Original Article
Orthopaedics

A PROSPECTIVE STUDY OF OSTEOMYELITIS IN FOOT OF DIABETIC PATIENTS USING AMIT JAIN'S CLASSIFICATION FOR DIABETIC FOOT OSTEOMYELITIS

Santosh MP[1], Gopal S[1]

[1] - Associate professor, Department of Surgery, Rajarajeswari medical college, Bengaluru, India

Corresponding Author:
Dr. Gopal S.
Associate professor
Department of Surgery
Rajarajeswari medical college,
Bengaluru, India
Email – shraddha.gopal@gmail.com
Ph - +919880642810

Article submitted on: 15 April 2019
Article Accepted on: 26 April 2019

Abstract

Aim: To validate the new Amit Jain's classification for diabetic foot osteomyelitis and to predict the outcome associated with different types of diabetic foot osteomyelitis.

Methods & Materials: A prospective descriptive study was done in Department of surgery of Rajarajeswari medical college, Bangalore. The study period was from August 2017 to July 2018. An IEC clearance was obtained for this study. Statistical analysis was done using SPSS 18.

Results: 32 patients were included in this study with 81% being males. 69% of them presented with ulcer. Type 1 diabetic foot osteomyelitis was the most common osteomyelitis affecting 87.5% of the patients and Subtype C was the most common subtype involving 59.4% of the cases. Majority of the patients were managed surgically with only 9.4% of them being managed medically with antibiotics alone. Around 6.8 % underwent major amputation and they were significantly associated with type 3 diabetic foot osteomyelitis. There was no mortality in this series.

Conclusion: In this validation study, it is seen that the most common type of osteomyelitis in clinical practice is type 1 diabetic foot osteomyelitis with subtype C being most common subtype. Vast majority of patients in country like India require surgical management in view of delayed presentation. Subtype A osteomyelitis and a few cases of Subtype B can be managed conservatively to manage with conservative treatment. Type 3 osteomyelitis is associated with major amputation and one should be extremely cautious when dealing with this of osteomyelitis. Amit Jain's classification for osteomyelitis is a simple, easy, practical classification specific for diabetic foot osteomyelitis that guides treatment and predicts outcome efficiently.

Keywords: *Diabetic foot, Amit Jain, Osteomyelitis, Ulcer, Amputation, Classification*

Introduction

Diabetic foot osteomyelitis is a frequently encountered challenge by general surgeons especially in country like India where diabetic foot is often treated by general surgeons. High prevalence of foot ulcers and infections in patients with diabetes make them more vulnerable for developing osteomyelitis.

Osteomyelitis can complicate around 10-20% of the diabetic foot ulcers[1, 2, 3] and it can be upto 60%.[4]

Most osteomyelitis is known to occur either in a long standing non healing ulcers or in acute infections and such cases are associated with high risk of amputation.[5,6] In fact, the risk of amputation in acute diabetic infections is four times higher when there is underlying osteomyelitis than with soft tissue infection alone.[6]

Osteomyelitis is usually the consequence of a soft tissue infection wherein the infection spreads into the bone, involving the cortex first and then the marrow.[5, 7]

Osteomyelitis can affect any bone but most frequently the forefoot (90%), followed by the midfoot (5%) and the hindfoot (5%).[4, 8]

In spite of knowing the high incidence of osteomyelitis and the consequences associated with osteomyelitis, there were no proper guidelines to manage the same over years. The patients with diabetic foot osteomyelitis were managed based on the treating doctor's individual preferences and the experiences. A proper classification of diabetic foot osteomyelitis was thus necessary to address this and strangely was not attempted for many years.

Amit Jain's classification for diabetic foot osteomyelitis, which was proposed in 2014 from Indian subcontinent, is a new, simple, easy to remember, practical and a focal classification [Table 1] that is specific for osteomyelitis in diabetic foot.[4, 9] This classification has 3 major types of diabetic foot osteomyelitis with 4 subtypes.

