



Therapeutic Management of Severe Infection in Patients with Diabetes Mellitus in Tertiary Care Hospitals - A Prospective Observational Study

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ABSTRACT

Diabetes mellitus (DM) is a chronic metabolic disorder characterised by hyperglycemia and associated immune dysfunction, increasing susceptibility to severe infections. Effective management of infections in diabetic patients is crucial to reducing morbidity and improving clinical outcomes. This prospective observational study was conducted in tertiary care hospitals to evaluate the therapeutic management of severe infections in patients with diabetes. A total of 154 patients were included, with females slightly more than males. The findings revealed a high prevalence of infections among older age groups. A total of 317 antimicrobial agents were prescribed, indicating frequent use of combination and broad-spectrum therapies. Commonly prescribed antibiotics included azithromycin, ceftriaxone, and cefoperazone-sulbactam. While many prescriptions aligned with standard guidelines, variations were observed, emphasising the need for improved antimicrobial stewardship. The study highlights the importance of individualised, evidence-based therapeutic strategies in managing infections in diabetic patients. Incorporating antimicrobial stewardship practices, regular monitoring, and interdisciplinary collaboration can significantly enhance treatment outcomes. This research provides valuable insights into current prescribing patterns and supports the development of standardised protocols to optimise infection management and reduce infection-related complications in diabetic patients.

Keywords: Diabetes Mellitus, Severe infections, Standard Antibiotic Guideline, Empirical Antibiotic Utilisation, Drug Utilisation review, Prospective Observational Study

INTRODUCTION

Diabetes mellitus is a clinical condition characterised by inadequate insulin secretion or impaired insulin action. It is recognised as one of the most significant emerging health challenges of the 21st century. Beyond its well-known complications, Diabetes has been linked to impaired immune responses, including diminished T cell activity, compromised neutrophil function, and abnormalities in humoral immunity. As a result, individuals with Diabetes are more prone to infections, ranging from common infections to rare ones that predominantly affect diabetic patients, such as rhinocerebral mucormycosis. These infections not only pose direct health risks but can also exacerbate diabetic complications like hypoglycemia and diabetic ketoacidosis ^[1].

Diabetes mellitus is a heterogeneous metabolic disorder classified into type 1, type 2, Gestational diabetes mellitus, and other specific forms. Type 1 diabetes is characterised by autoimmune destruction of pancreatic β -cells leading to absolute insulin deficiency, while type 2 diabetes, the most common form, involves insulin resistance and progressive β -cell dysfunction. Other specific types arise from genetic defects, pancreatic diseases, or drug-induced causes, whereas gestational diabetes mellitus is identified during pregnancy. ^[2]

Insulin resistance and hyperglycemia are central to the pathogenesis of diabetes. Normally, insulin facilitates glucose uptake into cells; however, impaired insulin secretion or action leads to persistent hyperglycemia, resulting in long-term organ damage. Inflammatory mediators such as TNF- α , IL-6, and metabolic stressors, including free fatty acids and reactive oxygen species, disrupt insulin signalling pathways, contributing to disease progression. ^[3]

Chronic hyperglycemia significantly increases susceptibility to infections by impairing immune function. It reduces cytokine production, leukocyte recruitment, and pathogen recognition. Neutrophil and macrophage dysfunction further impair phagocytosis and microbial killing, while natural killer cell activity and complement pathways are also compromised. ^[3] The mechanism of action of antihyperglycemic drugs differs, and each has a unique mechanism of action. ^[4]



The pathophysiology of infections in diabetes involves defects in both innate and adaptive immunity. Hyperglycemia alters polymorphonuclear leukocyte function, reduces ATP levels, and promotes apoptosis, leading to decreased microbial clearance. Advanced glycation end products further impair immune responses. Additionally, reduced antibody function and impaired T-cell responses contribute to increased infection severity. [5] The Management and Aetiology of Pneumonia and Tuberculosis [6] & not only that, First line agents for Types of Urinary tract infection [5], Diabetic Limb/Foot Infection [5], Treatment regime for Eye infection [7], Antibiotic for Gastric Infection [8].

The study aims to evaluate the therapeutic management of severe infection in diabetic patients who are admitted to tertiary care hospitals. The primary objective of this study is to evaluate the therapeutic management of diabetic patients diagnosed with severe infection, along with checking the compliance with standard guidelines in the therapeutic management of diabetic patients with severe infection and carrying out drug utilisation review of diabetic patients with severe infection.

