Section: Miscellaneous

Original Research Article

CLINICAL AND MICROBIOLOGICAL PROFILE OF TREATMENT FAILURE IN PATIENTS DIAGNOSED WITH CHRONIC OSTEOMYELITIS, ATTENDING TERTIARY CARE

Battu Vijayeswar Reddy[1], P S. Supriya Sree[2], Efshana Jabeen[3], Doddoju Veera Bhadreshwara Anusha[4]

[1]*Assistant professor, Department of Orthopaedics, RVM Institute of Medical Sciences and Research Centre, Siddipet, Telangana, India*
[2]*Associate Professor, Department of Microbiology, RVM Institute of medical Sciences and Research Centre, Siddipet, Telangana, India.*
[3]*Assistant Professor, Department of Microbiology, Gandhi Medical College, Hyderabad, Telangana, India.*
[4]*Professor and Head, Department of Community medicine, RVM institute of Medical Sciences and Research Centre, Siddipet, Telangana, India.*

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Corresponding Author:
Dr. P S. Supriya Sree,
MD, Associate professor, Department of Microbiology, RVM institute of medical sciences and research centre, Siddipet, Telangana, India.
Email: supriya1313@yahoo.com

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ABSTRACT

Background: Chronic osteomyelitis is a challenging condition characterized by persistent infection, devitalized bone, biofilm formation, and recurrent disease. Treatment failure may be influenced by patient-related, clinical, and microbiological factors. This study evaluated the clinical and microbiological factors associated with treatment failure in patients with chronic osteomyelitis.

Materials and Methods: A retrospective observational study was conducted among 223 patients with chronic osteomyelitis treated at a tertiary care teaching hospital over a four-year period. Demographic, clinical, microbiological, treatment, and follow-up data were retrieved from medical records. Microbiological findings included culture results, type of infection, causative organisms, and antimicrobial resistance patterns. Treatment failure was defined as persistence or recurrence of infection, persistent wound discharge or sinus, radiological progression, unplanned repeat surgery, or reinstitution of antimicrobial therapy. Associations between categorical variables and treatment outcome were assessed using the Chi-square or Fisher's exact test, with $p<0.05$ considered statistically significant using SPSS 28.

Results: Of the 223 patients, Diabetes mellitus was present in 112 (50.2%) patients, smoking in 53 (23.8%), trauma in 154 (69.1%), previous surgery in 78 (35.0%), sinus tract in 169 (75.8%), and exposed/sequestrated bone in 133 (59.6%). Culture positivity was observed in 163 (73.1%) patients. Treatment failure occurred in 29 (13.0%) patients, while 194 (87.0%) achieved treatment success. Treatment failure was significantly associated with age >60 years ($p<0.001$), diabetes mellitus ($p=0.010$), smoking ($p<0.001$), disease duration >2 years ($p<0.001$), previous surgery ($p=0.027$), and implant-associated infection ($p<0.001$). Culture positivity alone was not associated with treatment failure ($p=0.59$), whereas polymicrobial infection, S. aureus, MRSA, and multidrug-resistant organisms showed significant associations with treatment failure ($p<0.001$).

Conclusion: Treatment failure occurred in 13.0% of patients with chronic osteomyelitis and was associated with several clinical and microbiological factors. Older age, diabetes, smoking, prolonged disease duration, previous surgery, implant-associated infection, polymicrobial infection, and antimicrobial resistance were important correlates of unsuccessful treatment.

Keywords: Chronic osteomyelitis, treatment failure, microbiological spectrum, clinical profile, tertiary care.

