

Refining the management of diabetic foot osteomyelitis through the Amit Jain's classification for diabetic foot osteomyelitis: an experience from a limb salvage centre



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Aim. A validation study to analyse diabetic foot osteomyelitis using Amit Jain's new classification for osteomyelitis and predict various related outcomes. **Methods and materials.** A descriptive retrospective analysis of 28 patients (60.7% male; mean duration of diabetes 16.07 ± 9.8 years) was conducted at Amit Jain's Institute of Diabetic Foot and Wound Care at Brindhavvan Areion Hospital, Bangalore, India between August 2016 and October 2018. **Results.** Type 1 diabetic foot osteomyelitis was found in 85.7% of patients; 10.7% had type 3 osteomyelitis. Subtype C was the most common (57%). Ulcer most often caused osteomyelitis (82.1%). Major amputation had occurred in 7.1% of patients and was significantly associated with type 3 osteomyelitis. **Conclusion.** Type 1, subtype C osteomyelitis was most commonly seen in clinical practice and was usually treated with conservative surgeries. Minor amputations were most frequent in type 1 and 2 osteomyelitis; major amputation was significantly associated with type 3 osteomyelitis. Those who favour purely medical management of osteomyelitis are recommended to prescribe antibiotics alone in subtype A osteomyelitis and in some subtype B patients (without deep-seated pus, cellulitis or slough/necrotic tissue). Amit Jain's classification for diabetic foot osteomyelitis is a simple, easy-to-remember, practical classification that guides treatment and predicts associated outcomes.

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Diabetic foot is a common complication of diabetes and remains a major challenge worldwide (Yazdanpanah et al, 2018). Diabetic foot complications, be they acute or chronic, are major cause of morbidity and mortality (Embil et al, 2018). It is believed that 15–25% of people with diabetes will develop an ulcer during their lifetime (Priyadarshini et al, 2018; Yazdanpanah et al, 2018) and diabetic foot problems remain the most common reason for hospitalisation (Yazdanpanah et al, 2018).

The overall prevalence of diabetic foot ulcers (DFUs) is reported to be between 1.3% and 12% (Yazdanpanah et al, 2018). The DFU becomes infected in over half of cases (Common et al, 2018). Infection can affect the soft tissue or bone, in the form of osteomyelitis (Aragon-Sanchez 2012). The prevalence of

osteomyelitis in people with diabetes ranges from 10% to 20% (Ramoutar et al, 2010; Jain and Vishwanath, 2014).

Despite being a common clinical condition, there are few classifications exclusively for diabetic foot osteomyelitis (Aragon-Sanchez, 2012; Jain, 2013; Jain and Vishwanath, 2014). In Wagner's staging for DFUs, infection and osteomyelitis are mentioned in general, in association with grade 3 ulcers, where osteomyelitis may or may not be present (Jain 2012; Kalaivani 2014). Amit Jain's classification is a new, specific classification focusing on osteomyelitis in the diabetic foot [Box 1]. This study assessed the application of Amit Jain's classification in practice.

Methods and materials

A descriptive retrospective analysis was performed at Amit Jain's Institute of Diabetic Foot and Wound Care at Brindhavvan Areion Hospital, Bangalore,

Box 1. Amit Jain's classification of osteomyelitis of the diabetic foot.

Type of osteomyelitis	Description
Type 1	Osteomyelitis of the forefoot
Type 2	Osteomyelitis of the midfoot
Type 3	Osteomyelitis of the hindfoot
Subtypes	
A	Probe-to-bone positive but X-ray does not show clear osteomyelitis, elevated erythrocyte sedimentation rate; bone scan or magnetic resonance imaging needed to confirm diagnosis
B	X-ray clearly shows cortical destruction on one side
C	X-ray shows completely destroyed bone or joint
D	X-ray shows the involvement of more than one bone/joint

India. This dedicated wing recently developed a model for diabetic foot management in which the diabetic foot surgeon heads the diabetic foot team (Jain, 2018). During the study period — August 2016 to October 2018 — all case records and X-rays were reviewed.

To be included in the study, patients must:

1. Have been treated for diabetic foot osteomyelitis in Amit Jain's Institute
2. Have been treated elsewhere and come to Amit Jain's Institute for further management.

Patients were excluded if:

1. They had osteomyelitis, but did not have diabetes
2. They were being treated in another department
3. There were insufficient/incomplete records or missing X-rays
4. They had refused treatment.

