Drug Corner

Assessing the Therapeutic Effectiveness and Tolerability of Lincomycin Injectables in Skin and Soft Tissue Infections and Surgical Site Infections : A Comprehensive Real-World Evidence Study

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Objective : The open-label, observational, real-world evidence study evaluated the effectiveness and tolerability of Lincomycin injection in patients with Surgical Site Infections (SSI) or Skin and Soft Tissue Infections (SSTI).

Methodology : A total of 214 patients above 18 years of age, diagnosed with impetigo, folliculitis, or minor SSTI, were enrolled and received Lincomycin 600 mg (intramuscular or intravascular). The primary outcomes included the evaluation of signs and symptoms associated with SSI and SSTI wound healing and post-operative pain after the treatment with Lincomycin injection. Secondary outcomes included 30-day readmission rates and adverse events.

Result : Lincomycin 600 mg injectable significantly improved mean symptom score for fatigue, cellulitis, redness, and pain around the infectious area. Additionally, complete resolution of folliculitis and scar formation was observed after Lincomycin treatment ($P<0.05$). The drainage of fluid also significantly decreased. No major adverse events related to Lincomycin administration, such as diarrhoea or Clostridium Difficile Infection (CDI), were reported throughout the study period. Moreover, no patients required readmission, indicating that Lincomycin was generally well-tolerated without significant risks or adverse effects.

Conclusion : The study supports Lincomycin injection as an effective and safe option for treating SSI and SSTI.

[*J Indian Med Assoc* 2024; **122(1):** 56-9]

***Key words* : Surgical Site Infection, Skin & Soft Tissue Infection, Lincomycin Injection, Surgery.**

Skin and Soft Tissue Infections (SSTIs) result from a compromise of the skin's defences and microbial invasions and interactions therein. Since SSTIs are usually caused by bacteria, viral, fungal, or parasitic aetiologies[1]. In India, there are minimal data on the prevalence of SSTIs and only few studies have been done till date with one study reporting an incidence rate of 18.21/1000 person years in a tertiary care hospital in South India[2,3]. SSTIs are associated with risk factors such as diabetes, compromised immune system, trauma, obesity, injury, chronic skin conditions, etc[4]. SSTI can also be caused by other factors, such as viruses (eg, herpes simplex virus), fungi (eg, Candida or dermatophytes causing fungal infections) or parasites (eg, scabies mites). However, bacterial infections, particularly those caused by Staphylococcus spp. and Streptococcus spp. Staphylococcus aureus and Streptococcus pyogenes, are the most common culprits in SSTIs[5]. There are various types of SSTI, each characterized by specific symptoms, affected tissue such as cellulitis, folliculitis, abscesses, etc[6]. Severe infections often present with intense pain, rapidly spreading redness, significant swelling, systemic signs of infection (eg, high fever, rapid heart rate), diarrhoea, tissue destruction, fatigue and anaphylactic reactions[7].

The treatment options for SSTI depend on the specific type and severity of the infection, as well as individual patient factors. Therefore, antibiotics are a mainstay in the treatment of bacterial SSTI. Commonly used antibiotics include penicillin's, cephalosporins, macrolides and fluoroquinolones. In severe cases or when resistant bacteria are suspected, intravenous antibiotics may be necessary. Pain associated with SSTI can also be managed with acetaminophen and anti-inflammatory drugs (NSAIDs)[8]. While current treatment options for SSTI are generally effective, there are some limitations and challenges that healthcare professionals may encounter. Antibiotic resistance is a significant concern in the treatment of SSTI whereas some antibiotics have a narrower spectrum of activity, meaning they are effective against specific types of bacteria [9].

Lincomycin was isolated from the Streptomyces lincolnensis strain in 1962[10]. Lincomycin has been utilized in both its oral and injectable forms for the treatment of Respiratory Tract Infections (RTI), Skin and Soft Tissue Infections (SSTI) and Surgical Site Infection (SSI), bone and joint infections (osteomyelitis and septic arthritis) and oro-dental infections. It has

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Received on : 07/12/2023

Accepted on : 03/01/2024

proven to be particularly valuable in cases involving strains of bacteria that produce Penicillinase (an enzyme that inactivates penicillin) or those that are resistant to Erythromycin (another antibiotic). Therefore, Lincomycin serves as an effective antibiotic for combating infections caused by specific antibiotic-resistant strains[11]. This study aims to evaluate effectiveness and tolerability of Lincomycin injectable 600 mg/ml in the treatment of Surgical Site Infection (SSI) and Skin and Soft Tissue Infection (SSTI).