MATERIALS AND METHODS

1. Site of Study:

A study was conducted over 5 months (August-December 2025) at BAPS Pramukh Swami Hospital, Surat, and Smt. Rasilaben Shah Venus Hospital, Surat.

2. Study Design:

Multicentric Hospital-based Prospective Observational Study.

3. Study Criteria:

a. Inclusion Criteria:

- Patient's Age 18 years or above.
- Patients diagnosed with Diabetes Mellitus.
- Diabetic patients with confirmed or suspected Infection requiring antimicrobial treatment.
- Patients willing to sign an informed consent form.

b. Exclusion Criteria:

- Paediatric Population.
- Pregnant and Lactating Population.
- Patients who are not willing to sign informed consent forms.

4. Approval from the Ethics Committee:

The study was conducted after the approval of the Protocol by the Institutional Ethics Committee.

5. Data collection:

Suitable data was collected using a Case Report Form that was prepared for the study. Data collection was,

- IP number
- Patient demographics: Age, Gender
- Provisional and Final diagnosis



- Lab Parameters
- Specific tests
- Prescribed Drugs
- Concomitant Drugs

6. Follow up:

Appropriate follow-up was taken for all patients to the end of their therapy.

RESULTS & DISCUSSION

Demographic Data of Patients

Table 1: Demographic Data of Patients

(N = Number of Patients, % = Percentage of total number of patients)

Variables		Analysis	
Gender:	Male, N (%)	73 (47.40%)	Total Patient: 154
	Female, N (%)	81 (52.6%)	
Age Group:	35-40, N (%)	3 (1.95%)	
	41-50, N (%)	21 (13.64%)	
	51-60, N (%)	37 (24.02%)	
	61-70, N (%)	36 (23.37%)	
	71-80, N (%)	44 (28.57%)	
	81-90, N (%)	12 (7.79%)	
	91-95, N (%)	1 (0.65%)	
Total Antibiotics Prescribed:		317	

Prescription of Antihyperglycemic Drugs to Patients

Table 2 Antihyperglycemic Drugs Prescribed to Patients

No.	Antihyperglycemic Drugs	No. of Prescription
1.	Metformin	118 (49.16%)
2.	Glimepiride	56 (23.34%)
3.	Pioglitazone	10 (4.16%)
4.	Dapaglitazone	5 (2.08%)
5.	Empagliflozin	1 (0.42%)
6.	Linagliptin	1 (0.42%)
7.	Acarbose	4 (1.67%)
8.	Vildagliptin	8 (3.34%)
9.	Teneligliptin	9 (3.75%)
10.	Sitagliptin	14 (5.84%)
11.	Gliclazide	5 (2.08%)
12.	Voglibose	8 (3.34%)
13.	Saxagliptin	1 (0.42%)
Total		240 (100%)



