Section A-Research paper

THERAPEUTICAL AND OPERATIONAL FACTORS INFLUENCING THE DURATION OF ANTIBIOTIC TREATMENT IN CELLULITIS PATIENTS

Pranyini D[1], Prissilla Merlin S[1], Rakshana S[1], Sandhya A M[1], P Geetha*

1- Pharm.D Intern, Department of Pharmacy Practice, School of Pharmaceutical Sciences, Vels Institute of Science Technology and Advanced Studies (VISTAS), Chennai, Tamil Nadu, India – 600117.

*- Associate professor, Department of Pharmacy Practice, School of Pharmaceutical Sciences, Vels Institute of Science Technology and Advanced Studies (VISTAS), Chennai, Tamil Nadu, India – 600117.

*Corresponding author: Dr. P Geetha ,

Associate professor, Department of Pharmacy Practice, School of Pharmaceutical Sciences, Vels Institute of Science Technology and Advanced Studies (VISTAS)

Contact : +91 9940460178

Email ID : lgeethapharma@gmail.com

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ABSTRACT:

Objective: Cellulitis is one of the most common skin and soft tissue bacterial infection which is a frequent cause of hospitalisation in adults. This increasing prevalence paved way for the study to primarily aim and assess the predisposing therapeutical and operational factors influencing the duration of antibiotic treatment regimen.

Method: Prospective and observational study of 76 patients with cellulitis in their lower extremities admitted in government oriented tertiary care hospital. Patient demographics, social habits, comorbidities, complications, disease severity assessment through visual analogue scale, supportive laboratory and diagnostic parameters and treatment regimen were recorded with respect to hospital stay and analysed for their correlation in influencing treatment duration through SPSS software version 23.

Results: Majority of the patients about 42.1% fell under 46-60 years of age category. There were 59.22% of patients with prolonged length of hospital stay receiving longer duration of treatment. The median value of number of days of hospitalisation was calculated to be 7 days with 3 to 10 as interquartile range. Age, CRP, ESR, neutrophils, type of wound, previous history of cellulitis, smoking along with comorbidity like diabetes and complications as DVT, Venous insufficiency were the variables independently significant with p value less than 0.05 with confidence interval of 95 %.

Conclusion: The variables with significant p value showed association between treatment duration. Factors like antimicrobial medication choice, gender, causative micro organism showed negative response indicating no role in influence with treatment duration.

Key Words: therapeutical factors, operational factors, cellulitis, antibiotic treatment, Skin and soft tissue infections

INTRODUCTION:

Cellulitis is one among the commonest bacterial skin or flesh infections seen among people, emerging as a vital reason for hospital admission which paves way to financial and medical tribulation[1]. It occurs due to a breach in skin like cut fissure, broken, dry/flaky skin, surgical cuts, puncture wounds, ulcers, dermatitis, insect bites, and athlete's foot, which opens the way for microorganisms to enter the dermis and proliferate causing cellulitis. This is more prevalent as it is recurrent and the treatment is usually complicated. Mostly, cellulitis is treated with antibiotics, minor cellulitis can be treated with oral antibiotics at home, monitored by a close-linked physician whereas severe cases need hospital stay with IV Antibiotics after which oral therapy would be initiated if there's any improvement. There are many factors which would heighten or shorten the duration of antibiotic therapy for both oral and IV medications. Hospitalised patients are usually treated with antibiotics for 5 to 14 days, which is the recommended time duration[2]. Usually cellulitis is prevalent in the lower locus of the limbs but it can occur anywhere, including the eyes. Generally all the patients would be treated for Staphylococcus aureus bacteria, but it is to be noted that Methicillin-resistant Staphylococcus aureus and other bacterias are becoming prevalent[3]. The treatment can be complicated in such cases when no proper diagnosing is available and this might increase the financial burden on the patients. Additionally, cellulitis being recurrent, has further increased the healthcare expenses due to constant readmission, making it difficult economically for poor people. The treatment is further complicated among geriatrics, who have poor treatment response when compared to the adults and among patients with other comorbidities who tend to take multiple medications which might interfere with the antibiotic regimen. Therefore, it is vital to know about all the factors that can lead to substandard treatment and poor patient compliance associated with longer duration of antibiotic usage to prevent recurrence and provide beneficial treatment to the patients. Hence it is essential to select a proper antibiotic that treats the patient fast, economically beneficial and prevents further complications in the patient. For which, it is essential to analyse the therapeutic and operational factors that influence the antibiotic treatment duration in cellulitis patients. Cellulitis is a challenging clinical entity. Overutilization and underutilization of antibiotics happens more often in many cases due to many reasons and various diseases mimic the confirmation of cellulitis which delays the commencing of treatment[4]. Also, different types of antibiotics are used to treat cellulitis and are specific to each person. There are many formulations that are prevalent in the community and so proper choice of antibiotic selection is must for better patient compliance. Our study help identify people who require extended or shorter duration of antibiotic therapy which will assist in better formulation of medical review. The primary outcome of the study was to identify the proportion of patients cured, improved, recovered or symptoms freed/ reduced efficiently for the given duration of treatment . The study aimed to address the various factors influencing the duration and effectiveness of cellulitis treatment regimen to optimize the future management strategies[5].