Type Of Osteomyelitis	Description
Type 1 diabetic foot osteomyelitis	Osteomyelitis of forefoot
Type 2 diabetic foot osteomyelitis	Osteomyelitis of midfoot
Type 3 diabetic foot osteomyelitis	Osteomyelitis of hindfoot
Subtypes	
A	Probe to bone positive but x ray do not show clear osteomyelitis, ESR significantly elevated. Bone scan or MRI needed for confirmation. Occasionally, bone involvement can also be seen during surgery, bone involvement can also be seen sometimes during surgery.
B	X ray clearly shows cortical destruction on one side of the bone
C	X ray shows completely destroyed bone or joint
D	X ray shows involvement of more than one bone / joint

Table 1 showing the new Amit Jain's classification of diabetic foot osteomyelitis

This study aims to analyze the diabetic foot osteomyelitis using the new Amit Jain's classification system for osteomyelitis and also to predict the outcomes associated with the various types of osteomyelitis.

Materials And Methods

This is a prospective study done in Department of surgery of Rajarajeswari medical college which is a tertiary care teaching hospital that caters rural patients in majority. The department has 8 different surgical units with all units dealing with diabetic foot patients. The study period was from August 2017 to July 2018. The study was approved by our institutional ethics committee [RRMCH-IEC/165/2016-17]

The following were the inclusion and exclusion criteria.

Inclusion criteria

All patients admitted and treated for diabetic foot osteomyelitis in Department of Surgery in RRMCH during the study period.

Exclusion Criteria

1. Patients treated in other speciality department.
2. Patients who refused surgery and were discharged against medical advice.
3. Patients operated elsewhere.

Data / statistical analysis[10,11,12,13]: Data was analyzed using statistical software SPSS 18.0 and R environment Ver.3.2.2. Microsoft word and excel were used for general graphs and tables. Both descriptive and inferential statistical analysis was carried out in this study. Results on continuous

measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance.

The following assumption on data is made.

Assumptions

- Dependent variables should be normally distributed,
- Samples drawn from the population should be random
- Cases of the samples should be independent

Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher exact test was used when cell samples were very small.

Significant figures are as follows

+ Suggestive significance (P value: 0.05< P <0.10)
* Moderately significant (P value: 0.01< P 0.05)
** Strongly significant (P value: P ≤ 0.01).

Results

A total of 32 patients were included in the study. Majority of the patients [Figure 1] were between 41 to 70 years (85%). There were 26 male patients (81%) and 19% were females [Figure 2].

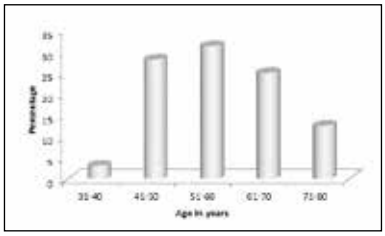

Figure 1 showing distribution of the age.

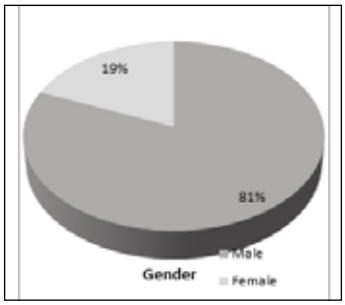

Figure 2 showing distribution of cases among males and females.

Around 19 patients [59.45%] had diabetes of less than 10 years duration and 13 patients [40.6%] had diabetes between 11-20 years duration.

In 69% (n = 22) of the patients, the presenting lesion was a foot ulcer. About 31% of the patients presented with abscess of the foot [Figure 3].

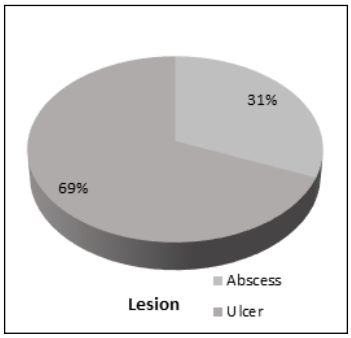

Figure 3 showing the type of presenting lesion.

The most common type of osteomyelitis encountered in the study was Type 1 osteomyelitis (n = 28, 87.5%). There were no patients with Type 2 osteomyelitis in this study and 12.5% had type 3 osteomyelitis.