INTRODUCTION

Chronic osteomyelitis is a persistent bone infection that remains difficult to eradicate because of necrotic bone, poor vascularity, sinus formation, and bacterial biofilms. Despite advances in surgery and antimicrobial therapy, recurrence and treatment failure remain important clinical concerns.[1,2]

Staphylococcus aureus is the most frequently isolated pathogen, although Gram-negative, polymicrobial, and antimicrobial-resistant infections are increasingly encountered.[3,4] Biofilm formation and infection with resistant organisms can reduce antimicrobial effectiveness and contribute to persistent disease.[5,6] Moreover, superficial sinus cultures may not reliably reflect the organisms within infected bone, making deep-tissue or intraoperative bone cultures important for appropriate antimicrobial selection.[5,7]

Treatment outcomes are also influenced by clinical factors such as prolonged disease duration, exposed or necrotic bone, inadequate debridement, poor soft-tissue coverage, diabetes, smoking, and vascular compromise.[6,8,9] Recurrence may represent persistence of the original pathogen or reinfection with a different organism, emphasizing the need for comprehensive clinical and microbiological assessment.[5]

Identifying factors associated with treatment failure can facilitate early risk stratification, optimize surgical and antimicrobial management, and improve long-term outcomes. Therefore, this study aims to evaluate the clinical and microbiological predictors of treatment failure in patients with chronic osteomyelitis, with particular emphasis on patient characteristics, disease features, causative organisms, antimicrobial resistance, and treatment-related factors.

Aim: To identify the clinical and microbiological predictors of treatment failure in patients with chronic osteomyelitis.

Objectives:

1. To assess the clinical profile of patients with chronic osteomyelitis, including demographic characteristics, comorbidities, disease duration, site, and extent of infection.
2. To determine the microbiological profile of chronic osteomyelitis, including the causative organisms and their antimicrobial susceptibility patterns.
3. To evaluate the association between clinical factors and treatment failure.
4. To assess the association between microbiological factors and treatment failure, particularly polymicrobial infection and antimicrobial-resistant organisms.

MATERIALS AND METHODS

Study Design and Setting: A retrospective observational study was conducted in the Department of Orthopaedics and Microbiology at a tertiary care teaching hospital. The study included patients diagnosed with chronic osteomyelitis and managed at the institution over a 4-year study period. Relevant clinical, microbiological, treatment, and follow-up information was retrieved from hospital records.

Study Population: The study population comprised patients with a documented diagnosis of chronic osteomyelitis who received treatment during the study period.

Sample Size: A total of 223 patients with chronic osteomyelitis were included in the study. All eligible patients identified from hospital records during the specified study period were considered for analysis.

Inclusion Criteria

Patient's medical records were included if they:

1. Had a documented diagnosis of chronic osteomyelitis based on clinical, radiological, operative, and/or microbiological findings.
2. Were treated at the study hospital during the 4-year study period.
3. Had adequate medical and microbiological records available for analysis.
4. Had documented treatment and follow-up information sufficient to determine treatment outcome.

Exclusion Criteria

Patient's medical records were excluded if they:

1. Had only acute osteomyelitis without evidence of chronic disease.
2. .Had incomplete records regarding treatment or outcome.
3. Had insufficient microbiological information where microbiological analysis was required.
4. Were referred elsewhere before definitive treatment or adequate follow-up at the study institution.

Data Collection: Patient information was extracted from inpatient records, outpatient records, operative notes, microbiology reports, imaging records, and follow-up documentation using a structured data collection proforma.

The following variables were recorded

- Demographic factors: age and sex.
- Clinical factors: comorbidities, diabetes mellitus, smoking status, duration of symptoms, previous surgery, previous antimicrobial therapy, history of trauma, and anatomical site involved.
- Disease-related factors: presence of sinus or wound discharge, exposed or sequestrated bone, pathological fracture, implant-associated infection, and extent of bone involvement.
- Laboratory and imaging findings: relevant hematological and inflammatory parameters and radiological evidence of chronic infection.
- Microbiological factors: specimen type, isolated organism(s), monomicrobial or polymicrobial infection, and antimicrobial susceptibility pattern.

Microbiological Assessment: Microbiological results from deep tissue, bone, or intraoperative specimens were recorded. Superficial wound or sinus cultures were documented separately. Organisms were classified as Gram-positive, Gram-negative, fungal, or polymicrobial infections according to the laboratory report. Antimicrobial susceptibility results were reviewed to identify resistant organisms and multidrug-resistant infections.

Definition of Treatment Failure: Treatment failure was defined as persistence or recurrence of clinical or microbiological evidence of osteomyelitis following completion of the initial treatment, including persistent wound discharge or sinus, recurrent infection at the same site, radiological progression, requirement for unplanned repeat surgical intervention, or reinstitution of antimicrobial therapy because of ongoing infection.