METHODOLOGY:

This research is a prospective type of investigation that's carried out in a government sector tertiary health care Hospital located in Chennai, India.

Patients Selection : The research focused on individuals above 18 years of age and have been given a diagnosis of cellulitis. A total of 76 patients with cellulitis affecting their lower extremities were chosen as subjects for the study. The study incorporated patients who were treated with antibiotics administered both intravenously and orally. Patients who have either been recently diagnosed with cellulitis or had a history of being diagnosed with cellulitis at some point in the past were considered for inclusion in the study. The study considered only those patients who had provided their consent for participation in the research analysis. The study exclusively enrolled individuals with lower extremity cellulitis as the subjects. Only hospitalised patients were included in the study. Patients who declined to participate in the study, patients who have undergone previous surgeries involving implants or plates, patients with particular drug sensitivities, patients with communicable skin diseases, as well as patients advised to have surgery for cellulitis, individuals with psychological issues, TB, cancer, and those with compromised immune systems were not included in the study. Patients with other extremities were not included in the study. It was essential of all patients who participated in the trial that they fill out an informed consent form so that they may provide their consent for the experiment.

Approval : The study was approved by Vels Institute of Science Technology and Advanced Studies' Institutional Ethical Committee: TN/2018/RR-21/012.

Monitoring parameters and study method: The Infectious Diseases Society of America and the U.S. Food and Drug Administration's criteria of cellulitis for clinical trials was used to diagnose a case: Cellulitis is a broad word for an inflammatory condition that may or may not cause pain and suggests infection by describing the warmth, erythema, and induration of the skin and/or subcutaneous tissue. General examinations like pain, erythema, edema were noted using a likert scaling Visual Analogue Scale(VAS) self - developed and validated, whereas warmth, tenderness, temperature were noted along with laboratory parameters such as C reactive protein (CRP), erythrocyte sedimentation rate (ESR), white blood cells count (WBC), Neutrophils and lymphocytes. These variables were ordered as initial clinical laboratory tests for confirming the diagnosis of cellulitis. It is important to note that the ESR, CRP, and WBC levels were collected 3 times as in, during the admission, after 48 hours, and at the time of discharge for extended diagnosis and marked treatment in order to determine the factors affecting treatment duration. Patients who presented with high fever, marked swelling, redness, malaise, and high pain were advised to be hospitalised after the severity of their cellulitis was evaluated. Patients who elicited negative response to initial empirical treatment were advised for wound culture sensitivity, and definitive treatment with antibiotics after the finding of causative organism was administered. The following parameters were assessed such as demographic details including age and gender, presence of comorbidities like Diabetes Mellitus (DM), peripheral vascular disease of the lower extremities, previous history of cellulitis along with social habits and occupation were noted. The presence of a portal of entry of microorganisms in skin such as via abscess, skin ulcers, blisters, necrosis, insect bites, surgical wounds, non surgical trauma wounds were noted. Antibiotic treatment through both IV and oral means were monitored, and follow-up care was administered in a

timely manner. The pathophysiology of the disease and the disease's hypothesised association with the total number of days spent in the hospital served as the basis for the selection of the variables.