Materials and Methods

Study design :

This was an open label, observational, real-world evidence study that assessed the effectiveness and tolerability of Lincomycin injection. Data was collected using a standardized case report form that included demographics, treatment dose and duration, symptom improvement, clinical condition, comorbidities, complications and details of concomitant medication.

Study participants :

Patients with SSI or SSTI were prescribed Lincomycin injection 600 mg (intramuscular or intravascular). Patients of either gender above 18 years of age, who were undergoing surgical operation and clinically diagnosed with impetigo, folliculitis, or minor SSTI including secondarily infected eczema presumed to be caused by Staphylococcus aureus were included. Pregnant or breastfeeding women were excluded. Patients with known sensitivity to Lincomycin or Clindamycin, signs of systemic infection (such as fever) or with evidence of abscess or cellulitis at the site of treatment were also excluded.

Outcome measures :

The primary outcome measures included evaluation of signs & symptoms associated with SSI (reduction in severity, signs of infection at surgical site, wound healing, postoperative pain) & SSTI (erythema, purulence, crusting, oedema, redness, swelling, warmth, and pain) after Lincomycin injection with incision and drainage after the end of original planned course. It also added therapy to the patients after hospital discharge. Secondary outcomes included change in wound size from baseline, SSI & SSTI related 30-day re-admission and incidence of adverse events such as (allergic contact dermatitis, antibiotic resistance and anaphylaxis. Safety outcomes included adverse effects reported by the patients and any abnormal findings reported through routine investigations. Data was collected from baseline till end of treatment.

Statistical analysis :

A sample size of 214 patients was considered adequate for the study. Descriptive statistics was used to present the data in mean and percentage. Paired t-test and Wilcoxon Sign Ranked Test were used to test significance.

Results

Demography and baseline data :

A total of 214 patients were enrolled for the study, comprising 62.15% of males and 37.85% of females. The distribution of patients across different age groups is summarized in Table 1, with the maximum number of patients belonging to the age group of 21-40 years (59.35%). Patients received Lincomycin injections at a dosage of 600 mg/ml. Majority of the patients in our study presented with various diagnoses including abscess, appendicitis, cellulitis, post-surgical infections and diabetic foot infections (Table 1).

The mean duration of treatment with Lincomycin injection was found to be 6 days (30.37%), with a minimum to maximum ranging from 5-10 days (Fig 1).

Effectiveness :

The results pertaining to ESR, WBC and Hb values in patients treated with injectable Lincomycin (IV + IM) are presented in Table 2. There was a significant change observed in mean ESR and WBC from 21.40mm/hr, 18388.57 million/mm^3 to 8.50 mm/hr and 8974.29 million/mm^3 respectively ($P<0.05$) (Table 2).

Symptoms such as fatigue, cellulitis, redness and pain around infectious area were reduced from 0.38, 2.11, 1.97, 2.35 to 0.02, 0.07, 1.03, 0.08 respectively. Also, folliculitis (0.80) and scar (0.01) formation completely reduced after the Lincomycin treatment

Table 1 — *Demographics details of patients*

Age wise distribution		
Age Group	No of Patients (N=214)	Percentage
< 20 Years	20	9.35%
21-30 Years	64	29.91%
31-40 Years	63	29.44%
41-50 Years	47	21.96%
51-60 Years	12	5.61%
61-70 Years	6	2.80%
> 70 Years	2	0.93%
Gender wise distribution		
Male	133	62.15%
Female	81	37.85%
Diagnosis based distribution		
SSTI	17	7.94%
Abscess	30	14.02%
Wound Infection	4	1.87%
Cellulitis	62	28.97%
Diabetic foot infection	15	7.01%
Injury	5	2.34%
SSI	8	3.74%
Appendicitis	14	6.54%
Post surgical infection	7	3.27%
Others	52	24.30%

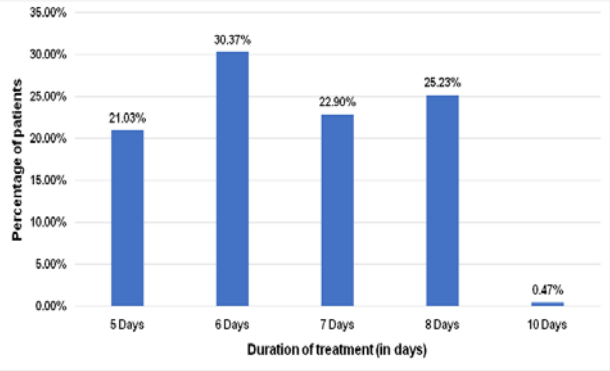

Fig 1 — Duration of Treatment

(P<0.05). The drainage of fluid was also decreased from 2.2 to 1.01.The graphical representation of the outcomes is presented in Fig 2.

