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A Prospective cohort study on cellulitis in adult patients with analysis of the factors related to the response to treatment.

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Abstract

Background
The hallmarks of cellulitis include heated, red, and swollen purulent or non-purulent skin patches that can develop into more serious issues like sepsis and lymphedema. Cellulitis can strike anyone at any age, but it is more frequent in middle-aged and older people, with a small male preponderance.
Objectives- The goal of this research is to clarify the many factors that affect how well cellulitis treatments work.

Materials and methods
Patients with cellulitis diagnosed between May 2022 and April 2023 were the subjects of this prospective observational study, which was carried out at the Department of General Surgery, Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, India. The study included 100 individuals in total.

Results
Among 100 patients with cellulitis, factors such as age ≥65 years, diabetes, leg and foot location, and abscess formation were significantly associated with poor treatment response. Abscess formation showed the strongest association, with a nearly threefold higher risk (OR: 2.8, $p<0.05$). Imaging findings like venous insufficiency also predicted poor outcomes. The logistic regression model demonstrated good predictive accuracy with an AUC of 0.77.

Conclusion
The significance of a thorough strategy that takes into account patient demographics, co-morbidities, clinical characteristics, microbiological variables, and imaging results when customizing treatment for cellulitis is highlighted by this study. It emphasizes how important focused interventions are to enhancing treatment results, particularly for high-risk patients.

Recommendation
Multicenter studies with larger sample sizes are recommended to validate these findings and improve generalizability.

Keywords: *Cellulitis, treatment response, predictors, microbiological, logistic regression, imaging studies*.
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Introduction

A serious clinical and financial problem is cellulitis, an acute, spreading infection of the skin and subcutaneous tissues that is typically caused by bacteria [1, 2]. The hallmarks of cellulitis include heated, red, and swollen purulent or non-purulent skin patches that can develop into more serious issues like sepsis and lymphedema. Cellulitis can strike anyone at any age, but it is more frequent in middle-aged and older people, with a small male preponderance. Many risk factors for cellulitis in the elderly, including diabetes mellitus, obesity, cardiovascular co-morbidities, venous insufficiency, previous cellulitis episodes, and lymphedema, highlight the need for a better understanding of the illness, particularly about treatment response and recurrence [3, 4, 5, 6].

Despite routine antibiotic treatments, cellulitis has a significant recurrence rate, making therapy challenging. According to previously published research, relapse rates can reach 20% within a year of starting treatment, which frequently results in prolonged antibiotic treatment and high hospital readmission rates [7]. In addition to placing a strain on healthcare systems, its recurrent nature lowers quality of life and raises treatment expenses. The high probability of recurrence underscores the complexity of managing cellulitis, necessitating a multimodal approach to risk assessment and treatment. Prior cellulitis episodes, venous insufficiency, and immunosuppression are among the factors that have been independently linked to treatment response [8].

Clinicians can choose antibiotics, treatment durations, and preventative measures that are specific to high-risk patients. Additionally, early and precise evaluation of the infection's severity and its repercussions is crucial to cellulitis care. Doppler studies and other advanced imaging techniques are non-invasive diagnostic methods that can be useful in identifying underlying disorders such as venous insufficiency or abscess formation. These conditions are crucial in deciding on the best course of treatment and forecasting its results [9].

Healthcare practitioners can obtain a thorough grasp of the infection by combining clinical evaluation with various imaging methods, enabling individualized and successful treatment plans. The goal of this research is to clarify the many factors that affect how well cellulitis treatments work. We hope to contribute to the current understanding and aid in the creation of improved management protocols in the treatment of cellulitis by investigating the connections between demographics, clinical characteristics, co-morbidities, laboratory parameters, and advanced imaging findings.

Methodology

Study design

This was a prospective observational study conducted to assess the clinical outcomes and factors affecting treatment response in patients diagnosed with cellulitis.

Study setting

The study was carried out in the Department of General Surgery at Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar, India, a tertiary care teaching hospital that caters to a large population from both urban and rural regions of Bihar and neighboring states. The institute has specialized facilities for infectious diseases, surgical management, and microbiology diagnostics.

Study population

Overall, 100 participants were enrolled in the study. The inclusion criteria were patients ≥18 years of either gender diagnosed with cellulitis based on established clinical criteria of erythema, warmth, oedema, and localized tenderness with or without associated purulent collection, regardless of microbiological or radiological diagnostic procedure. The severity of cellulitis was assessed using the Eron classification [10].

Class I: no signs of systemic toxicity. No uncontrolled co-morbidity (e.g., diabetes mellitus).

Class II: systemically unwell or systemically well but with a comorbidity.