Statistical Analysis: In the descriptive analysis, categorical variables were reported as frequency percentages, whilst continuous variables were presented as either means and standard deviations.The length of a patient's stay in the hospital was used to categorise them into one of two categories: either a short stay (defined as less than five days) or a lengthy stay (defined as more than six days). In bivariate analysis, the correlation between categorical variables were examined using the Pearsons chi square test and the two tailed p value was considered significant if <0.05 with 95% confidence interval. Statistically significant variables that describe various parameters related to prolonged length of stay were used to create a logistic regression model with estimated odds ratio employing a stepwise data entry approach. Data analysis was made by use of the SPSS version 23 software.

RESULTS:

76 individuals with lower extremity cellulitis were admitted to the hospital throughout the study period. A patient's stay lasted for three days at the shortest and up to ten days at the longest. Patients' length of stay was divided into two categories: ≤ 5 days and > 6 days. The duration of the IV antibiotic therapy for each group is represented by the length of stay (LOS). A protracted hospital stay was experienced by 59.22% of the patients, who received care for more than six days. The characteristics of the patients are shown in Table 1, which examines the factors that could influence the course of the antibiotic therapy. About 42.1% of patients admitted to hospitals were in the 46–60 age range, which is a notably higher percentage. Although more male patients were admitted at the longer LOS, there were no statistically significant correlation found in terms of patient gender and hospitalisation days. In the group of patients admitted to the hospital, 64.47% had a new diagnosis, and 35.52% had recurred conditions, with a p value of 0.015 in the 95% confidence interval indicating shorter hospital stays in recurrent patients. As shown in table 1, factors such as age, smoking, deep vein thrombosis, diabetes, and venous insufficiency contributed to patients' treatment lengthening.

About 38.2% of patients received Cefeperazone + Sulbactum 1.5g dose combination as a prescription in majority, compared to 2.6% who received Ciprofloxacin 200 mg and Metronidazole 500mg intravenous antibiotic. Cefaperazone + sulbactum 1.5g (48.9%) & Piperacillin + Tazobactum 4.5g (31.1%) serves to be the physician choice of antibiotics for prolonged LOS patients. According to the infectious diseases society of America's (IDSA) recommendations for oral antibiotics, 30.3% of patients received Linezolid 600 mg following IV treatment, while 3.9% of patients received no medication advice (Table 2). As many factors underlying the hospital admission, the presence of complication was significantly more frequent in patients with increased length of stay with chi square test pearson’s significancy of 0.023 with 95% Confidence interval (CI). The complications enlisted in Table 3 elicits the identification of portal entry for microorganism. Blisters (19.7%), Skin ulcer (19.7%), Non-surgical trauma (19.7%) and Insect bite (17.1%) is noted to be prevalent among the patients.

For the purpose of determining the severity of the condition, a self-developed and validated visual analogue scale (VAS) of pain, erythema, and edema was used. The edema scoring of 0-4, 0 indicates no swelling at it’s minimum wheras 4 indicates severe swelling at

it's maximum, pain scoring of (0-5), 0 is no pain whereas 5 illustrates severe pain, erythema scoring of (0-4), 0 depicts no redness whereas 4 illustrates severe hyperpigmentation/ discoloration of the skin. The likert scaling technique was used to represent. The length of therapy and patients' LOS were significantly influenced by the severity of the condition. The more the score, the greater the LOS. In relation to hospital stay, the frequency distribution and pearson's chi square significance scoring of the VAS are displayed in table 4 respectively. Among 76 patients, 16 who did not respond to the initial empirical therapy had a wound/pus culture sensitivity test, and the cultures were positive. Figure 1 shows the microorganisms that were cultured. Of the 16 patients, Staphylococcus aureus is suspected in 50% of cases as the cause of infection.

Clinical factors (Table 5) as in CRP levels ($p = 0.001$), ESR levels ($p = 0.002$), neutrophils ($p = 0.010$) and lymphocytes ($p = 0.001$),indicates the presence of infection and inflammation in a patient, that is associated with hospital LOS and treatment duration among the factors that are found to be predictive for long duration of treatment in our study. The estimation of the logistic regression (Table 6) model paved the way for the findings of patient age ($p = 0.003$), smoking ($p = 0.022$), previous history of cellulitis ($p = 0.009$), WBC levels ($p = 0.044$), lymphocytes value ($p = 0.005$), CRP ($p = 0.028$), type of wound ($p = 0.02$) specifically blisters, insect bites, and skin ulcers as factors associated with prolonged antibiotic therapy with increased days of hospitalisation. The patients were enquired for the type of occupation and recorded. Among the patients admitted, 30% spent their time standing for extended periods of time (security, clerks, machine operators, etc.), whereas 12% worked in hot environments (welders, chemical engineers, factory workers, etc.). Figure 2 highlights the occupational factors that could be associated with etiological factor for disease development.

