had not been a part of a similar investigation within the preceding four weeks were included in the study.

Individuals 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. No comparator group was used.

### 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 Scale (PGA). The TSS scale evaluated the clinical cure, while the PGA was used to assess the successful treatment outcome at the end of the Lincomycin treatment.

### Data analysis

A sample size of 286 patients was considered appropriate. Categorical data were expressed in numbers and percentages. The effectiveness was tested using the Wilcoxon signed rank test. All adverse events were recorded and their causality was

evaluated using the causality assessment tool; causality was categorized as definite, probably, possible or unlikely.

## Results

### Demographic details

A total of 286 patients were enrolled in the study. The patients belonged to an age group ranging from 11 to 80 years old who underwent surgical intervention. Most patients who underwent surgical interventions were male 167(58.39%). The individuals in the 31-40 age group contributed to the highest percentage of patients (Table 1).

### Indications for Lincomycin

The study included 48 surgical procedures for which Lincomycin was recommended. Patients in each group with abscesses, boils, cellulitis, diabetic foot, infected wounds, postoperative infection, and skin and soft tissue infection accounted for more than 5% of the indications. (Figure 1). The remaining interventions 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 abdominal pain, pus, burning micturition, swelling, fever, and induration. At baseline, an estimated 63(22.03%) and 102(35.66%) patients suffered from moderate and severe symptoms, respectively (Figure 2). After 5 days of Lincomycin treatment, the number of patients with moderate and severe symptoms was substantially less, with a significant reduction in the TSS score (p=0.0000001256) (Table 3). There was a significant decrease in the average TSS score at day 5 versus baseline (Figure 3).

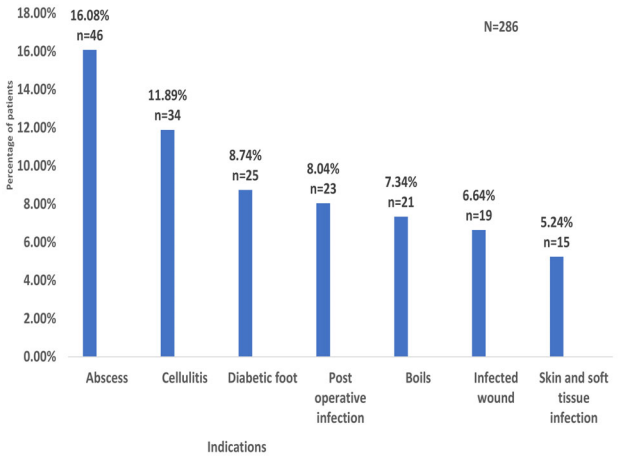


Figure 1: Each group of surgery-dependent indications contributing to more than 5% of the total population.

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

| Age Group | No of Patients | Percentage |
|---|---|---|
| 11-20 Years | 8 | 2.80% |
| 21-30 Years | 61 | 21.33% |
| 31-40 Years | 64 | 22.38% |
| 41-50 Years | 63 | 22.03% |
| 51-60 Years | 55 | 19.23% |
| 61-70 Years | 32 | 11.19% |
| 71-80 Years | 3 | 1.05% |
| TOTAL | 286 | 100.00% |

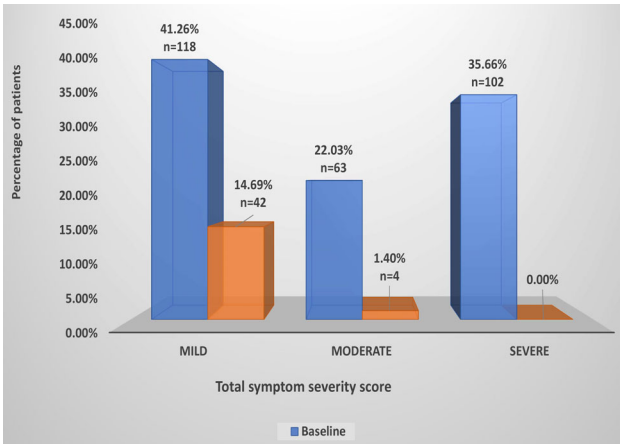


Figure 2: Total symptom severity score of patients at baseline versus 5 days of lincomycin treatment.