Prescription of Antibiotics in different genders

Table 3: Antibiotic Drug Prescription Pattern in different gender

No.	Drugs associated with	Gender		Total
		Male	Female	
1.	T. Cefuroxime 500mg twice a day	0	1	1
2.	Cefuroxime 1.5g STAT	0	1	1
3.	Cefoperazone+Sulbactam 1.5g twice a day	14	14	28
4.	Cefoperazone+Sulbactam 1.5g three times a day	2	1	3
5.	Cefoperazone+Sulbactam 3g twice a day	21	22	43
6.	Cefoperazone+Sulbactam 3g STAT	1	0	1
7.	Ceftriaxone 1g twice a day	1	0	1
8.	Ceftriaxone 2g twice a day	12	23	35
9.	Ceftriaxone+Sulbactam 1.5g twice a day	2	0	2
10.	Ceftriaxone+Sulbactam 3g twice a day	1	0	1
11.	Cefpodoxime+Clavulanic acid 200+125mg twice a day	3	3	6
12.	Cefixime 200mg twice a day	1	1	2
13.	Cefixime+Clavulanic acid 200+125mg twice a day	1	1	2
14.	Piperacillin+Tazobactam 4.5g twice a day	2	3	5
15.	Piperacillin+Tazobactam 4.5g three times a day	5	6	11
16.	T. Azithromycin 500mg once daily	27	31	58
17.	Metronidazole 5mg/ml twice a day	1	0	1
18.	Metronidazole 200mg three times a day	1	4	5
19.	Metronidazole 500mg three times a day	3	2	5
20.	Meropenem 500mg twice a day		1	1
21.	Meropenem 500mg three times a day	1	2	3
22.	Meropenem 500mg four times a day	1	2	3
23.	Meropenem 1g twice a day	1	2	3
24.	Meropenem 1g three times a day	12	3	15
25.	Meropenem 1g four times a day	0	1	1
26.	Meropenem 1g STAT	0	1	1
27.	Levofloxacin 250mg once daily	1	1	2
28.	Levofloxacin 500mg once daily	1	0	1
29.	Levofloxacin 500mg twice a day	0	1	1
30.	Levofloxacin 750mg once daily	0	2	2
31.	I. Levofloxacin 750mg once daily	1	0	1
32.	Linezolid 600mg once daily	1	2	3
33.	Linezolid 600mg twice a day	5	5	10
34.	Rifaximin 550mg twice a day	1	0	1
35.	Rifaximin 550mg three times a day	1	1	2
36.	Nitrofurantoin 100mg twice a day		1	1
37.	Amikacin 500mg twice a day	1	2	3
38.	Amikacin 750mg STAT	0	1	1
39.	Doxycycline 100mg twice a day	0	3	3
40.	Doxycycline 400mg twice a day	0	1	1
41.	Doxycycline 500mg twice a day	0	1	1
42.	Tigecycline 50mg twice a day	1	2	3
43.	Teicoplanin 400mg twice a day	0	1	1
44.	Ivermectin+Albendazole 6+400mg once daily	2	1	3
45.	Ivermectin+Albendazole 6+400mg twice a day	0	1	1
46.	Acyclovir 500mg twice a day	0	1	1
47.	Acyclovir 500mg three times a day	1	0	1
48.	Oseltamivir 75mg twice a day	2	4	6



49.	Moxifloxacin 400mg once daily	1	0	1
50.	Amoxicillin+Potassium clavulanate 500+125mg twice a day	0	1	1
51.	Fosfomycin Sachet 3g once daily	0	2	2
52.	T. Clarithromycin 500mg twice a day	0	1	1
53.	Clindamycin 300mg three times a day	1	0	1
54.	Clindamycin+Clotrimazole 100+100mg once daily	0	1	1
55.	Fluconazole 100mg once daily	1	2	3
56.	Fluconazole 150mg twice a day	0	2	2
57.	T. Fluconazole 200mg once daily	1	1	2
58.	Fluconazole 200mg twice a day	2	0	2
59.	Fluconazole 400mg once daily	1	4	5
60.	I. Polymyxin B 7.5IU twice a day	0	1	1
61.	Ornidazole+Ofloxacin 500+200mg twice a day	1	0	1
62.	Trimethoprim+Sulfamethoxazole 160+800mg twice a day	1	1	2
63.	Isoniazid+Rifampicin 300+450mg once daily	2	0	2
64.	Pyrazinamide 750mg twice a day	1	0	1
65.	Ethambutol 400mg once daily	1	0	1
66.	Ethambutol 1000mg once daily	1	0	1
Total		145	172	317

In the present study, a total of 66 distinct antimicrobial formulations were prescribed to 317 patients, comprising 145 prescriptions for males and 172 prescriptions for females. The most frequently prescribed antimicrobial was Tab. Azithromycin 500 mg once daily, accounting for 58 prescriptions—27 in males and 31 in females—reflecting its widespread use in upper respiratory tract infections due to its broad-spectrum and once-daily dosing convenience. The second most commonly used formulation was Cefoperazone + Sulbactam 3g twice a day, prescribed 43 times, nearly equally among 21 prescriptions for males and 22 prescriptions for females, typically for moderate to severe systemic infections.

Occurrence of Diseases in different Gender

Table 4 Disease occurrence in different gender group

Disease	Male	Female	Total
Tuberculosis	1	-	1
Liver Damage	1	-	1
Eye Infection	1	-	1
Gastrointestinal Infection	15	15	30
Respiratory Tract Infection	32	41	73
Urinary Tract Infection	12	22	34
Limb Infection	8	5	13
Encephalitis	2	1	3
Systemic Infection	3	2	5
Meningitis	2	-	2
Pancreatitis	1	1	2
Cholelithiasis	-	1	1
Kidney Injury	1	-	1
Total	79	88	167

Among 154 patients, 167 diagnoses were recorded, including 88 in females and 79 in males. Respiratory tract infection was the most common condition with 73 cases (41 females, 32 males), followed by Urinary tract infection with 34 cases (22 females, 12 males) and Gastrointestinal infection with 30 cases equally distributed between males and females (15 each). Limb infections (LI) accounted for 13 cases (8 males, 5 females), while systemic infections and encephalitis were reported in 5 (3 males, 2 female,s) and 3 cases respectively. Less common conditions included eye infections, pancreatitis, and meningitis (1–2 cases each), whereas cholelithiasis, liver damage, kidney injury, and TB were rare, with 1 male case each.