Table 1 : Patient Characteristics influencing days of hospitalisation & treatment

CHARACTERISTICS		**General (N=76)**	**≤ 5 Days (LOS) (N = 31)**	**>6 days (LOS) (N=45)**	**P value**
Age	**18 – 29**	7 (9.2%)	4 (12.9%)	3 (6.6%)	0.005
	30 – 45	18 (23.68%)	9 (29.03%)	9 (20%)	
	46 – 60	32 (42.1%)	11 (35.48%)	21 (46.6%)	
	Above 60	19 (25%)	7 (22.58%)	12 (26.6%)	
Gender	**Male**	46 (60.52%)	18 (58.06%)	28 (62.22%)	0.716
	Female	30(39.47%)	13 (41.94%)	17 (37.78%)	
BMI	**Low**	1 (1.31%)	1 (3.2%)	0	0.659
	Normal	39 (51.31%)	15 (48.38%)	24 (53.33%)	
	Overweight	20 (26.31%)	8 (25.81%)	12 (26.66%)	
	Obese	16 (21.05%)	7 (22.58%)	9 (20%)	
Diabetes (Yes)		49 (64.47%)	16 (51.61%)	33 (73.33%)	0.042
Venous Insufficiency (Yes)		8 (10.52%)	0	8 (17.78%)	0.001
Varicose veins (Yes)		16 (21.05%)	7 (22.58%)	9 (20%)	0.786
Deep vein Thrombosis (Yes)		3 (3.94%)	3 (6.67%)	0	0.033
Smoking (Yes)		30 (39.47%)	8 (25.81%)	22 (48.89%)	0.045
Recurrent Diagnosis		27 (35.52%)	16 (51.61%)	11 (24.44%)	0.015

BMI – Body mass index, Data are N (%) unless otherwise stated, p value – chi square pearsons significancy.

Table 2: Antibiotic treatment regimen utilization

ANTIBIOTICS	GENERAL (n=76)	≤5 DAYS (n=31)	>6 DAYS (n=45)
IV ANTIBIOTICS			
Augmentin 650mg	4(5.3%)	1(3.2%)	3(6.7%)
Cefaperazone+Sulbactum 1.5g	29(38.2%)	7(22.6%)	22(48.9%)
Cefotaxime 1g	10(13.2%)	6(19.4%)	4(8.9%)
Ciprofloxacin 200mg	2(2.6%)	2(6.5%)	0
Metronidazole 500mg	2(2.6%)	2(6.5%)	0
Piperacillin + tazobactum 4.5g	24(31.6%)	10(32.3%)	14(31.1%)
Ceftriaxone 1g	5(6.6%)	3(9.7%)	2(4.4%)
ORAL ANTIBIOTICS			
Cefalexin 500mg	14(18.4%)	8(25.8%)	6(13.3%)
Cefixime 200mg	10(13.2%)	6(19.4%)	4(8.9%)
Linezolid 600mg	23(30.3%)	7(22.6%)	16(35.6%)
Metronidazole 400mg	26(34.2%)	7(22.6%)	19(42.2%)
None	3(3.9%)	3(3.9%)	0

Augmentin 650 mg (Amoxycillin + clavulanic acid), Flagyl 500 mg (Metronidazole), 4.5g Piperacillin + tazobactum, 400 mg Metronidazole. Data are N (%) unless otherwise stated.