Patients who achieved clinical resolution without evidence of recurrence during the available follow-up period were categorized as having successful treatment.

Statistical Analysis: Data were entered into a statistical software package and analyzed using appropriate descriptive and inferential statistical methods. Continuous variables were expressed as mean ± standard deviation or median with interquartile range, depending on data distribution. Categorical variables were presented as frequencies and percentages.

Associations between categorical variables and treatment outcome were assessed using the Chi-square test or Fisher's exact test, as appropriate. A p-value <0.05 was considered statistically significant.

Ethical Considerations: The study was conducted after obtaining approval from the Institutional Ethics Committee. As this was a retrospective study based on existing medical records, patient confidentiality was maintained throughout data collection and analysis. Patient identifiers were removed from the study database, and the information was used solely for research purposes.

RESULTS

A total of 223 patients with chronic osteomyelitis who fulfilled the eligibility criteria during the four-year study period were included in the analysis. Among 223 patients with chronic osteomyelitis, 43.5% were aged 41–60 years, and 52.5% were male. Diabetes mellitus was present in 50.2%, while 23.8% were smokers. Trauma was reported in 69.1% of patients. A history of previous surgery was present in 35.0%, while 75.8% had a sinus tract and 59.6% had exposed or sequestrated bone. Pathological fracture was documented in 25.1% of patients. [Table 1, Figure 1].

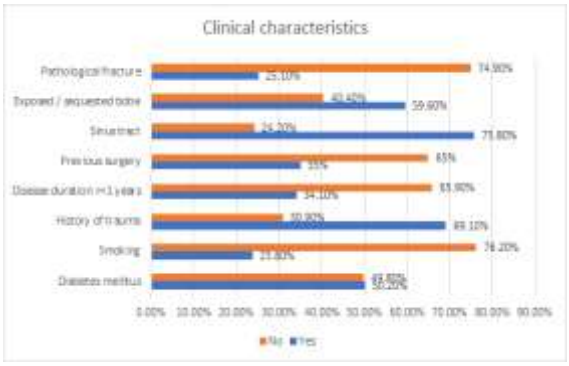


Figure 1: Clinical characteristics of the study population

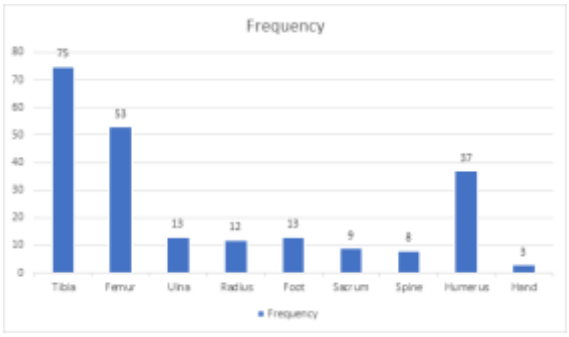


Figure 2: Distribution by anatomical sites involved.

Table 1: Demographic and clinical characteristics of patients with chronic osteomyelitis (N=223)

Variable	Category	n	%
Age (years)	≤40	69	30.9
	41–60	97	43.5
	>60	59	26.5
	Mean ±SD	48±14.5	
Sex	Male	117	52.5
	Female	106	47.5
Diabetes mellitus	Present	112	50.2
	Absent	111	49.8
Smoking	Present	53	23.8
	Absent	170	76.2
Disease duration	<1 year	76	34.1
	1–2 years	82	36.8
	>2 years	65	29.1
History of trauma	Present	154	69.1
	Absent	69	30.9
Previous surgery	Yes	78	35
	No	145	65
Sinus tract	Present	169	75.8
	Absent	54	24.2
Exposed/sequestrated bone	Present	133	59.6