This data shows that Respiratory tract infections, Gastrointestinal infections, and Urinary tract infections are the most frequent reasons for prescribing antibiotics, and while infections like Respiratory tract infections and systemic infections are somewhat balanced between genders, females are more prone to Urinary tract infections, and males slightly lead in systemic and rare infections. The findings can help in tailoring health awareness and preventive strategies by gender.

Occurrence of Diseases in Different Ages and Gender

Table 5 Disease occurrence in different age and gender group

Age	Male	Female	System affected
35-40	1	2	1(GII) 2(RTI)
41-50	8	13	10(RTI) 2(LI) 1(Systemic) 6(GII) 4(UTI) 1(Meningitis)
51-60	21	16	15(RTI) 11(UTI) 1(Systemic) 8(GII) 1(Cholelithiasis) 2(Pancreatitis) 1(Eye infection)1(Liver damage)
61-70	12	24	14(RTI) 11(UTI) 4(LI) 6(GII) 1(Meningitis) 1(Encephalitis) 1(TB)
71-80	22	22	1(Kidney injury) 7(LI) 22(RTI) 7(UTI) 2(Systemic) 8(GII) 2(Encephalitis)
81-90	9	3	9(RTI) 1(Systemic) 1(UTI) 1(GII)
91-95	0	1	1(RTI)
Total	73	81	73(RTI) 30(GII) 34(UTI) 13(LI) 1(KI) 2(Meningitis) 3(Encephalitis) 5(Systemic)1(EI) 1(TB) 1(Liver damage) 1(cholelithiasis) 2(Pancreatitis)

Respiratory tract infections (RTIs) were the most common, with 73 cases, mainly affecting patients aged 51–80 years. Urinary tract infections (UTI) accounted for 34 cases, occurring mostly in females and in the 61–80 years age group, while gastrointestinal infections (GII) had 30 cases, equally affecting both genders and peaking in the 61–70 years group. Overall, older adults aged 61–80 years, particularly women, received more antibiotic prescriptions due to higher infection rates, highlighting the need for careful antibiotic use and infection monitoring in the elderly population.

Comparison of Prescribed drugs with Guidelines

Table 6 Comparison of Prescribed Drugs with Guidelines

System Affected	Drugs according to the Guidelines	Drugs prescribed	Drugs following guidelines
Limb Infection	<ul style="list-style-type: none"> 1st generation Cephalosporin 2nd generation Cephalosporin Amoxicillin Clavulanic Acid Clindamycin Doxycycline Fluoroquinolones Linezolid Macrolide Piperacillin + Tazobactam Trimethoprim + Sulfamethoxazole 	<ul style="list-style-type: none"> Cefuroxime-1 Cefoperazone-6 Ceftriaxone-2 Cefpodoxime-2 Meropenem-4 Levofloxacin-1 Linezolid-5 Clindamycin-1 Clavulanic Acid-2 Tigecycline-1 <p>Total 10 Drugs and 25 Prescriptions</p>	<ul style="list-style-type: none"> -Clavulanic Acid 2 (8%) -Clindamycin 1 (4%) -Levofloxacin 1 (4%) -Linezolid 5 (20%) -Meropenem 4 (16%) <p>Total 5 drugs and 13 Prescriptions were according to guidelines</p>
Encephalitis	<ul style="list-style-type: none"> -Azathioprine -Methylprednisolone -Rituximab 	<ul style="list-style-type: none"> -Ceftriaxone 2 -Metronidazole 1 -Meropenem 1 	<ul style="list-style-type: none"> -Acyclovir 1 <p>A total of 1 drug and 1</p>