Table 3 : Types of wounds / Complications contributing to the LOS & Treatment duration

Type of wounds / complications		LOS (Days)		Total (n=76)
		≤5 (n=31)	>6 (n=45)	
Abscess	**Count**	2	8	10
	% within days of stay	6.5%	17.8%	13.2%
Blisters	**Count**	3	12	15
	% within days of stay	9.7%	26.7%	19.7%
Insect bite	**Count**	7	6	13
	% within days of stay	22.6%	13.3%	17.1%
Necrosis	**Count**	0	1	1
	% within days of stay	0%	2.2%	1.3%
Non-surgical	**Count**	9	6	15
	% within days of stay	29.0%	13.3%	19.7%
None	**Count**	4	0	4
	% within days of stay	12.9%	.0%	5.3%
Skin ulcer	**Count**	6	9	15
	% within days of stay	19.4%	20.0%	19.7%
Surgical wound	**Count**	0	3	3
	% within days of stay	0%	6.7%	3.9%

Non - surgical wounds represent the wound from physical trauma & surgical wound represents wound from varicose veins surgery, Data are N (%) unless otherwise stated.

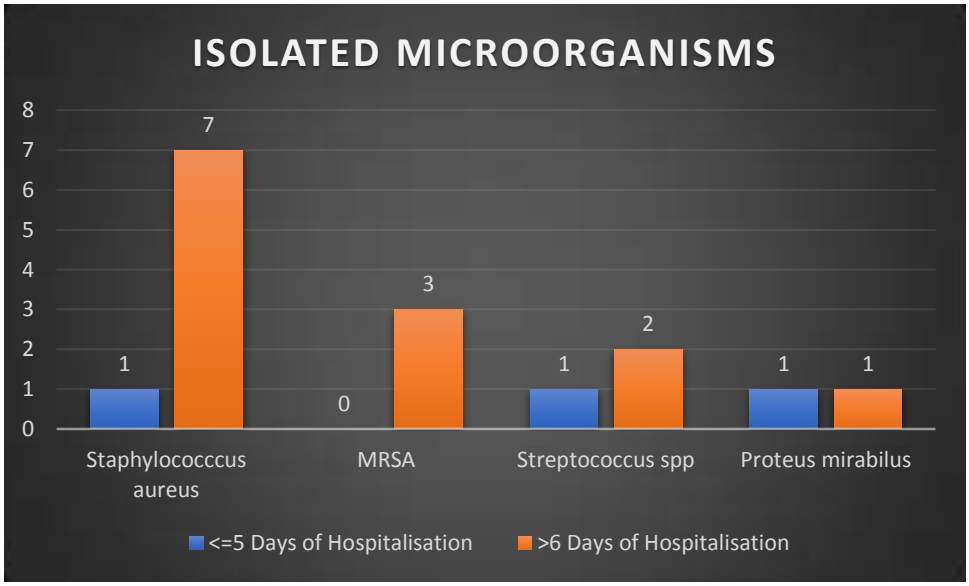
Table 4 : Severity of the disease influencing the treatment of antibiotic and LOS.

Disease severity (symptoms)		Days of stay		P VALUE
EDEMA		**≤ 5**	**>6**	
2	**Count**	12	4	0.001
	% within days of stay	38.7%	8.9%	
	% of Total	15.8%	5.3%	
3	**Count**	18	29	

	% within days of stay	58.1%	64.4%	
	% of Total	23.7%	38.2%	
4	**Count**	1	12	
	% within days of stay	3.2%	26.7%	
	% of Total	1.3%	15.8%	
PAIN				
2	**Count**	4	0	
	% within days of stay	12.9%	.0%	
3	**Count**	12	4	
	% within days of stay	38.7%	8.9%	0.000
4	**Count**	13	23	
	% within days of stay	41.9%	51.1%	
5	**Count**	2	18	
	% within days of stay	6.5%	40.0%	
ERYTHEMA				
1	**Count**	1	0	
	% within days of stay	3.3%	.0%	
2	**Count**	16	7	
	% within days of stay	53.3%	15.6%	0.002
3	**Count**	9	27	
	% within days of stay	30.0%	60.0%	
4	**Count**	4	11	
	% within days of stay	13.3%	24.4%	

Disease Severity scoring is self prepared Likert scaling visual analogue scale. Datas are N (%) unless stated, p value is chi square pearsons significancy with 95% Confidence interval.

Figure 1 Wound / Pus culture sensitivity – Isolated microorgnaisms



MRSA – Methicillin Resistant Staphylococcus aureus, Data represented as N unless otherwise stated.