	Absent	90	40.4
Pathological fracture	Present	56	25.1
	Absent	167	74.9

Among the 223 anatomical sites involved in chronic osteomyelitis, the tibia was the most commonly affected bone, accounting for 75 (33.6%) sites, followed by the femur in 53 (23.8%) sites. The humerus was involved in 37 (16.6%) sites. The ulna and foot were each involved in 13 (5.8%) sites, while the radius accounted for 12 (5.4%) sites. The sacrum was involved in 9 (4.0%) sites and the spine in 8 (3.6%) sites. The hand was the least commonly involved site, accounting for 3 (1.3%) cases. Overall, the tibia and femur constituted the predominant sites of chronic osteomyelitis in the study population. [Figure 2]

Of the 223 patients, 163 (73.1%) had positive cultures, while 60 (26.9%) were culture negative. Among culture-positive cases, 129 (79.1%) were monomicrobial and 34 (20.9%) were polymicrobial. Gram-positive organisms predominated (60.7%), with Staphylococcus aureus being the most frequently isolated pathogen (25.8%), followed by Streptococcus spp. (13.5%) and coagulase-negative Staphylococcus (10.4%). Gram-negative organisms accounted for 39.3%, with Escherichia coli being the most common (12.9%). Methicillin-resistant S. aureus was identified in 9.8%, while multidrug-resistant organisms were found in 4.9% of culture-positive cases. [Table 2]

Table 2: Microbiological characteristics of chronic osteomyelitis (N=223)

Microbiological characteristic	n	%
Culture positive	163	73.1
Culture negative	60	26.9
Type of infection		
Monomicrobial	129	79.1
Polymicrobial	34	20.9
Gram-positive organisms	99	60.7
Staphylococcus aureus	42	25.8
Coagulase-negative Staphylococcus	17	10.4
Streptococcus spp.	22	13.5
Enterococcus spp.	18	11.0
Gram-negative organisms	64	39.3
Escherichia coli	21	12.9
Klebsiella spp.	15	9.2
Pseudomonas aeruginosa	9	5.5
Other Gram-negative bacilli	11	6.7
Antimicrobial resistance		
Methicillin-resistant S. aureus	16	9.8
Multidrug-resistant organism	8	4.9
No significant resistance identified	139	85.3

Among 223 patients, 29 (13.0%) experienced treatment failure, while 194 (87.0%) achieved treatment success. Treatment failure was significantly associated with older age (>60 years), diabetes mellitus, smoking, longer disease duration (>2 years), previous surgery, and implant-associated infection ($p < .05$). The strongest associations were observed with smoking and age ($p < .001$). Sex, sinus tract, and exposed/sequestrated bone were not significantly related to treatment outcome. [Table 3, Figure 3].

Table 3: Association between clinical factors and treatment failure

Clinical factor	Category	Treatment success, n (%)	Treatment failure, n (%)	χ^2	p
Age	≤60 years	155 (79.9)	9 (31.0)	30.96	< .001
	>60 years	39 (20.1)	20 (69.0)		
Sex	Male	96 (49.5)	21 (72.4)	0.25	.620
	Female	98 (50.5)	8 (62.1)		
Diabetes mellitus	Present	91 (46.9)	21 (72.4)	6.56	.010
	Absent	103 (53.1)	8 (27.6)		
Smoking	Present	33 (17.0)	22 (75.9)	67.20	< .001
	Absent	161 (83.0)	7 (24.1)		
Disease duration	≤2 years	144 (74.2)	14 (48.3)	47.03	< .001
	>2 years	50 (25.8)	15 (51.7)		
Previous surgery	Present	56 (28.9)	22 (75.9)	4.87	.027
	Absent	138 (71.1)	7 (24.1)		
Sinus tract	Present	149 (76.8)	20 (69.0)	0.85	.358
	Absent	45 (23.2)	9 (31.0)		
Exposed/sequestrated bone	Present	114 (58.8)	19 (65.5)	0.48	.490
	Absent	80 (41.2)	10 (34.5)		
Implant-associated infection	Present	16 (8.2)	9 (31.0)	13.16	< .001
	Absent	178 (91.8)	20 (69.0)		