Type of osteomyelitis	No. of patients	%
Type 1	28	87.5
Type 2	0	0.0
Type 3	4	12.5
Total	32	100.0

Table 2 showing the distribution of type of osteomyelitis.

Among the subtypes, subtype C (59.4%) was the most common osteomyelitis [Table 3] seen followed by subtype B (21.9%). Subtypes A and D were seen in 9.4% of the patients each.

Subtype of osteomyelitis	No. of patients	%
A	3	9.4
B	7	21.9
C	19	59.4
D	3	9.4
Total	32	100.0

Table 3 showing subtype distribution of patient studied

Almost 90% (n=29) of the patients in the study underwent some form of surgical treatment [Table 4]. Only 3 patients were managed medically with antibiotics alone. 28 patients underwent some form of amputation, while one patient underwent conservative surgery (partial calcanectomy). We were able to salvage the foot with partial calcanectomy with it being in subtype C category as it involved calcaneum near tendoachilles insertion region. Further, calcaneum being the largest bone of the foot, removal of a part of this bone did not hamper the integrity of the foot.

Treatment	No. of patients	%
Medical (Antibiotics alone)	3	9.4
Surgical	29	90.6

Table 4 showing Treatment distribution of patient studied

Among the 29 patients who underwent surgical management [Table 5], 26 patients (89.8%) underwent minor amputation and 1 patient underwent partial calcanectomy (3.4%). 2 patients underwent major amputation (6.8%).

Type of Surgery (n=29)	No. of patients	%
Minor amputation	26	89.8
Partial calcanectomy	1	3.4
Major amputation	2	6.8
Total	29	100.0

Table 5 showing distribution of surgery

There was no significant correlation of age, gender, presenting lesion and duration of diabetes with major amputation. However, a significant association (P - 0.012*) was seen between type of osteomyelitis with major amputation. All the patients who underwent major amputation had Type 3 osteomyelitis [Table 6].

Variables	Major Amputation		Total (n=32)	P value
	Yes (n=2)	No (n=30)		
Age in years				
• 31-40	0(0%)	1(3.3%)	1(3.1%)	0.657
• 41-50	1(50%)	8(26.7%)	9(28.1%)	
• 51-60	0(0%)	10(33.3%)	10(31.3%)	
• 61-70	1(50%)	7(23.3%)	8(25%)	
• 71-80	0(0%)	4(13.3%)	4(12.5%)	
Gender				
• Male	2(100%)	24(80%)	26(81.3%)	1.000
• Female	0(0%)	6(20%)	6(18.8%)	
Lesion				
• Abscess	0(0%)	10(33.3%)	10(31.3%)	1.000
• Ulcer	2(100%)	20(66.7%)	22(68.8%)	
Type of Osteomyelitis Type				
• Type 1	0(0%)	28(93.3%)	28(87.5%)	0.012*
• Type 2	0(0%)	0(0%)	0(0%)	
• Type 3	2(100%)	2(6.7%)	4(12.5%)	
Duration of Diabetes				
• <10yrs	0(0%)	19(63.3%)	19(59.4%)	0.157
• 11-20 yrs	2(100%)	11(36.7%)	13(40.6%)	
• >21yrs	0(0%)	0(0%)	0(0%)	

Chi-Square/Fisher Exact Test

Table 6 showing frequency distribution of clinical variables according to major amputation of patients studied

There was no correlation of age, gender, presenting lesion and duration of diabetes mellitus with the type of osteomyelitis. There was however a statistically significant association between type of osteomyelitis and type of treatment and amputation done [Table 7]. It was seen that significant number of minor amputation [92.6%] was seen in type 1 diabetic foot osteomyelitis and all the major amputation [Figure 4] occurred in type 3 diabetic foot osteomyelitis (P <0.001**).