Data analysis

Data were analysed using SPSS 18.0 and R environment Version 3.2.2 software. Microsoft Word and Excel were used to create graphs and tables. Descriptive and inferential statistical analyses were carried out. The results of continuous measurements are presented as mean with standard deviation and the categorical measurements are presented as numbers and percentages. A *P*-value >0.05 was considered significant.

A number of assumptions were made about the data:

- Dependent variables were normally distributed
- Samples were drawn from the population at random
- Cases from the samples were independent.

Chi-squared/Fisher's exact test were used to find the significance of study parameters on a categorical scale between two or more groups. Analysis of variance (ANOVA) was used to find the significance of study parameters between three or more groups of patients. A non-parametric setting for was used for qualitative data analysis. Fisher's exact test was used when the cell samples were very small.

Results

Of 37 patients, 28 fulfilled the inclusion criteria and were included in this study. Seventeen patients were male (60.7%) and 11 were female (39.3%). The majority of the patients were older, with 39.3% being aged 50–60 and 28.6% being 61–70 years of age [Table 1].

The right foot was involved in 17 patients, the left in 10 patients, and 1 patient had bilateral involvement [Figure 1]. Ten patients had a 6–10-year duration of diabetes and two patients had had diabetes for over 30 years [Table 2]. The mean duration of diabetes was 16.07 ± 9.80 years. One patient had type 1 diabetes and the remainder had type 2 diabetes.

All three types of osteomyelitis were found in the patient group [Figure 2]. The majority of patients (85.7%) had type 1 osteomyelitis. All four subtypes were present [Figure 3]. The most common subtype

Table 1: Age distribution of patients studied.

Age in years	No. of patients	%
<50	2	7.1
50-60	11	39.3
61-70	8	28.6
71-80	6	21.4
>80	1	3.6
Total	28	100.0

Mean \pm SD: 61.71 ± 12.51 .

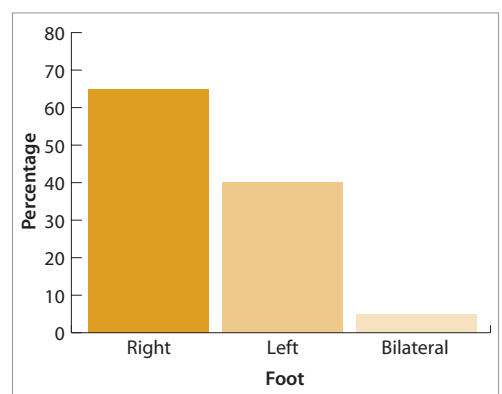


Figure 1: Distribution of osteomyelitis in patients' feet.

Table 2: Duration of diabetes in the patients studied (n=28).

Duration	No. of patients	Percentage
1-5	2	7.1
6-10	10	35.7
11-20	9	32.1
21-30	5	17.9
>30	2	7.1

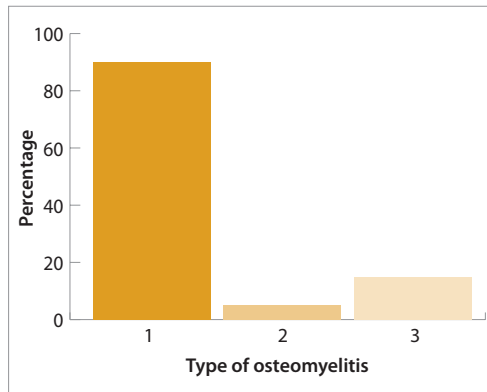


Figure 2: Distribution of type of osteomyelitis.

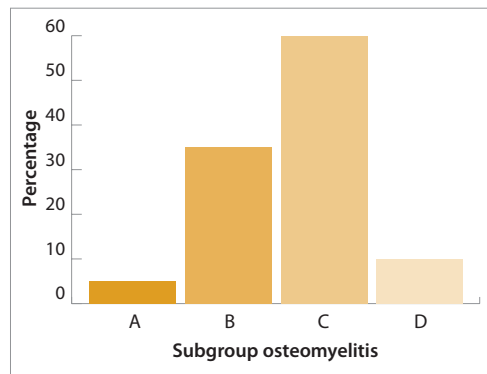


Figure 3: Subtype osteomyelitis distribution of patients studied.

was subtype C, which affected 16 patients (57%). Subtype B affected 9 patients (32.1%). Ulcer was most commonly associated with osteomyelitis (23 patients; 82.1%), followed by abscess (five patients; 17.9%) [Figure 4].