Table 5 : Clinical factors that influences the antibiotic treatment duration & LOS

LAB PARAMETERS	≤5 DAYS	>6 DAYS	P VALUE
CRP	43.15(19.058)	32.61(10.201)	0.001
ESR	6.67(5.231)	10.29(5.194)	0.002
WBC	11967.74 (976.52)	13473.33(3005.7)	0.058
NEUTROPHILS	77.83 (8.285)	78.14(10.731)	0.010
LYMPHOCYTES	21.13(4.425)	23.89(5.360)	0.001

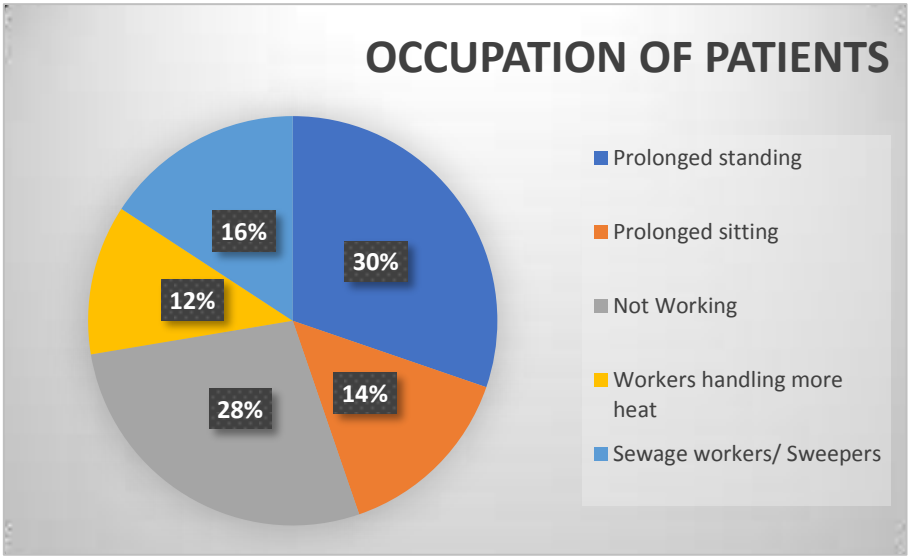
CRP – C reactive protein, ESR – Erythrocyte sedimentation rate, WBC – White bloodcell count. Data are Mean ± SD unless otherwise stated, p value is chi square pearson significancy with 95 % Confidence interval.

Table 6 : Logistic regression of factors that influences LOS

VARIABLES	ESTIMATED ODDS RATIO (95%CI)	p VALUE
Age	1.02(1.01-1.04)	0.003
Smoking	0.210(0.55-0.79)	0.022
Previous History of cellulitis	0.227(0.075-0.693)	0.009
WBC	1.000(1.000-1.001)	0.044
Lymphocytes	1.154(1.018-1.309)	0.025
CRP	0.942(0.894-0.994)	0.028
Diabetes Mellitus	0.167(0.048-0.585)	0.005
Type Of Wound	0.333(1.235-15.206)	0.022

CRP – C Reactive protein, Datas are represented as Logistic regression odds ratio and p value significancy with 95 % Confidence interval.

Figure 2: Occupational factors associated with Disease development



Datas are represented in pie chart as N% unless otherwise stated.

DISCUSSION:

Inspired by a few international studies carried out all over the world, this prospective study was carried out in a government-oriented tertiary care centre. The study emphasises the impact of therapeutic and operational factors on the length of time patients with cellulitis receive antibiotic therapy. The duration of the patient's hospitalisation, or length of stay (LOS), reflects the amount of time that IV and oral antibiotics were given to them. Reducing the overall length of hospitalisation was the study's goal in order to provide the best possible treatment for the patients and enhance their quality of life. Monitoring the elements that have a significant impact on extended satiety might help achieve this. Antibiotic treatment duration evaluations can lower the incidence of adverse effects and antimicrobial medication resistance in people. Despite the lack of a perfect regimen, it is required to develop a therapeutical protocol or regimen based on the severity of the disease, the presence of comorbidities, the availability of drugs and diagnostic features, and the patient's financial situation in order to rationally justify the antibiotic treatment regimen.

The enrolled patients were divided into two groups depending on their LOS, which was defined as 5 days and > 6 days. We found that the median length of IV antibiotic therapy was 7 days, with an interquartile range of 3 to 10 days. Therapeutic variables like CRP, ESR, WBC, lymphocytes, neutrophils, comorbidities (such as diabetes), and complications like varicose veins, venous insufficiency, and deep vein thrombosis affect the length of treatment. In addition to the aforementioned, longer treatment times may result from greater treatment costs, the need for more diagnostic testing, invasive surgical debridement, and the risk of non-socomial infection.