variables	OM Type			Total (n=32)	P value
	Type 1 (n=28)	Type 2 (n=0)	Type 3 (n=4)		
Age in years					
• 31-40	1(3.6%)	0(0%)	0(0%)	1(3.1%)	0.381
• 41-50	7(25%)	0(0%)	2(50%)	9(28.1%)	
• 51-60	10(35.7%)	0(0%)	0(0%)	10(31.3%)	
• 61-70	6(21.4%)	0(0%)	2(50%)	8(25%)	
• 71-80	4(14.3%)	0(0%)	0(0%)	4(12.5%)	
Gender					
• Male	22(78.6%)	0(0%)	4(100%)	26(81.3%)	0.566
• Female	6(21.4%)	0(0%)	0(0%)	6(18.8%)	
Lesion					

• Abscess	10(35.7%)	0(0%)	0(0%)	10(31.3%)	0.283
• Ulcer	18(64.3%)	0(0%)	4(100%)	22(68.8%)	
Treatment					
• Conservative	2(7.1%)	0(0%)	1(25%)	3(9.4%)	<0.001**
• Minor amputation	26(92.9%)	0(0%)	0(0%)	26(81.3%)	
• Partial calcanectomy	0(0%)	0(0%)	1(25%)	1(3.1%)	
• Major amputation	0(0%)	0(0%)	2(50%)	2(6.3%)	
Duration of Diabetes					
• <10yrs	18(64.3%)	0(0%)	1(25%)	19(59.4%)	0.279
• 11-20yrs	10(35.7%)	0(0%)	3(75%)	13(40.6%)	
• >21yrs	0(0%)	0(0%)	0(0%)	0(0%)	
Any Amputation					
• No	26(92.9%)	0(0%)	2(50%)	28(87.5%)	0.066+
• Yes	2(7.1%)	0(0%)	2(50%)	4(12.5%)	

Chi-Square/Fisher Exact Test

Table 7 Showing correlation of clinical variables in relation to type of osteomyelitis in patients studied

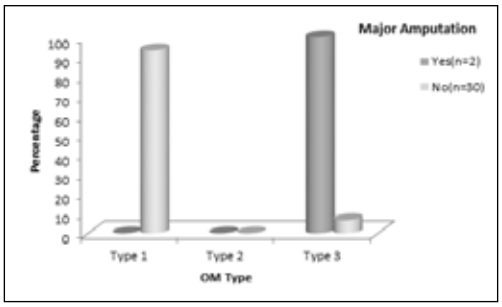

Figure 4 showing distribution of major amputation in different type of osteomyelitis.

There was no correlation of gender and presenting lesion with the treatment of the patients. However, a statistically significant association was seen between subtype of osteomyelitis and treatment given [Table 8]. All the patients with subtype A osteomyelitis (100%) underwent conservative treatment whereas all the major amputation (100%) occurred in subtype C osteomyelitis (P – 0.006**). There was no mortality in this study.

variables	Treatment				Total (n=32)	P value
	Conservative (n=3)	Minor amputation (n=26)	Partial calcanectomy (n=1)	Major amputation (n=2)		
Gender						
• Male	2(66.7%)	21(80.8%)	1(100%)	2(100%)	26(81.3%)	0.746
• Female	1(33.3%)	5(19.2%)	0(0%)	0(0%)	6(18.8%)	
Lesion						
• Abscess	2(66.7%)	8(30.8%)	0(0%)	0(0%)	10(31.3%)	0.530
• Ulcer	1(33.3%)	18(69.2%)	1(100%)	2(100%)	22(68.8%)	
Subtype						
• A	3(100%)	0(0%)	0(0%)	0(0%)	3(9.4%)	0.006**
• B	0(0%)	6(23.1%)	0(0%)	0(0%)	6(18.8%)	
• C	0(0%)	17(65.4%)	1(100%)	2(100%)	20(62.5%)	
• D	0(0%)	3(11.5%)	0(0%)	0(0%)	3(9.4%)	

Chi-Square/Fisher Exact Test

Table 8 showing correlation of clinical variables in relation to treatment of patients studied