	-Tocilizumab -Acyclovir -Ganciclovir -Oseltamivir	-Linezolid 1 -Tigecycline 1 -Acyclovir 1 Total 6 Drugs and 7 Prescriptions	Prescriptions were according to guidelines
GI Infection	-Ampicillin -Azithromycin -Ceftriaxone -Ciprofloxacin -Doxycycline -Trimethoprim Sulfamethoxazole -Rifaximin	+ -Cefoperazone 10 -Ceftriaxone 14 -Cefpodoxime 2 -Cefixime 2 -Azithromycin 3 -Piperacillin Tazobactam 6 -Metronidazole 9 -Ornidazole 1 -Ofloxacin 1 -Clindamycin 1 -Clotrimazole 1 -Tigecycline 1 -Linezolid 1 -Rifaximin 1 -Amikacin 1 -Ivermectin Albendazole 4 -Fluconazole 1 -Meropenem 2 Total 18 drugs and 61 Prescriptions	-Azithromycin 3 (4.92%) -Ceftriaxone 14 (22.95%) -Rifaximin 1 (1.64%) Total 3 drug and 18 Prescriptions were according to guidelines
Meningitis	-Amoxicillin -Ampicillin -Cefotaxime -Ceftriaxone -Penicillin G	-Ceftriaxone 2 -Metronidazole 1 -Linezolid 2 -Tigecycline 1 Total 4 drugs and 6 Prescriptions	-Ceftriaxone 2 (33.34%) Total 1 drug and 2 Prescriptions were according to guidelines
RTI	-Amoxicillin -Cephalosporins -Clavulanic Acid -Doxycycline -Fluoroquinolones -Macrolides	-Cefoperazone 38 -Levofloxacin 1 -Linezolid 4 -Ceftriaxone 23 -Rifaximin 1 -Cefpodoxime 1 -Cefixime 1 -Piperacillin Tazobactam 7 -Amikacin 1 -Azithromycin 45 -Metronidazole 2 -Meropenem 10 -Doxycycline 4 -Tigecycline 1 -Acyclovir 1 -Oseltamivir 6 -Moxifloxacin 1 -Clarithromycin 1 -Clavulanic Acid 1 -Fluconazole 3 -Polymyxin-B 1	-Azithromycin 45 (29.4%) -Cefixime 1 (0.65%) -Cefoperazone 38 (24.8%) -Ceftriaxone 23 (15%) -Cefpodoxime 1 (0.65%) -Clarithromycin 1 (0.65%) -Clavulanic acid 1 (0.65%) -Doxycycline 4 (2.61%) -Levofloxacin 1 (0.65%) -Moxifloxacin 1 (0.65%) Total 10 drugs and 116 Prescriptions were according to



		Total 21 drugs and 153 Prescriptions	guidelines
UTI	-Amikacin -Cefuroxime -Ciprofloxacin -Ertapenem -Gentamicin -Nitrofurantoin -Ofloxacin -Piperacillin + Tazobactam -Trimethoprim + Sulfamethoxazole If Fungal Fluconazole	-Cefoperazone 21 -Meropenem 8 -Ceftriaxone 8 -Levofloxacin 3 -Cefixime 1 -Piperacillin + Tazobactam 3 -Linezolid 1 -Azithromycin 1 -Metronidazole 4 -Rifaximin 1 -Nitrofurantoin 1 -Amikacin 2 -Doxycycline 2 -Tigecycline 2 -Teicoplanin 1 -Amoxicillin 1 -Fosfomycin 1 -Clindamycin 1 -Clotrimazole 1 -Fluconazole 7 -Trimethoprim + Sulfamethoxazole 1 Total 21 drugs and 71 Prescriptions	-Amikacin 2 (2.77%) -Fluconazole 7 (9.72%) -Nitrofurantoin 1 (1.38%) -Piperacillin + Tazobactam 3 (4.16) -Trimethoprim + Sulfamethoxazole 1 (1.38%) Total 5 drug and 14 Prescriptions of it were according to guidelines
Eye Infection	-Ciprofloxacin -Gentamicin -Tobramycin -Moxifloxacin -Levofloxacin -Vancomycin	-Cefoperazone 1	None

