Pathology and Microbiology Concordance Testing between Surgeon and Interventional Radiology obtained Bone Biopsy Samples in the setting of Calcaneal Osteomyelitis

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Introduction, Purpose & Methods

Introduction

Standardizing diagnostic methods for osteomyelitis (OM) in lower extremity diabetic ulcerations has proven difficult. Characterization of possible OM requires clinical, laboratory, and radiographic evaluation[1,2,3,4,5]. The most effective combination of testing remains unclear[6]. Current testing is not binary in nature and confounds the diagnosis of OM, making surgical planning challenging. Furthermore, some locations in the foot are high risk for amputation and an inaccurate diagnosis can adversely affect limb salvage[9].

The Infectious Disease Society of America (IDSA) diabetic foot infection guidelines state when inadequate or confounding pre-biopsy information exists, bone biopsy by either surgeons or interventional radiologists be performed under the guidance of fluoroscopy[5].

Pre-biopsy clinical, laboratory, and radiographic/MRI imaging are employed to identify pedal OM. Unsuccessful initial diagnosis of calcaneal OM can have serious, life-threatening consequences for the patient (i.e. sepsis, bacteremia, end-organ damage, etc.) and can be excessively expensive in terms of quality of life and financial measures.

Figure 1 (below) demonstrates the difficulty in detecting bone infection. It also indicates the importance of high quality histo-pathology/microbiology specimens for appropriate treatment selection.

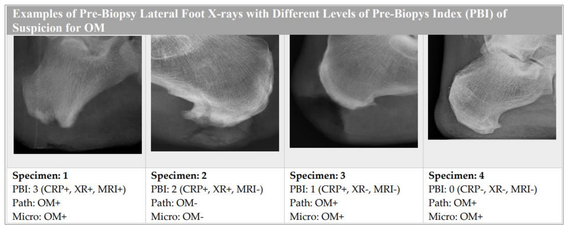

Figure 1 (above): Specimen 2 demonstrates cortical erosions of the plantar calcaneus with communicating wound sinus tract, but has no detectable OM. Specimen 4 has no pre-biopsy evidence for OM and yet bone biopsy specimens are histologically and microbiologically positive for OM.

Purpose

This work retrospectively examines bone biopsy results obtained by either surgeons or interventional radiologists (IR) of patients with calcaneal OM. The two groups are compared using patient stratification based on: advanced diabetes co-morbidities, pre biopsy evidences for OM (i.e. C-reactive protein (CRP), x-ray, MRI), and histopathologic and microbiologic biopsy results.

Methods

Between January 1, 2014 and January 1, 2019, pathology records obtained by Baylor Scott & White Memorial Hospital, Temple, TX were examined via EMR (Epic, Powerpath), producing 1,671 pathology samples. Samples were filtered to contain only specimens obtained from the calcaneus and with potential OM diagnosis. Patients that previously sampled OM+ at the calcaneus were also excluded. 57 total samples met this criteria.

Patients were divided into associated surgeon and IR groups (based on respective specialist type performing bone biopsy). Descriptive variables (age, gender, height, weight) and co-morbidities (tobacco history, diabetes, renal failure, peripheral neuropathy, peripheral vascular disease, cardiac disease, prior amputation history) were recorded. The co-morbidity score gave one point for each positive co-morbidity detailed above. The scores helped determine if a disproportionate number of unhealthy patients were sent to one of the biopsy groups to identify selection bias.

Histopathology bone biopsy results were recorded as being positive or negative for OM. Positive results were further classified as acute, chronic, or acute & chronic OM. Microbiologic culture results were identified as positive or negative for growth. Positive samples were further categorized into gram positive, gram negative, or anaerobic organisms.

Results & Discussion

Demographics and Diabetic Stratification of the Sample Groups

Table 1 summarizes patients' demographic and co-morbidity information. The co-morbidity risk stratification in Figure 2, demonstrates relative consistency between number of patients per group and co-morbidity distribution.

	N	Mean Age (yrs.)	Gender	Tobacco Use	Diabetic	Renal Failure	Peripheral Neuropathy	Peripheral Vascular Disease	Cardiac Disease
Surgeon	37	56.9	F(14), M(23)	38%	68%	43%	65%	35%	49%
IR	20	58.7	F(8), M(12)	35%	60%	60%	50%	45%	35%

Table 1 (above): demographic and co-morbidity summary for respective surgeon and IR bone biopsy groups.

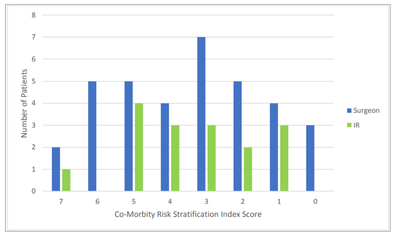

Figure 2 (left): Co-morbidity spectrum risk stratification for respective surgeon and IR bone biopsy groups.

Pre-Biopsy Index (PBI) Suspicion for Osteomyelitis with Biopsy Results

A pre-biopsy suspicion index score was created by giving one point for each positive criterion met, with a maximum score of three. Pre-biopsy data included: C-reactive protein levels (14 mg/L)[8], radiologist x-ray, and MRI reports noting OM. The results of the histopathologic and microbiologic analyses of the bone biopsies for both surgeons (Table 2) and IR (Table 3) are shown below. Table 4 summarizes the results of the two sampling groups. In the case of OM negative, neither the pathologic or microbiologic analysis yielded positive findings. The relative number of OM positive patients in the surgeons group more than tripled the number of OM positive patients in the IR group.