Twenty patients (71.4%) had associated comorbidities. Hypertension was the most common comorbidity (71.4%). Four patients (14.3%) had ischaemic heart disease. Although there was no association between age and comorbidity, female patients had greater associated comorbidity compared to males ($P=0.099$) [Table 3].

Patients underwent various forms of surgery [Table 4]. Conservative surgery, consisting of debridement and/or curettage and phalangectomy, was performed in seven patients (25%). The most common procedure was toe amputation (50%). Two patients (7.1%) underwent major amputation. No patients were on antibiotic

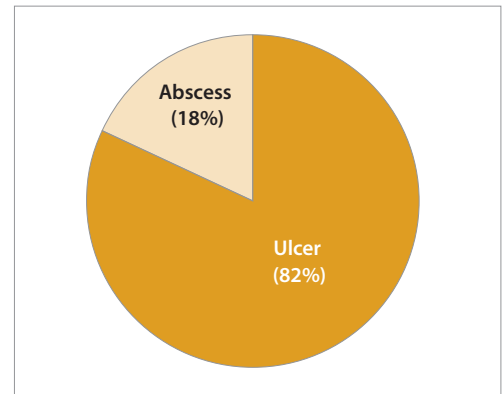


Figure 4: Types of lesion present in participants.

Table 3: Correlation of age and gender in relation to comorbidity.

Variable	Comorbidity		Total (n=28)	P-value
	Yes (n=20)	No (n=8)		
Age				
<50	0 (0.0%)	2 (28.6%)	2 (7.1%)	0.108
50-60	7 (33.3%)	4 (57.1%)	11 (39.3%)	
61-70	6 (28.6%)	2 (28.6%)	8 (28.6%)	
71-80	6 (28.6%)	0 (0.0%)	6 (21.4%)	
>80	1 (4.8%)	0 (0.0%)	1 (3.6%)	
Gender				
Male	10 (47.6%)	7 (85.7%)	17 (60.7%)	0.099*
Female	10 (47.6%)	1 (14.3%)	11 (39.3%)	

Chi-square/Fisher's exact test; *significant ($0.05 < p < 0.10$)

Table 4: Type of surgery performed.

Surgery	No. of patients	Percentage
Debridement ± curettage	5	17.9
Phalangectomy	2	7.1
Toe amputation	14	50.0
Transmetatarsal amputation	4	14.3
Midfoot amputation	1	3.6
Below-knee amputation	2	7.1

treatment alone. Overall, some form of amputation was performed in three-quarters of patients.

There was no correlation of age, gender, foot involved, type of diabetes, type or subtype of osteomyelitis, associated lesion or comorbidities with amputation [Table 5]. The type of lesion and type or subtype of osteomyelitis were not correlated [Table 6]. In this study, there was no correlation between subgroup of osteomyelitis with major amputation in this study. A significant association ($P=0.016$) was noted between type of osteomyelitis and major amputation [Table 7]. It was

Table 5: Correlation of clinical variables in relation to amputation of patients studied.

Variable	Amputation		Total (n=28)	P-value
	Yes (n=21)	No (n=7)		
Age (years)				
<50	2 (9.5%)	0 (0.0%)	2 (7.1%)	0.343
50–60	7 (33.3%)	4 (57.1%)	11 (39.3%)	
61–70	7 (33.3%)	1 (14.3%)	8 (28.6%)	
71–80	5 (23.8%)	1 (14.3%)	6 (21.4%)	
>80	0 (0.0%)	1 (14.3%)	1 (3.6%)	
Gender				
Male	14 (66.7%)	3 (42.9%)	17 (60.7%)	0.381
Female	7 (33.3%)	4 (57.1%)	11 (39.3%)	
Foot involved				
Right	12 (57.1%)	5 (71.4%)	17 (60.7%)	0.759
Left	8 (38.1%)	2 (28.6%)	10 (35.7%)	
Bilateral	1 (4.8%)	0 (0.0%)	1 (3.6%)	
Type of diabetes				
Type 1	1 (4.8%)	0 (0.0%)	1 (3.6%)	1.000
Type 2	20 (95.2%)	7 (100.0%)	27 (96.4%)	
Type of osteomyelitis				
1	18 (85.7%)	6 (85.7%)	24 (85.7%)	1.000
2	1 (4.8%)	0 (0%)	1 (3.6%)	
3	2 (9.5%)	1 (14.3%)	3 (10.7%)	
Subtype of osteomyelitis				
A	1 (4.8%)	0 (0%)	1 (3.6%)	0.421
B	5 (23.8%)	4 (57.1%)	9 (32.1%)	
C	13 (61.9%)	3 (42.9%)	16 (57.1%)	
D	2 (9.5%)	0 (0.0%)	2 (7.1%)	
Lesion				
Ulcer	18 (85.7%)	5 (71.4%)	23 (82.1%)	0.574
Abscess	3 (14.3%)	2 (28.6%)	5 (17.9%)	
Comorbidities				
Yes	14 (66.7%)	6 (85.7%)	20 (71.4%)	0.633
No	7 (33.3%)	1 (14.3%)	8 (28.6%)	