Tolerability :

The tolerability of Lincomycin injection was assessed and it was found to be safe and well tolerated by the patients. Throughout the study period, no major adverse events related to Lincomycin administration such as diarrhoea or CDI were reported. Re-admission was not observed in any patient.

Discussion

The findings of our study support the use of Lincomycin as an effective treatment option for SSTI. The significant reduction observed in various outcomes and their related parameters, such as fatigue, pain, cellulitis, folliculitis and redness, indicate the therapeutic benefits of Lincomycin in managing these infections. These results align with previous studies highlighting the efficacy of Lincomycin in treating Respiratory Tract Infections (RTI), SSTI and bone infections.

The present study demonstrated that Lincomycin injection has a generally favourable safety profile in the study population, with a low incidence of adverse events. The most reported adverse events, such as diarrhoea and pain around the area, were typically mild and self-limiting, indicating good tolerability of the drug. Severe adverse reactions were rare and no unexpected safety concerns were identified. These findings contribute to the body of evidence supporting the safety and tolerability of Lincomycin in clinical practice.

Several studies have investigated the role of Lincomycin in different clinical settings, demonstrating its efficacy in treating diabetic foot infections and reducing the risk of SSI and SSTI. A study conducted in 2013 in China focused on the prevention of central venous catheter infections in the ICU setting. The study randomized 172 patients with central venous catheters into trial and control groups. The trial group received

Table 2 — *Mean values for ESR, WBC, Hb*

Parameter		Mean	N	SD	P-Value
ESR (mm/hr)	BT	21.40	10	16.02	0.008
	AT	8.50	10	4.95	
WBC (million/mm^3)	BT	18388.57	35	4527.42	0.000
	AT	8974.29	35	2016.31	
Hb (g/dL)	BT	11.37	13	0.84	0.717
	AT	11.30	13	0.78	

BT : Before Treatment; AT : After Treatment

Lincomycin combined with heparin sodium, while the control group received normal saline and heparin sodium. The trial group showed significantly lower incidence rates of infection at 1-2 weeks (2.33%) and 2-3 weeks (5.81%) after catheterization compared to the control group (10.47% and 15.12%, respectively). The total incidence of infection was also significantly lower in the trial group (9.30%) compared to the control group (30.23%). The positive rate of blood culture was significantly lower in the trial group (12.50%) compared to the control group (53.85%). These findings highlight the efficacy of Lincomycin combined with heparin sodium in reducing central venous catheter infections[11].

Furthermore, a study involving 40 randomly allocated patients evaluated the effect of intra-abdominal lavage with an antibiotic solution containing Lincomycin and gentamicin in decreasing the risk of postoperative infections after colorectal cancer surgeries. Group 1 patients underwent lavage with normal saline followed by gentamicin-Lincomycin solution, while Group 2 patients underwent lavage with normal saline only. The study found a significant difference in the incidence of postoperative wound sepsis between the two groups, with a lower incidence in Group 1 (5%) compared to Group 2 (45%). The isolated organisms in Group 1 were Pseudomonas, while Group 2 had cases of *E coli*, Pseudomonas, Klebsiella and Enterobacter infections. These findings suggest that intra-abdominal lavage with Lincomycin and gentamicin may reduce the risk of postoperative infections in colorectal cancer surgeries[12].

These studies collectively support the efficacy of Lincomycin in preventing central venous catheter infections, treating diabetic foot infections and reducing postoperative infections in colorectal cancer surgeries. However, it is important to consider the specific study designs, patient populations and limitations of each study when interpreting the results. Further research and well-designed clinical trials are necessary to validate.