Histopathologic and Microbiologic Bone Biopsy Results: Surgeon Group					
Pre-Biopsy OM Suspicion Index	Number of Samples	Path OM+	Path OM-	Micro Positive for Bacterial Growth	Micro Negative for Bacterial Growth
3	3	3	0	1	2
2	11	5	6	7	5
1	17	9	8	14	3
0	4	3	1	4	0

Table 2 (above): Surgeon bone biopsy histopathologic (Path) and microbiologic (Micro) results stratified based on pre-biopsy suspicion index. A score of 0 indicates there were no qualified evidences indicating OM presence.

Histopathologic and Microbiologic Bone Biopsy Results: IR Group					
Pre-Biopsy OM Suspicion Index	Number of Samples	Path OM+	Path OM-	Micro Positive for Bacterial Growth	Micro Negative for Bacterial Growth
3	1	0	1	0	1
2	9	1	8	1	8
1	6	2	4	1	5
0	0	0	0	0	0

Table 3 (above): IR bone biopsy histopathologic (Path) and microbiologic (Micro) results stratified based on pre-biopsy suspicion index. A score of 0 indicates there were no qualified evidences indicating OM presence.

Table 4 (right): Bone biopsy results for the surgeon and IR groups.

Summarized Patient Totals for Osteomyelitis in Bone Biopsy Samples		
	OM Positive	OM Negative
Surgeons	33 (89%)	4 (12%)
IR	5 (25%)	15 (75%)

Results & Discussion Cont.

Path/Micro Result Concordance

Table 5 and Table 6 are summaries of the pathology and microbiology results of acute OM, chronic OM, and positive culture results. These tables demonstrate the respective testing overlap. Findings are congruent with previously published generalized diabetic osteomyelitis results [10]. Pathology and microbiology analysis are critical in capturing potential OM presence.

Pathologic/Microbiologic Bone Biopsy Concordance Results: Surgeons Group				
Acute Path Reported	Chronic Path Reported	Microbiologic Culture Results	Samples	Meaning
+	-	+	7	OM+
+	+	+	3	OM+
-	+	+	5	OM+
-	-	+	11	OM+
-	-	-	**4**	**OM-**
+	-	-	0	OM+
-	+	-	3	OM+
+	+	-	2	OM+

Table 5 (above): Concordance of pathology and microbiology results are displayed for the surgeon group.

Pathologic/Microbiologic Bone Biopsy Concordance Results: IR Group				
Acute Path Reported	Chronic Path Reported	Microbiologic Culture Results	Samples	Meaning
+	-	+	0	OM+
+	+	+	0	OM+
-	+	+	0	OM+
-	-	+	3	OM+
-	-	-	**13**	**OM-**
+	-	-	2	OM+
-	+	-	2	OM+
+	+	-	0	OM+

Table 6 (above): Concordance of pathology and microbiology results are displayed for the IR group.

Further analysis was conducted on samples positive for microbiologic growth. Table 7 indicates presence of gram positive, gram negative, or anaerobic bacteria in the samples. Both groups demonstrated similar rates of various organism growth. The surgeon group had more positive samples.

Summarized Results for Type of Microbial Infection in Culture Positive Bone Biopsy Samples				
	Samples Micro +	Gram+ Samples	Gram- Samples	Anaerobic Samples
Surgeon	26	24	12	11
IR	3	2	1	0

Table 7 (above): Microbial infection results from samples that tested positive for microbiologic growth.

Corresponding Treatment

Table 8 compares treatment rates (surgical/antibiotic vs. antibiotic only) between the two groups. Data revealed a higher number of surgeon group patients received treatment, and IR group patients are under treated for OM and more likely to face limb/life-threatening sequela.

Summarized Treatment Results for Patients Diagnosed with Osteomyelitis		
	Surgery/Antibiotics	Antibiotics Only
Surgeons	12 (36%)	21 (63%)
IR	2 (40%)	3 (60%)

Table 8 (above): Summarized treatment results for the surgeon and IR groups.

Limitations & Conclusion

Limitations

There are limitations using histopathology for OM diagnosis, particularly in the context of inter-rater reliability[7]. This work did not address this limitation. However, all pathology samples obtained in this study were analyzed by the same pathologist, subjecting samples from both groups to the same intrinsic error. This work also used biopsy culture results for OM positive characterization, which has been recommended in OM diagnosis in the recent literature[10].

Conclusion

This research attempted to address one of the most difficult components of complicated diabetic limb salvage: the correct diagnosis of OM and subsequent treatment. This work selected patients with suspected calcaneal OM, one of the highest at-risk populations for proximal leg amputations.

This work also investigated whether surgeon or interventional radiologist obtained bone biopsy samples had better rates of OM detection. Correct detection of OM allows proper surgical and/or medical treatment of underlying disease. Prior to this work, no other investigations have explored consistencies between bone samples obtained from these groups for diagnosis of OM.

Based on the findings presented here, it suggests that surgeon obtained biopsies should be utilized for diagnosis of OM and corresponding treatment.

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