Discussion

Over past few years, the management of diabetic foot osteomyelitis has been an issue of debate.[3,5,6] For decades, diabetic foot osteomyelitis was treated surgically. However, in past few years, it was seen that there were studies in which diabetic foot osteomyelitis was treated with antibiotics alone.[6] It can be observed that the antibiotic alone as treatment for osteomyelitis in diabetic foot was supported exclusively by few physicians.[14,15] Most of these studies that recommend antibiotic alone were done in western countries. On the contrary, the surgeons who favored surgical therapy for diabetic foot osteomyelitis, recommended it due to associated severity of underlying soft tissue infection, fear of more proximal amputation in case antibiotics fail and to deliver fast results in terms of healing and early return to work.[16]

Amit Jain's classification for diabetic foot osteomyelitis is a new specific focal classification that is a component of Amit Jain's principle and practice which is now a "***modern diabetic foot surgery system***".[17,18,19] This classification is simple, easy to remember, practical, can be used in day-to-day practice, effectively guides therapy and helps to predict outcomes.[20] Amit Jain's classification provides a better insight on diabetic foot osteomyelitis, and can be a better communication tool among treating doctors. More importantly it should be a foundation for formulating management guidelines for diabetic foot osteomyelitis, henceforth.

We compared our series with the recent Jain et al series [Table 9]

Parameters	Jain et al series (2019)	Our series
Gender	Males commonest [60.7%]	Males [81%]
Commonest lesion	Ulcer [82%]	Ulcer [69%]
Commonest type of osteomyelitis	Type 1 [85.7%]	Type 1 [87.5%]
Commonest subtype of osteomyelitis	Subtype C [57%]	Subtype C [59.4%]
Percentage of Major amputation	7.1%	6.7%
Commonest cause of Major Amputation	Type 3 osteomyelitis	Type 3 osteomyelitis

Table 9 showing comparison of our series with Jain et al series

In this study, 91% of the patients were managed surgically. Only 9% of the patients received medical treatment and all the patients were of subtype A (100%). This again reiterates the fact that medical management can be tried only in select few patients with diabetic foot osteomyelitis with subtype A. All the patients in the recent Jain et al study underwent surgical management.[20]

Lesser preference for medical management in developing country like India can be due to several factors like late presentations, long duration of antibiotic therapy and their problems with cost, compliance, resistance and side effects. Patients are less likely to have patience to wait for healing and remission.[20] Also, repeated x rays are needed to confirm radiologic resolution and long term dressing may be needed when patient on antibiotics till ulcer heals. Further, frequent visit to doctor to ensure that the wound does not worsen till it heals, adds to the financial burden to the patients many of whom may be of middle and lower socioeconomic status.

Majority of the patients in the current study underwent some form of amputation (96.5%) and so was the case in Jain et al (75%).[20] Only one patient (3.5%) underwent conservative surgery in our series, whereas in Jain et al series[20], 25% of the patients had conservative surgeries like debridement, curettage, metatarsal bone resection, partial calcanectomy, etc. In an earlier study by Jain et al on this classification, it was seen that around 28.5% underwent conservative surgery.[4]

In literature, major amputation from osteomyelitis ranges from 8 – 25%.[4] Higher incidence of major amputation in Jain et al first series[4] compared to other two studies on this classification including ours, may be attributed to the higher percentages of type 3 osteomyelitis seen in their study done in a premier referral hospital.[4] This underlines the strong association between type 3 diabetic foot osteomyelitis and the risk of major amputation. Further, Subtype C [Figure 5] is also associated significantly with minor and major amputation.

Figure 5 showing Amit Jain's type 1-C osteomyelitis of great toe. Note the cortical destruction on both sides.

The limitations in our study include a small sample size. Also, we did not analyze the culture and sensitivity reports as many of the surgeons send

pus / tissue for culture and sensitivity and do not have habit of sending bone for culture.

Conclusion

In this study, it is seen that type 1 osteomyelitis is the most common type seen in clinical practice. Subtype C is the most common subtype encountered and it is similar to earlier studies. Only 9.4% of the patients received medical management alone and all the patients receiving conservative treatment alone were done so only in subtype A osteomyelitis in this series. Major amputation significantly occurred in type 3 diabetic foot osteomyelitis and one should be cautious while dealing with this type of osteomyelitis.