Class III: significant systemic upset (e.g., tachycardia, tachypnoea), unstable co-morbidities or limb-threatening infection due to vascular compromise.

Class IV: sepsis or severe life-threatening infection (e.g., development of necrotizing fasciitis).

Participants in the study were excluded if they were 18 years of age or younger, pregnant or nursing, immunocompromised (known or incidentally diagnosed with AIDS), intravenous drug users, immunosuppressant users, had a known allergy to antibiotics used in the treatment, had pre-existing skin conditions or infections that

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interfered with our treatment plan, or did not give their consent.

Sample size

The sample size of 100 patients was determined based on patient admissions for cellulitis at the institute over one year, ensuring a representative sample for statistical analysis. Convenience sampling was used due to the observational design of the study and the availability of eligible patients within the study timeframe.

Data collection

All participants gave their informed consent, and their privacy was protected. Our study carefully gathered the factors that affected the treatment's response, including demographics, co-morbidities, and clinical characteristics.

Study procedure

Every patient who was diagnosed with cellulitis clinically, microbiologically, or radiologically received therapy according to a predetermined regimen. All received intravenous amoxicillin and clavulanic acid as a usual initial monotherapy treatment, in addition to other symptomatic drugs and supportive measures, such as local wound care and limb elevation. The systemic antibiotics were changed in response to the "poor" response to the first antibiotic and the quick availability of the microbiological culture and sensitivity data. Depending on the amount of necrotic tissue and pus collected, local wound treatment could range from straightforward bandages to intensive surgical debridement. The partial or full clinical clearance of the erythema, warmth, oedema, and localized soreness, as well as the settling of systemic symptoms and disturbed hematological parameters without relapses or hospital readmissions within 30 days, were used to assess the response to treatment. "Poor" response was defined as recurrence or hospital readmission within 30 days, deterioration of clinical parameters, and failure to resolve physical symptoms. All of the patients were monitored for 30 days after being discharged. Imaging studies, such as ultrasound or MRI, were performed as clinically indicated to assess the extent of infection. Imaging findings were recorded and analyzed for their association with treatment response.

Bias

To minimize selection bias, strict inclusion and exclusion criteria were applied consistently throughout the study. Standardized treatment protocols were followed for all patients. Diagnostic confirmation involved clinical, microbiological, and radiological assessments where appropriate. Data collection procedures were standardized to reduce information bias.

Statistical analysis

A variety of statistical techniques are used to analyze the relationship between factors and "poor" responses. For statistical computations, SPSS v. 28 (IBM CORP., Armonk, NY, USA) was utilized. Statistical significance was defined as a p-value of less than 0.05. Demographics, comorbidities, and clinical aspects were summarized using mean, median, range, and frequencies. For categorical variables, univariate analysis (Chi-square or Fisher's exact test) was employed, and for continuous variables, an independent t-test or Mann-Whitney U test was utilized to evaluate their relationships with "poor" responses. To find independent predictors of a "poor" response while accounting for any confounding variables, multivariate analysis—such as logistic regression analysis—was carried out. Probability ratios and 95% CI were computed for every significant predictor.

Ethical considerations

The study was approved by the Institutional Ethics Committee of Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, India.

Results

After removing 33 patients who didn't fit the inclusion criteria, 100 participants in total were added to the research. People under 65 made up the majority of the study population (65%), with the remaining 35 (35% being 65 or older. There were 45 (45%) female participants and 55 (55%) male volunteers, making up the slight majority. Ninety-eight percent, or 98 people, were Indian. Table 1 presents the consolidated findings encompassing demographic data, co-morbidity profiles, and clinical features of the patients.

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Table 1: Demographics and predisposing factors of patients with cellulitis

Characteristic	Category	Frequency (n)	Percentage (%)
Demographics			
Age	< 65 years	65	65%
	≥ 65 years	35	35%
Gender	Male	55	55%
	Female	45	45%
Ethnicity	Indian	98	98%
	Other	02	2%
Education	No Formal Education	15	15%
Socioeconomic Status	Low	35	35%
	Middle	45	45%
	High	20	20%
Co-morbidities			
Diabetes	Present	40	40%
	Absent	60	60%
Cardiovascular Disease	Present	25	25%
	Absent	75	75%
Chronic Respiratory Disease	Present	12	12%
	Absent	88	88%
Chronic or acute renal disease	Present	0	0%
	Absent	100	100%
Immunosuppression	Present	5	5%
	Absent	95	95%

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Table 1b): Demographics and predisposing factors of patients with cellulitis