### Overall treatment outcome of Lincomycin

The overall treatment outcome of Lincomycin was assessed using the Physician Global Assessment (PGA) scale. A significantly high percentage of patients, 257(89.86%), achieved clinical success with Lincomycin. Importantly, no fatal outcomes were recorded throughout the study.

### Safety outcomes of Lincomycin treatment

A total of 276 (96.5%) patients did not experience any adverse reactions Post-Lincomycin treatment.

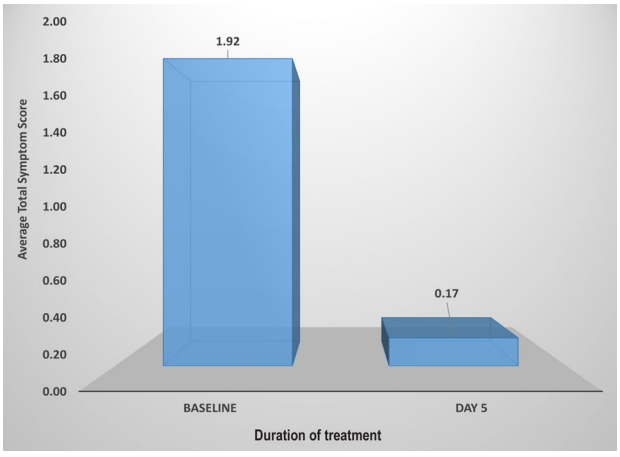


Figure 3: Average total symptom score of patients at baseline versus day 5 of Lincomycin treatment

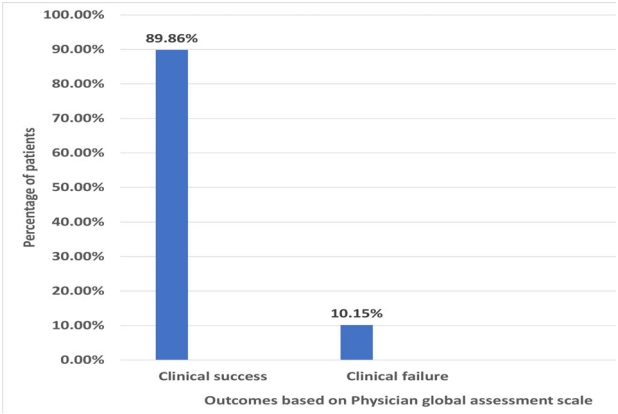


Figure 4: Outcome assessment of Lincomycin treatment using PGA scale

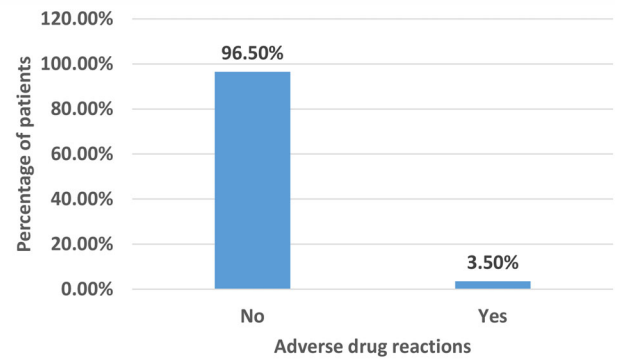


Figure 5: Incidence of adverse drug reactions due to Lincomycin treatment

(Figure 6) Only 10(3.5%) of patients experienced adverse drug reactions primarily related to gastrointestinal (GI) disturbance (10%), GI intolerance (30%), diarrhea (30%), nausea (20%) and vomiting (10%).

## Causality assessment of lincomycin treatment

The causality assessment scale used in this study aimed to determine the probability of an adverse event being linked to Lincomycin treatment. The majority of patients, accounting for 28 (54.90%), reported the causal relationship between Lincomycin and the GI disturbances as unlikely. Further, only 6(11.76%) patients reported a possible causal relationship between Lincomycin and drug reactions.

## Discussion

SSIs are becoming increasingly common among hospital-acquired infections as surgeries become more frequent, leading to longer hospital stays, higher costs, and increased morbidity and mortality rates. The use of antibiotic prophylaxis method surgery has been an evidence-based practice, significantly reducing the incidence of SSIs by up to four times. Therefore, this study aimed to assess the safety and effectiveness of Lincomycin in the treatment of SSIs. The results of the study showed a significant reduction in symptoms on Day 5 versus baseline levels in patients receiving Lincomycin therapy, indicating its potential as a therapeutic intervention for managing SSIs. The significant improvement from baseline symptoms highlights the positive impact of Lincomycin on patient outcomes.