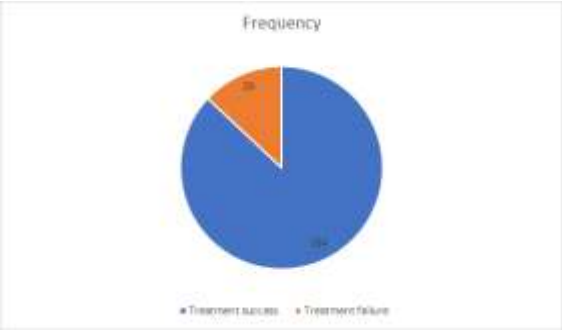


Figure 3: Treatment status

Treatment failure occurred in 29 (13.0%) of the 223 patients. Culture positivity alone was not significantly associated with treatment failure (p = .59). However, polymicrobial infection showed a significant association with treatment failure (p < .001). S. aureus infection was also significantly associated with treatment failure (p < .001). A particularly strong association was observed with MRSA, with treatment failure occurring more frequently among MRSA-positive patients (p < .001). Similarly, multidrug-resistant organisms were significantly associated with treatment failure (p < .001). Overall, these findings suggest that the type of infection and antimicrobial resistance, rather than culture positivity alone, were important microbiological factors associated with treatment failure. [Table 4]

Table 4: Association between microbiological factors and treatment failure

Microbiological factor	Category	Treatment success (n =194)	Treatment failure (n=29)	p-value
Culture result	Positive	143	20	0.2889/0.59
	Negative	51	9	
Infection type	Monomicrobial	174	15	28.14/0.00
	Polymicrobial	20	14	
Organism	S. aureus	30	14	18.64/<0.00
	Gram-negative organisms	56	8	
	Other organisms	108	7	
MRSA	Present	1	15	99.3/ 0.00
	Absent	193	14	
MDR organism	Present	2	6	28.18/0.00
	Absent	192	23	

DISCUSSION

The present study assessed the clinical and microbiological characteristics of treatment failure among 223 patients with chronic osteomyelitis. Treatment failure occurred in 29 patients (13.0%), while 194 (87.0%) achieved treatment success. Chronic osteomyelitis is difficult to treat because of devitalised bone, poor vascularity, biofilm formation and persistent infection despite antimicrobial therapy and surgical intervention.[9-11]

The present study included 223 patients with chronic osteomyelitis, of whom 43.5% belonged to the 41–60-year age group and 52.5% were male. Diabetes mellitus was present in 50.2%, while trauma was reported in 69.1% of patients.

Taruna Singh et al. reported a lower mean age of 39.6 ± 17.2 years, with the largest proportion of patients (40.2%) belonging to the 31–50-year age group. In contrast, the present study demonstrated a higher mean age of 48 ± 14.5 years, with the 41–60-year age group predominating. This difference may be related to the inclusion of exclusively chronic osteomyelitis cases in the present study, whereas the comparative study included both acute and chronic infections. The prolonged course of chronic osteomyelitis and the greater contribution of age-related comorbidities may also explain the older age distribution in the present cohort.[12]

Male patients constituted 52.5% of the current study population, compared with 65% in the study by T Singh et al,.[12] and 74.3% by Anupama singh et al,.[13] Both studies demonstrated male predominance, although the difference was less marked in the present study. Variations in occupational exposure, trauma patterns, referral characteristics and the inclusion of acute cases may have contributed to this difference.

Diabetes mellitus was observed in 50.2% of patients in the present study, compared with 25.6% in the study by Taruna Singh et al,.[12] The higher prevalence of diabetes in the current cohort may reflect the exclusive inclusion of chronic osteomyelitis patients and the potential role of diabetes in delayed healing, impaired immune response and persistent infection. Singh et al. also identified a significant association between diabetes and chronic osteomyelitis, reporting chronic disease in 70% of diabetic patients compared with 58.6% of non-diabetic patients (p = 0.021)12, which is a finding similar to our study.

Trauma was reported in 69.1% of patients in the present study, where as it was 33.8% in the study by Anupama Singh et al,.[13] As, trauma and surgical intervention are recognized routes for the direct introduction of microorganisms into bone, and trauma-related infection may contribute to the development of chronic osteomyelitis.