Characteristic	Category	Frequency(n)	Percentage(%)
Clinical Features			
Duration of Symptoms (days)	≤ 7 days	40	40%
	> 7 days	60	60%
Cellulitis Location	Leg and foot	75	75%
	Arm	20	20%
	Other	5	5%
Fever with Chills	Present	42	42%
	Absent	58	58%
Lymphangitis	Present	18	18%
	Absent	82	82%

For age-related treatment response, 43% of patients < 65 years had a 'poor' response, whereas this increased slightly to 49% in patients aged > 65 years. The p-value for age as a factor approached statistical significance a p-value of 0.045). The analysis of gender revealed that 45% of the male patients had a 'poor' response to treatment, compared to 55% of the female patients, although this difference was not statistically significant with a p-value of 0.121. Table 2 delineates the distribution of factors associated with 'poor' treatment response.

Table 2: Distribution of factors associated with 'poor' response (n=30)

Factor	Category	Poor Response	Good Response	p-value
Age	< 65 years	13 (43%)	52 (58%)	0.045
	≥ 65 years	17 (49%)	18 (51%)	
Gender	Male	15 (45%)	40 (65%)	0.121
	Female	15 (55%)	30 (67%)	
Diabetes	Present	18 (45%)	22 (55%)	0.032
	Absent	12 (30%)	48 (70%)	
Cellulitis Location	Leg and foot	25 (33%)	50 (67%)	0.018
	Others	5 (25%)	25 (75%)	
Fever	Present	22 (40%)	33 (60%)	0.452
	Absent	8 (44%)	17 (56%)	

Out of the 100 patients studied, abscess formation was observed in 20 (20%). A significant proportion of these patients with abscesses, 12 out of 20, showed a 'poor' response to treatment, equating to a 60% rate of 'poor' treatment outcomes within this group. The statistical analysis revealed that the presence of abscesses was a

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significant predictor of treatment response ($p<0.05$), with an Odds Ratio (OR) of 2.8 (95% CI: 1.3 - 5.9), indicating a nearly threefold increased risk of 'poor' treatment response.

Table 3 represents findings of imaging and their association with treatment response.

Table 3: Imaging study findings and their association with treatment response

Imaging Finding	Prevalence (N=100)	"poor" Response Frequency	'poor' Response Rate	Odds Ratio (OR)	95% Confidence Interval (CI)	p-value
Abscess Formation	20 (20% patients)	12 patients	60%	2.8	1.3 - 5.9	<0.05
Venous Insufficiency	15 (15% patients)	8 patients	55%	2.3	1.1 - 4.7	<0.05

Note: The Odds Ratios (OR) presented are crude odds ratios (COR) derived from univariate analysis.

The Receiver Operating Characteristic (ROC) Curve above displays the performance of the logistic regression model in classifying the treatment response. The curve plots the True Positive Rate against the False Positive Rate at various thresholds. The area under the curve (AUC) is 0.77, indicating a good model performance. An AUC of 1.0 represents a perfect model, while an AUC of 0.5 suggests no discriminative ability. Figure 1 depicts the ROC Curve, which shows a measure of the model's overall predictive accuracy.

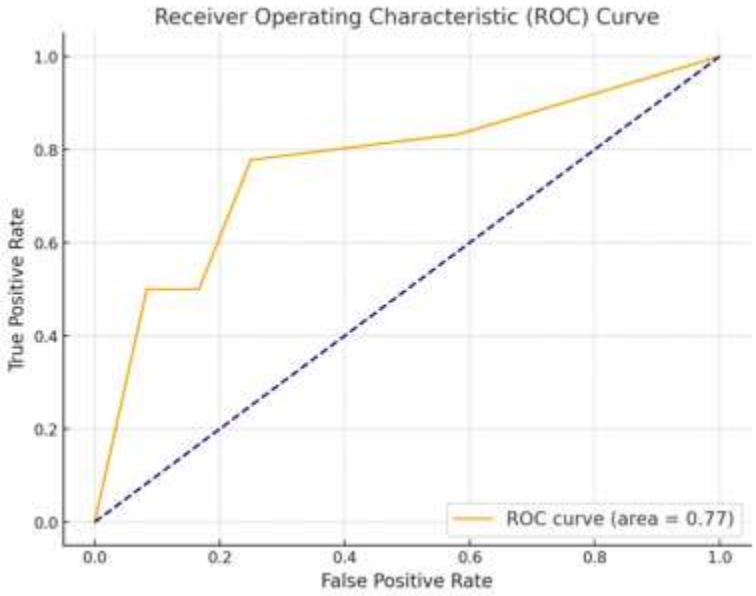

Figure 1. Receiver Operating Characteristic (ROC) Curve showing a measure of the model's overall predictive accuracy

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Discussion

The study provides important new information on the variables affecting how well adults with cellulitis respond to treatment. Age (≥65 years), diabetes mellitus, involvement of the legs and feet, later abscess formation, and chronic venous insufficiency were all found to be significant predictors of "poor" response by the logistic regression analysis. Each of these factors adds differently to the complexity of managing cellulitis. On the other hand, a strong response to treatment was linked to age <65 years, the absence of diabetes, the lack of systemic characteristics, or a shorter clinical presentation period of less than 7 days.