Chi-square/Fisher's exact test.

observed that 80% of type 1 osteomyelitis patients had debridement and/or curettage (conservative surgery) compared to 20% of patients with type 3 osteomyelitis. There was no major amputation in type 1 or 2 osteomyelitis [Table 8]; both below-knee amputations occurred in type 3 osteomyelitis ($P < 0.001$). The association between type of surgery and type of osteomyelitis was statistically significant [Figure 5]. Toe and transmetatarsal amputations were most frequent in type 1 osteomyelitis. There was no correlation between type of osteomyelitis with age, gender, diabetes mellitus duration and subtype of osteomyelitis [Table 9]. There was one case of osteomyelitis along

Table 6: Correlation of clinical variables in relation to lesion of patients studied.

Variable	Lesion		Total (n=28)	P-value
	Ulcer (n=23)	Abscess (n=5)		
Type of osteomyelitis				
1	19 (82.6%)	5 (100%)	24 (85.7%)	1.000
2	1 (4.3%)	0 (0.0%)	1 (3.6%)	
3	3 (13%)	0 (0.0%)	3 (10.7%)	
Subtype of osteomyelitis				
A	1 (4.3%)	0 (0.0%)	1 (3.6%)	1.000
B	7 (30.4%)	2 (40.0%)	9 (32.1%)	
C	13 (56.5%)	3 (60.0%)	16 (57.1%)	
D	2 (8.7%)	0 (0.0%)	2 (7.1%)	

Chi-square/Fisher's exact test.

with Charcot foot, and the patient underwent major amputation. No patients had peripheral arterial disease and there was no mortality in the authors' series.

Discussion

Osteomyelitis in the diabetic foot is often a challenge to diagnose and treat (Hoffman et al, 2009; Jain and Vishwanath, 2014). A major issue is the lack of an agreed guideline for diagnosis or management, which has led to controversies (Berendt et al, 2008). Another issue is that osteomyelitis of foot is associated with amputation (Ramoutar et al, 2010).

Osteomyelitis in adults with diabetes can occur in acute (abscess) or chronic (long-standing ulcers) circumstances (Jain, 2012). It is believed that osteomyelitis results from infection of an adjacent wound in 94% of cases (Nube et al, 2007). In a study by Jain and Vishwanath (2014), almost all of the cases of diabetic foot with osteomyelitis were due to local pathology.

Amit Jain's classification is unique and specific to osteomyelitis of the diabetic foot (Jain, 2013). It is a component of Amit Jain's principle and practice of diabetic foot management (Gopal, 2018). The classification is simple, easy to remember, practical, can be used in day-to-day practice, effectively guides therapy and helps to predict outcomes.

This classification is divided osteomyelitis into three main types based on location (the forefoot, midfoot and hindfoot) and four subtypes (A–D) based on radiological findings. Subtypes B, C and D are evident in X-rays; subtype A has a positive probe-to-bone test and elevated erythrocyte sedimentation rate, but no visible changes on X-ray (Jain, 2013; Jain et al, 2014). It may take several weeks for X-rays to show change due to osteomyelitis (Nube et al, 2007; Ramoutar et al, 2010; Berendt et al, 2008), therefore, nuclear or MRI

scan of the foot should be used to help confirm osteomyelitis in subgroup A (Lipsky, 1997).

Studies have shown that the majority of DFUs occur in the forefoot (90%) and, hence, osteomyelitis is common in this region (Crim and Wukich, 2009; Jain et al, 2014). Calcaneal osteomyelitis occurs in 4–8% of cases (Wang et al, 1992; Crim et al, 2009). In a series (Jain et al, 2014) at a teaching referral hospital, type 1 osteomyelitis with forefoot involvement was seen in 57.14% of cases and the calcaneum was involved in 23.81% of cases (type 3 osteomyelitis). The reason for the high proportion of calcaneal osteomyelitis in this series was possibly due to delayed referral, as many clinicians avoid treating calcaneal osteomyelitis (Jain and Vishwanath, 2014). In the current series, 85.7% had type 1 osteomyelitis (forefoot) and 10.7% had type 3 osteomyelitis (hindfoot/calcaneum).