The microbiological profile in the present study demonstrated that 73.1% of patients had positive cultures, with Gram-positive organisms predominating (60.7%). Staphylococcus aureus was the most frequently isolated organism (25.8%), followed by Escherichia coli (12.9%), Streptococcus spp. (13.5%), Enterococcus spp. (11.0%), and coagulase-negative Staphylococcus (10.4%). Gram-

negative organisms accounted for 39.3% of isolates, including Klebsiella spp. (9.2%) and Pseudomonas aeruginosa (5.5%).

These findings are comparable with those of Anupama Singh et al,.[13] who reported S. aureus as the predominant pathogen (43.6%), followed by Pseudomonas spp. (12%), E. coli (8.5%), and Klebsiella spp. (5.1%). However, their study reported mixed infections in only 5.1% of cases, compared with 20.9% polymicrobial infections among culture-positive patients in the present study. The higher proportion of polymicrobial infections may reflect the chronic nature of the current study population, prolonged disease duration, repeated interventions, and possible healthcare-associated exposure.

Similarly, Anupama Singh et al reported culture positivity in 82.4% of cases, with monomicrobial infections accounting for 91.8% and polymicrobial infections for 8.2%. S. aureus was the leading organism (43.9%), followed by E. coli (18.9%) and Klebsiella spp. (11.4%).[13] In comparison, the present study showed a lower proportion of S. aureus but a higher frequency of polymicrobial infection. This variation may be related to differences in patient age, disease chronicity, prior surgical exposure, specimen collection methods, and institutional microbiological patterns.

Antimicrobial resistance was also clinically relevant in the present study, with MRSA detected in 9.8% and multidrug-resistant organisms in 4.9% of culture-positive patients. Anupama Singh et al. reported MRSA in 32.7% of S. aureus isolates.[13]

Smoking demonstrated a strong association with treatment failure ($p<0.001$) in this chronic osteomyelitis study. Smokers accounted for 75.9% of treatment failures compared with 17.0% of successful outcomes. Tobacco exposure can reduce tissue oxygenation and impair bone healing. Similar findings have been reported in studies of limb osteomyelitis, where smoking was associated with increased recurrence.[14,15]

Disease duration exceeding two years was significantly associated with treatment failure ($p<0.001$) also reported in study by Taruna singh et al,.[12] Prolonged infection may promote sequestrum formation, tissue destruction and biofilm development. Previous surgery and implant-associated infection were also significantly associated with failure. These findings may reflect persistent infection, complex disease and the presence of biofilm on implant surfaces.[16,17]

Sinus tract formation and exposed or sequestrated bone were not significantly associated with treatment failure. This differs from some previous studies that identified bone exposure as a predictor of relapse.[18] Such differences may be explained by variations in disease severity, surgical management and follow-up duration.

Overall, the study demonstrates that treatment failure in chronic osteomyelitis is associated with both clinical and microbiological factors. Smoking, diabetes, advanced age, prolonged disease duration, previous surgery, implant-associated infection, polymicrobial infection and antimicrobial resistance were important correlates. Early diagnosis, adequate surgical debridement, optimisation of comorbidities and culture-directed antimicrobial therapy may improve treatment outcomes. Multivariable analysis is required to establish whether these factors act as independent predictors.

CONCLUSION

This retrospective study of 223 patients with chronic osteomyelitis identified a treatment failure rate of 13.0%, while 87.0% of patients achieved treatment success. Treatment failure was significantly associated with older age (>60 years), diabetes mellitus, smoking, disease duration exceeding two years, previous surgery, and implant-associated infection. Smoking, advanced age, and implant-associated infection demonstrated particularly strong associations with unsuccessful treatment outcomes.

Microbiological evaluation showed culture positivity in 73.1% of patients, with Gram-positive organisms, particularly Staphylococcus aureus, predominating. Polymicrobial infection, S. aureus, MRSA, and multidrug-resistant organisms were significantly associated with treatment failure. These findings highlight the importance of appropriate microbiological assessment and antimicrobial selection.

Early identification of high-risk patients, optimisation of comorbid conditions, smoking cessation, adequate surgical management, and culture-directed antimicrobial therapy may improve treatment outcomes in chronic osteomyelitis. Multivariable analysis in larger prospective studies is required to establish independent predictors of treatment failure.

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