Amit Jain's classification is a simple, easy to remember classification for diabetic foot osteomyelitis which gives a good guide to treatment and predicts outcomes of amputation. We strongly suggest that antibiotics alone as the treatment for diabetic foot osteomyelitis should be attempted in selected patients with subtype A osteomyelitis as most patients in developing country like India presents late with extensive underlying soft tissue infection.

Acknowledgement

All the authors would like to thank Dr. K.P. Suresh, Scientist (Biostatistics), National Institute of Veterinary Epidemiology and Disease Informatics (NIVEDI), Bangalore, India, for reviewing the research methodology and statistical results of the study.

References

1. Game F. Management of osteomyelitis of foot in diabetes mellitus. Nat Rev Endocrinol 2010;6:43-47.
2. Game FL. Osteomyelitis in the diabetic foot: Diagnosis and management. Med Clin N Am 2013;97:947-956.
3. Aragon-Sanchez FJ, Cabrera-Galvan JJ, Quintana-Marrero Y et al. Outcomes of surgical treatment of diabetic foot osteomyelitis: A series of 185 patients with histopathological confirmation of bone involvement. Diabetologia 2008;51(11):1962-70
4. Jain AKC, Vishwanath S. An analysis of osteomyelitis in diabetic foot using Amit Jain's classification of diabetic foot osteomyelitis. SEAJCRR 2014;3(4): 794–801.
5. Giurato L, Meloni M, Izzo V, Uccioli L. Osteomyelitis in diabetic foot: A comprehensive overview. World J Diabetes 2017; 8(4): 135-142.
6. Malhotra R, Chan CSY, Nather A. Osteomyelitis in diabetic foot. Diabetic Foot & Ankle 2014;5: 24445.
7. Loupa CV, Meimeti E, Voyatzoglou E et al. Successful nonsurgical therapy of a diabetic foot osteomyelitis in a patient with peripheral artery disease with almost complete radiological restoration. BMC Research Notes 2018;11:579.
8. Crim BE, Wukich DK. Osteomyelitis of the foot and ankle in the diabetic population: Diagnosis and treatment. J Diab Foot Comp 2009;1(2):26-35.
9. Jain AKC. A new classification of diabetic foot osteomyelitis. OA Case Reports 2013;2(3):121.
10. Suresh KP, Chandrasekhar S. Sample Size estimation and Power analysis for Clinical research studies. J Human Rep Sc. 2012;5(1):7-13.
11. Rosner B. In: Fundamentals of Biostatistics, 5th Edition, Duxbury, 2000.
12. Riffenburg RH. In: Statistics in Medicine, 2nd Edition, Academic press; 2005.
13. Rao PSSS, Richard J. In: An Introduction to Biostatistics, A manual for students in health sciences, New Delhi: Prentice hall of India. 4th Edition; 2006.
14. Game FL, Jeffcoate WJ. Primarily non-surgical management of osteomyelitis of the foot in diabetes. Diabetologia 2008; 51:962–967.
15. Lipsky BA. Treating Diabetic Foot Osteomyelitis Primarily With Surgery or Antibiotics: Have We Answered the Question?. Diabetes Care 2014;37(3):593-595.
16. Aragón Sánchez FJ. Why do I Choose Surgery to Treat Diabetic Foot Osteomyelitis? A Personal View. Clin Res Foot Ankle 2013;1: e103.
17. Gopal S. Amit Jain's classification for diabetic foot complications: The universal classification supreme. Int J Surg Sci 2018;2(2): 8–10.
18. Jain AKC, Apoorva HC, Kumar H, Kumar K, Rajagopalan S. Analyzing diabetic foot ulcer through Amit Jain's classification: a descriptive study. Int J Surg Sci 2018;2(4):26-32.
19. Jain AKC. Extended application of Amit Jain's 'SCC' classification concept for diabetic foot. Int J Surg Sci 2019;3(1):188-191.
20. Jain AKC, Apoorva HC, Kumar S. Refining the management of diabetic foot osteomyelitis through the Amit Jain's classification for diabetic foot osteomyelitis: an experience from a limb salvage centre. Wounds Middle East 2019;6(1):51-57.