Subtype C was the most common subtype in this study [Figure 6] and in Jain and Vishwanath's (2014). In the earlier series, 9.52% had associated Charcot foot, whereas the proportion was lower in the current study, at 3.6%.

Several studies favour antibiotic therapy alone for the treatment of osteomyelitis. These studies have not described the type/subtype of osteomyelitis, extent of infection, any deterioration of condition or types of associated lesions, or even the associated outcomes (Senneville et al, 2008; Lipsky 2014; Veeranna et al, 2014). Furthermore, there are many reasons why many surgeons refrain from relying on antibiotics alone, such as the presence of drug resistant organisms, the associated complications of prolonged usage of antibiotics, patient compliance and the need for prompt results. In fact, many experts prefer surgical therapy ranging from conservative surgery to amputation (Van et al, 1996; Senneville et al, 2008; Aragon-Sanchez, 2013). Van et al (1996) defined conservative surgery as limited resection of the infected part of the phalanx or metatarsal bone with removal of the ulcer site and no other resection. They showed an improved outcomes with conservative surgery compared to medical treatment alone.

Using Amit Jain's classification for osteomyelitis, 28.57% of patients underwent conservative surgery, 38.09% had a minor amputation and 33.33% had major amputation in Jain and Vishwanath's (2014) study, with type 3 osteomyelitis being the most common reason for major amputation. None of the patients in the current study were on antibiotics alone. This may be due to the fact that most patients were referred and had some form of delayed presentation. Many physicians try antibiotic treatment and, when the wound deteriorates, refer their patient to the surgeon. Even direct presentation by patients may be late.

Table 7: Type and subtype of osteomyelitis in relation to major amputation.

Variables	Amputation		Total (n=28)	P-value
	Yes (n=2)	No (n=26)		
Type of osteomyelitis				
1	0 (0.0%)	24 (92.3%)	24 (85.7%)	0.016*
2	0 (0.0%)	1 (3.8%)	1 (3.6%)	
3	2 (100%)	1 (3.8%)	3 (10.7%)	
Subtype of osteomyelitis				
A	0 (0%)	1 (3.8%)	1 (3.6%)	1.000
B	1 (50%)	8 (30.8%)	9 (32.1%)	
C	1 (50%)	15 (57.7%)	16 (57.1%)	
D	0 (0%)	2 (7.7%)	2 (7.1%)	

Chi-square/Fisher's exact test; *moderately significant (0.01 < P > 0.05).

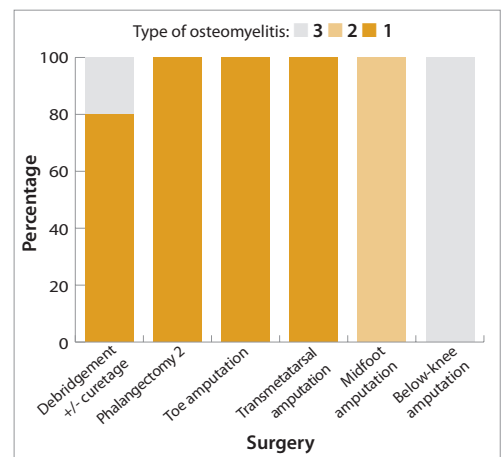


Figure 5: Relationship between type of surgery and type of osteomyelitis (1, 2 or 3).

In our study, 75% of patients had some form of amputation, with toe amputation being most common. The authors initiated intravenous antibiotics (preferably fluoroquinolones or a third-generation cephalosporin with or without clindamycin) prior to surgery and later modified antibiotics based on culture and sensitivity report. The duration of antibiotics depended upon the clinical scenario of the wound, the type and subtype of osteomyelitis, the type of surgery performed and systemic condition of the patients. Overall, we rarely prescribed antibiotics for longer than 4 weeks. Other modalities of care, such as wound dressings and offloading, also formed part of our treatment.

Conservative surgery occurred in four-fifths of type 1 osteomyelitis cases and 20% of type 3 osteomyelitis cases. Minor amputations were seen in type 1 and 2 osteomyelitis; whereas major amputation was significantly associated with type 3 diabetic foot osteomyelitis. From this and the previous series (Jain and Viswanath, 2014), the authors recommend that the use of antibiotics

Table 8: Type of osteomyelitis/subgroup osteomyelitis in relation to surgery of patients studied.