The results of the overall treatment outcome showed that the majority of patients achieved positive treatment outcomes, indicating the potential clinical benefits associated with Lincomycin administration in SSIs. Additionally, a study conducted by Keighley MRB, *et al* concluded that 24-hour prophylaxis with lincomycin is as effective as 5-day therapy in reducing complications caused by anaerobic organisms[15].

Table 2 — *Each group of surgery-dependant indications contributing to less than 5% of the total population.*

| Surgical interventions (N=286) | Other interventions (N=286) |
|---|---|
| Accidental burns, ulcers (2.1%) | Control infection (0.35%) |
| Appendicitis, furuncle, inflammatory bowel disease, lower segment cesarean section, paronychia, urinary tract infection (4.2%) | Gastroenteritis (0.35%) |
| Breast lump, calcified lump in the neck, otitis media, dilation and curettage, ectopic, oedema, granuloma, injury sutured wound, laparoscopic cholecystectomy, foot gangrene, lipoma, mastitis, oozing wounds, operate wound part site infusion, gastrointestinal tract, orchitis, perianal fistula, sebaceous cyst, skin ulcer and SSI (7%) | Mild diarrhoea (0.35%) |
| Folliculitis (3.15%) | Pain and swelling (4.9%) |
| Foot ulcer, right axillary hidradenitis, sepsis (4.2%) | |
| Infected cyst, wound infection, and carbuncle over the back (5.25%) | |
| Leg ulcer and multiple furuncles (4.2%) | |

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

| TSS | Mean | N | Median | SD | SE | Wilcoxon W | P-Value | % Effect | Result |
|---|---|---|---|---|---|---|---|---|---|
| Baseline | 1.92 | 286 | 2.00 | 0.90 | 0.0532 | -14.810 | 0.0000001256 | 90.91 | Significant |
| Day 5 | 0.17 | 286 | 0.00 | 0.42 | 0.0246 | | | | |

TSS: Total symptom score; N: number of patients; SD: Standard Deviation; SE: Standard error; P: Probability value

Similarly, in another research, Alaa A, *et al* studied the effect of peritoneal lavage with a Lincomycin-gentamycin mixture compared to normal saline lavage on postoperative infections in 40 patients undergoing colorectal cancer surgery. The normal saline lavage did not significantly reduce the number of positive cultures, while antibiotic lavage resulted in negative cultures in 90% of cases. The antibiotic lavage was associated with a reduced occurrence of intra-abdominal abscesses and wound infections[16].

Safety considerations are paramount in any medical intervention and our study indicates a reassuring safety profile for Lincomycin. Minor Gastrointestinal disturbances emerged as the primary adverse reactions, affecting only a small population of patients. Our study findings support the findings reported by ACC, *et al*. The study reported that prophylactic use of Lincomycin in patients undergoing appendicectomy was associated with no side effects[17]. In another study by Moodley J, *et al* patients undergoing cesarean section showed no adverse events due to lincomycin in either mothers or babies[18].

Causality assessments further support the safety profile of Lincomycin, with the majority of cases indicating that lincomycin administration did not lead to the onset of Gastrointestinal disturbances. This suggests a broad applicability of Lincomycin across diverse surgical scenarios without compromising safety.

This study has certain limitations, including the absence of a comparator group and a short 5-day assessment period, which may not capture long-term effects or complications. While conducted across multiple centers, broader patient diversity and settings are needed to improve external validity. Future research should conduct comparative studies with other antibiotics and implementing extended follow-up studies would be essential for evaluating safety.

## Conclusion

In conclusion, the study affirms the effectiveness of Lincomycin hydrochloride (1000mg) sustained release tablet in treating SSIs and highlights its overall positive treatment outcomes. The favourable safety profile emphasizes Lincomycin's potential as a well-tolerated pharmacological intervention in SSIs, supporting the consideration of Lincomycin as a viable treatment option for managing SSIs in India.

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