Thirty (30%) of the patients in the present study had "poor" responses, and every one of them had one or more risk factors. This is marginally higher than the 20.5% data from a previously published study on simple cellulitis [11]. Ten to twenty-one percent of adult cellulitis treatment failures have been reported in other comparable trials of poor predictors [12, 13, 14, 15].

It is generally believed that cellulitis arises as a result of a breach in the cutaneous barriers, which provides a point of entry for commensals or pathogenic bacteria to colonize in the deeper layers of the skin and subcutaneous tissue. Purulent or non-purulent cellulitis is the result of an intricate interplay between virulent bacterial components of adhesion, invasion, and toxin release and innate and adaptive host immunity [16, 17, 18].

Although the majority of the participants in this study were middle-aged, age—specifically, ≥65 years—came to light as a significant predictor of "poor" response to treatment for cellulitis, which is consistent with previous research [6,7].

Recurrent infections, lymphedema, and venous insufficiency all contributed to the advancing age. No independent analysis of the recurrence rate has been conducted. As a result, there were more "poor" response rates in the cohort of people over 65. Skin atrophy, decreased circulatory function, immunosenescence, and comorbid conditions like diabetes mellitus, congestive heart failure, or nutritional deficiencies are characteristics of the aging process. These conditions can lead to a state of relative immunosuppression, impaired wound healing, and decreased skin elasticity and structural integrity. Highlighting the necessity of increased watchfulness in this group [19].

As medical precision continues to grow, our study's findings support the idea that advanced analytics can be used to guide treatment plans. Still, the art of medicine cannot be replaced. Clinical expertise in analyzing model predictions, taking into account the unique histories of each patient, and incorporating thorough diagnostics, such as Doppler and ultrasonography, is still crucial.

Generalizability

The findings apply to similar tertiary care hospital settings but may not generalize to primary or community healthcare centers. Broader studies with diverse populations are needed for wider applicability.

Conclusion

The study emphasizes how important it is to treat cellulitis with a thorough and individualized strategy. The study's conclusions emphasize how important it is to take into account a variety of factors when developing treatment plans, such as patient demographics, comorbidities like diabetes mellitus, clinical characteristics, microbial profiles, and information from imaging tests like color Doppler and echography. Tailored treatment regimens are crucial, especially for high-risk groups including elderly persons and those with limb involvement or abscess formation. In order to improve patient care and recovery, this strategy seeks to address the urgent clinical demands and enhance overall treatment outcomes in the management of cellulitis.

Limitations

The study's main limitation was the small sample size, limited to one ethnicity, curbing its implementation to a large population. The prospective observational design identified the associations but could not confirm the causality of the proposed risk factors. Due to the diverse causative organisms responsible for cellulitis, no unified treatment strategies were implemented. There was an evaluation of responses to the same antibiotics. Despite logistic regression's ability to adjust for many variables, unmeasured confounding factors, particularly social and environmental, might still influence the results. Given the relatively small sample size, there's a risk of overfitting the predictive model, potentially compromising its performance on new data.

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Recommendations

To improve the accuracy and dependability of the model, future research should concentrate on growing the dataset, adding a greater variety of factors, and continuously improving the model. The objective of individualized care, in which treatment plans are customized to each patient's unique risks and requirements, will be a step closer thanks to such initiatives.

List of abbreviations

IGIMS- Indira Gandhi Institute of Medical Sciences
AIDS- Acquired Immune-Deficiency Syndrome
CI- Confidence Interval
AUC- Area under the curve
ROC- Receiver Operating Characteristic

Recommendations

Larger, multicenter studies with extended follow-up periods are suggested to validate these findings and explore long-term outcomes.

Acknowledgement

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Conflict of interest

The authors declare no conflict of interest related to this study.

Source of funding

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Data availability

The data generated and analyzed during this study are available from the corresponding author upon reasonable request.

Author biography

All authors are affiliated with the Department of General Surgery, IGIMS, Patna. Their clinical and research expertise focuses on surgical infections and related interventions.

Author contributions

All authors contributed equally to the study design, data collection, analysis, and manuscript preparation. All authors approved the final manuscript.

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