Variable	Surgery						P value
	Debridement +/- curetage (n=5)	Phalangectomy (n=2)	Toe amputation (n=14)	Transmetatarsal amputation (n=4)	Midfoot amputation (n=1)	Below-knee amputation (n=2)	
Type Osteomyelitis							
1	4 (80%)	2 (100%)	14 (100%)	4 (100%)	0 (0%)	0 (0%)	<0.001*
2	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	
3	1 (20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (100%)	
Subtype of osteomyelitis							
A	0 (0%)	0 (0%)	1 (7.1%)	0 (0%)	0 (0%)	0 (0%)	0.103
B	4 (80%)	0 (0%)	3 (21.4%)	1 (25%)	0 (0%)	1 (50%)	
C	1 (20%)	2 (100%)	10 (71.4%)	2 (50%)	0 (0%)	1 (50%)	
D	0 (0%)	0 (0%)	0 (0%)	1 (25%)	1 (100%)	0 (0%)	

Chi-square/Fisher's exact test; *high level of significance.

Table 9: Correlation of clinical variables in relation to type of osteomyelitis of patients studied.

Variable	Type of osteomyelitis			Total (n=28)	P-value
	1 (n=24)	2 (n=1)	3 (n=3)		
Age (years)					
<50	1 (4.2%)	0 (0%)	1 (33.3%)	2 (7.1%)	0.345
50–60	8 (33.3%)	1 (100%)	2 (66.7%)	11 (39.3%)	
61–70	8 (33.3%)	0 (0%)	0 (0%)	8 (28.6%)	
71–80	6 (25%)	0 (0%)	0 (0%)	6 (21.4%)	
>80	1 (4.2%)	0 (0%)	0 (0%)	1 (3.6%)	
Gender					
Male	14 (58.3%)	1 (100%)	2 (66.7%)	17 (60.7%)	1.000
Female	10 (41.7%)	0 (0%)	1 (33.3%)	11 (39.3%)	
Duration of diabetes (years)					
1–5	2 (8.3%)	0 (0%)	0 (0%)	2 (7.1%)	0.907
6–10	8 (33.3%)	1 (100%)	1 (33.3%)	10 (35.7%)	
11–20	7 (29.2%)	0 (0%)	2 (66.7%)	9 (32.1%)	
21–30	5 (20.8%)	0 (0%)	0 (0%)	5 (17.9%)	
>30	2 (8.3%)	0 (0%)	0 (0%)	2 (7.1%)	
Subtype of osteomyelitis					
A	1 (4.2%)	0 (0%)	0 (0%)	1 (3.6%)	0.167
B	7 (29.2%)	0 (0%)	2 (66.7%)	9 (32.1%)	
C	15 (62.5%)	0 (0%)	1 (33.3%)	16 (57.1%)	
D	1 (4.2%)	1 (100%)	0 (0%)	2 (7.1%)	

Chi-square/Fisher's exact test.

alone be considered only in subtype A, and possibly in few cases of subtype B osteomyelitis, providing there is no pus being discharged, no surrounding cellulitis or necrosis/slough over the ulcer. Subtypes C and D invariably require more radical surgical resection/amputation in view of the risk of deep-seated infection, ascending/worsening infection. Medical management (antibiotic) alone for type 2 and 3 osteomyelitis with subgroup A/B should be

attempted with extreme caution. Foot surgeons should rule out the presence of deep-seated infection, pus and necrotic tissue, keeping in mind that osteomyelitis involving the hindfoot is significantly associated with major amputation.

Conclusion

In this validation study, type 1 diabetic foot osteomyelitis subtype C, was most common in clinical practice. Conservative surgeries were

most frequent in type 1 osteomyelitis, minor amputations in type 1 and 2 osteomyelitis, and major amputation in type 3 osteomyelitis. It is strongly recommended that those who favour purely medical management give antibiotics alone in subtype A and in cases of subtype B with no deep-seated pus or surrounding cellulitis or slough/necrotic tissue to impede healing. In such cases, conservative surgeries may be required. Physicians can consider antibiotic therapy alone in type 1 osteomyelitis, as failure of treatment has no major consequences. Type 3 osteomyelitis is associated with major amputation and requires expertise to decide upon the best treatment.

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Figure 6. X-ray of osteomyelitis of great toe: Amit Jain's type 1C osteomyelitis.