Like any other study, our research has certain limitations that should be acknowledged. The study design and methodology may have inherent limitations, such as the lack of a control group or a relatively small

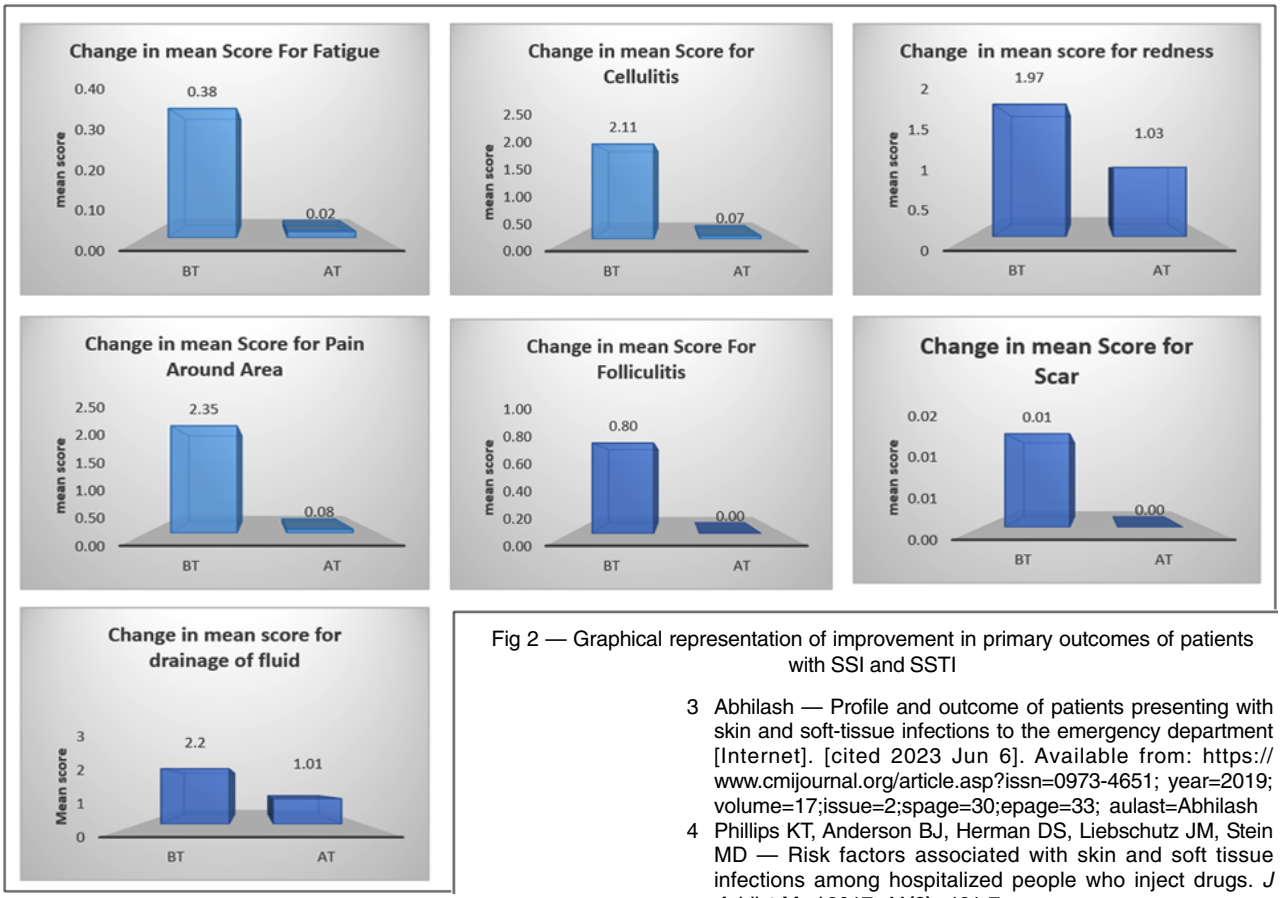

Fig 2 — Graphical representation of improvement in primary outcomes of patients with SSI and SSTI

sample size. Future research should focus on larger, well-designed studies to further investigate the effectiveness, tolerability and optimal dosage regimens of Lincomycin injection in various patient populations and indications.

Conclusion

In this real-world study, Lincomycin 600 mg injectables has shown to be effective and well-tolerated in the treatment of SSI and SSTI.

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

Acknowledgments : The authors thank all the study investigators, study coordinators and other study personnel who participated in the study, for their contributions.

Conflict of Interest : No

Fundings : The study and publication were financially supported by Wallace Pharmaceuticals Pvt Ltd.

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