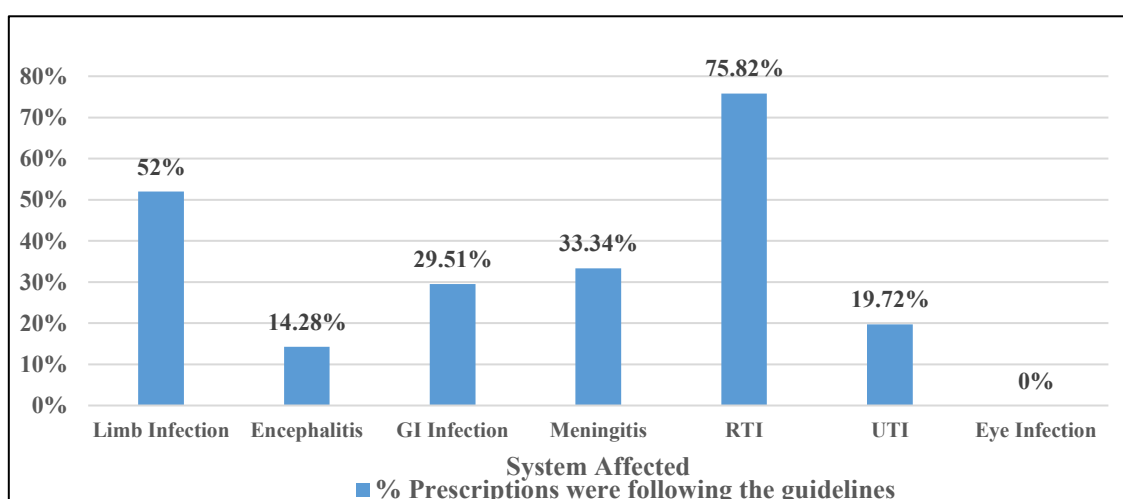


Figure 1 Percentage of Prescriptions Following Guidelines by System Affected

This figure provides a comparative analysis of prescribed antimicrobial drugs versus guideline-recommended drugs across various systems affected by infections. The data includes the number and type of drugs prescribed, how many align with standard treatment guidelines, and percentages indicating compliance with the guideline.



1. Limb/Foot Infection: Out of 25 prescriptions, 13 prescriptions (52%) were followed by the guidelines. Total 10 different types of drugs were prescribed from which 5 drugs were according to guideline (e.g., Linezolid, Meropenem).
2. Encephalitis: 1 out of the 7 prescriptions (14.28%) were aligned with the recommended guideline. One drug was under the guideline among 6 prescribed drugs.
3. GI Infection: From 61 prescriptions, only 18 prescription (29.51%) were according to the mentioned guidelines in which Azithromycin, Ceftriaxone, Rifaximin were empirical for the treatment out of 17 prescribed drugs.
4. Meningitis: Only 2 prescriptions (33.34%) of only one drug Ceftriaxone (33.34%) followed guidelines among 6 prescriptions and 4 prescribed drugs.
5. Respiratory Tract Infection: 153 prescriptions with 21 drugs; 116 prescriptions followed guidelines (75.82%), in which Azithromycin, Ceftriaxone and 8 more drugs were empirical according to guidelines among 21 prescribed drugs.
6. Urinary Tract Infection: From 71 prescriptions, 14 prescriptions (19.72%) containing drugs like Amikacin, Fluconazole and 3 more drugs followed guidelines among 21 prescribed drugs.
7. Eye Infection: Only one drug (Cefoperazone) from one prescription (0%) did not align with guidelines like Ciprofloxacin or Gentamicin.

This study evaluated the management of severe infections in 154 hospitalized diabetic patients, in total of 81 females (52.6%) and 73 males (47.4%). Most patients were elderly, falling under the age group of 71–80 years (28.57%) indicates greater susceptibility to severe infections. Guideline adherence for antimicrobial prescribing varied across infections, with the highest compliance to lowest was seen in respiratory tract infections at 75.8% with 153 prescriptions, while limb infections showed moderate compliance at 52% (13 of 25 prescriptions), Gastrointestinal infections (29.51%), urinary tract infections (19.72%), and meningitis (33.34%) and least compliance Encephalitis (14.28%). Alarmingly, there was complete non-adherence observed in case of ocular infections, where none of the prescribed agents matched guideline-based recommendations. This Study has also seen that Females are more susceptible to Infections like Respiratory Tract infections (41 cases) and following the trend of vulnerability to Urinary Tract infection (22 cases) when compared to male cases.

CONCLUSION

Guideline adherence in antimicrobial prescriptions varied across systems, with Respiratory Tract Infections showing the highest compliance (75.8%) and Encephalitis and Eye Infections the lowest (0%). Limb infections showed moderate adherence (52%), while Gastro Infection, Urinary Tract infection and Meningitis had lower rates. These findings highlight a critical need for improved antimicrobial stewardship, targeted clinician education, and routine auditing of prescription patterns to enhance guideline adherence. Strengthening evidence-based prescribing is vital for optimizing therapeutic outcomes, minimizing antimicrobial resistance, and ensuring high standards of clinical care.

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