Many additional research have looked at other characteristic mimics with regard to the length of stay in patients with cellulitis in the wake of our findings. Similar to a research by Makoto Inaoki et al. with 102 cellulitis patients, the findings of our study showed that age, CRP, and diabetes mellitus as comorbidity were independently connected with the longer treatment duration[6]. Another previously completed study confirms our finding that patient

age strongly correlates with treatment length, with the majority of patients requiring longer stays falling within the 46–60 age range[5,6]. This underlines the possibility that aging-related decline in bodily function might cause cellulitis wound healing to proceed more slowly[7]. Similar to how it works as a major direct or indirect predisposing factor for extended treatment duration, C Reactive Protein and its relationship with prolonged hospitalisation in several research, including ours, say as much[11].

In this study, factors like edema, erythema, and pain that indicate the severity of the illness were also proportionately significant in relation to prolonged hospitalisation. These findings are similar to those of a study by Morpeth SC et al. on 51 patients with lower limb cellulitis that showed factors like the degree of edema and neutrophils were associated with prolonged LOS[2]. In line with a few other research, our study also took comorbid conditions like diabetes into consideration[7,8] and found that patients with diabetes had longer antibiotic treatment courses owing to their impaired ability to recover. Due to altered immunological pathology and altered phagocytic function linked to hyperglycemia, diabetic patients are also more vulnerable to increased bacterial infection severity, which may interrupt the healing process and lead to longer stays in the hospital[9]. Our study also showed that the estimated odds ratio calculated for the type of wound complications correlated with the length of stay elicits independent significance in influencing the treatment duration similar to a study conducted in Spain during 2018[10].

Only 16 of the 76 patients had a poor response to the first empirical treatment, and it was required that they undergo antimicrobial and wound culture sensitivity testing. A few microbes were found in the test, which was positive. The majority of the patients who underwent testing have Staphylococcus aureus. However, there was no discernible relationship between the examined organisms and the length of the patients' antibiotic treatments in our research[6].

The length of therapy was not only influenced by the therapeutic considerations outlined above; several operational factors also played a part. Our research focused on patient age, gender, type of profession, and social habits with regard to hospitalisation days since no prior study had clearly examined operational elements that may affect treatment. As far as age and social habits like smoking were concerned, they showed a modest slowdown in the wound healing process, which indirectly affected the length of the therapy. The study's discussion of the various occupations focuses on the work environment, the nature of the task, and the length of time that employees spend working consistently, all of which may be indirect etiological factors for the development of the illness and its recurrence in patients. Other than the above-mentioned factors, the study also emphasises physicians majority choice of drug and its role in therapeutical progression of the disease, which may also influence the duration of drug therapy with respect to an individual’s pharmacokinetic and pharmacodynamic characteristics. Other individual factors, such as patient understanding of the illness, changes in lifestyle related to disease prevention and treatment, the importance of medication adherence, and the completion of an antibiotic course, may also have a direct or indirect impact on the length of therapy in a patient[8].

Our research has certain limitations, much like previous studies. The trial was conducted among a relatively small population, and the study also only targeted carrying out the definitive treatment among the few patients with culture sensitivity that play a significant role

in treatment management in cellulitis patients. The study also lacked unified antibiotic treatment regimen, to assess the responses to the same medication. To track the variables that affect the length of therapy for cellulitis patients, the research needs a large population with more specific therapeutical characteristics.

CONCLUSION:

With this study we identified that factors such as age of the patients, CRP levels, comorbid conditions such as Diabetes mellitus, smoking habit, prior hospitalization for cellulitis, laboratory parameters-WBC, lymphocytes and type of wound was independently associated with duration of antibiotic treatment for cellulitis. These results have paved way towards construction of effective and rationalised regimen in the treatment of cellulitis. We believe that our study would help both physicians and clinical pharmacists in better understanding of factors to be considered during antibiotic treatment in cellulitis patient. This could also aid in counselling the cellulitis patient with their presenting factors on the longer duration of antibiotic therapy.

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