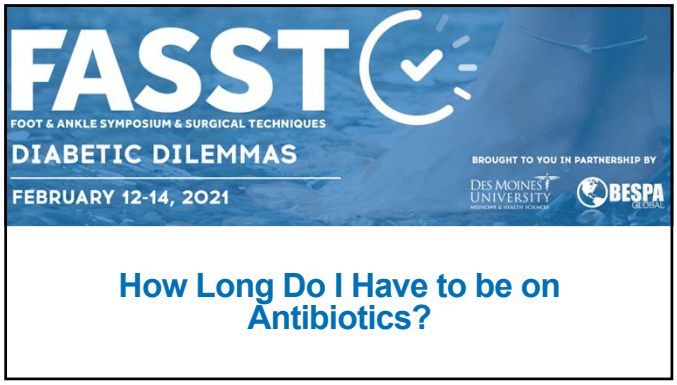
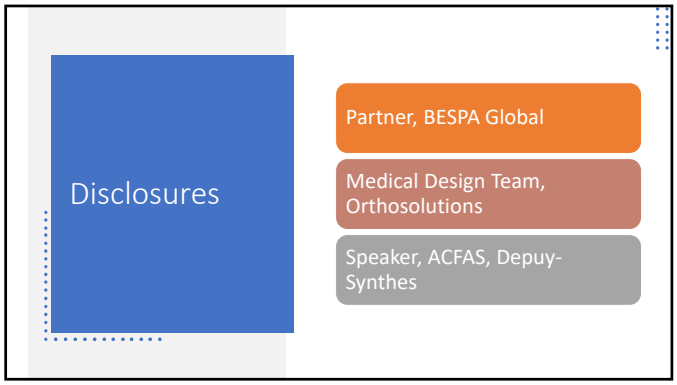

FASST
FOOT & ANKLE SYMPOSIUM & SURGICAL TECHNIQUES
DIABETIC DILEMMAS
FEBRUARY 12-14, 2021
BROUGHT TO YOU IN PARTNERSHIP BY
DES MOINES UNIVERSITY
BESPA
How Long Do I Have to be on Antibiotics?

1


Disclosures
Partner, BESPA Global
Medical Design Team, Orthosolutions
Speaker, ACFAS, Depuy-Synthes

2


Diabetic Foot Infections
• High Burden of Morbidity
• High Costs
• Recurrence or new episodes of infection occur frequently

3

Thought Process…

- **Prescribing an unnecessarily broad-spectrum regimen**
- **Parenteral rather than oral therapy**
- **Longer duration than necessary**

4

SUPPLEMENT ARTICLE

WILEY

Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update)

Benjamin A. Lipsky[1,2] | Eric Senneville[3] | Zulfiqarali G. Abbas[4] | Javier Aragón-Sánchez[5] | Mathew Diggle[6] | John M. Embil[7] | Shigeo Kono[8] | Lawrence A. Lavery[9] | Matthew Malone[10,11] | Suzanne A. van Asten[12] | Vilma Urbančič-Rovan[13] | Edgar J.G. Peters[14] on behalf of the International Working Group on the Diabetic Foot (IWGDF)

Principles and practice of antibiotic stewardship in the management of diabetic foot infections

Ilker Uçkay[a,b], Martin Berli[a], Parham Sendi[b,c], and Benjamin A. Lipsky[d,e]

Table 2. Ten major rules for antimicrobial stewardship in diabetic foot infection (DFI)

Prevent DFI. Closely monitor diabetic patients at risk for infection and optimize all aspects related to foot care, including appropriate foot ware, nail and skin care and treatment of any wounds.
Diagnosing DFI correctly: Be precise and consistent when diagnosing, and describing the severity of, infection.
Exclude noninfectious causes of foot inflammation: These include trauma, gout/pseudogout, Charcot neuro-osteoarthropathy, fracture, phlebothrombosis, and venous stasis.
Identify causative pathogens: Send samples of tissue (not swabs) and preferably bone (for suspected osteomyelitis). Review results of any previously obtained cultures. Attempt to differentiate pathogens (requiring treatment) from colonizing or contaminating organisms.
Differentiate between soft-tissue and bone infection: This helps in making decisions with respect to medical versus surgical, urgency of, and duration of, treatment.
Ensure specialist consultation for most moderate and all severe infections: Evaluate and individualize treatment options for each patient. In severe cases, involve specialists (or optimally multidisciplinary teams), especially surgeons.
Choose an effective antibiotic regimen with the narrowest spectrum: For empiric, and especially definitive, therapy select an antibiotic regimen based on the likely or proven causative pathogen(s), their antibiotic susceptibilities, and, evidence of efficacy for DFIs. Consider testing in cases of reported 'penicillin allergy'.
Optimize patient-related effectiveness of antibiotic therapy: Evaluate for factors such as adherence to the treatment regimen, impaired gastrointestinal absorption, key comorbidities (obesity, renal failure), and presence of clinically significant peripheral arterial disease in affected limb.
Medical therapy – as long as necessary and as short as possible: For most mild and moderate soft tissue infections 1–2 weeks of therapy is sufficient. For osteomyelitis with residual infected bone, prescribe no more than 6 weeks of antibiotic therapy. Consider shorter treatment durations if infection resolves quickly.
Surgical treatment – can limit need for antibiotic therapy: Draining abscesses and resecting infected bone can limit the duration of antibiotic therapy required.

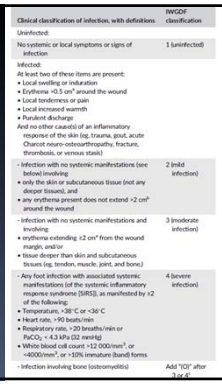
5

#1 Prevent DFI

- Closely monitor diabetic patients at risk for infection and optimize all aspects related to foot care, including appropriate footware, nail and skin care and treatment of any wounds

6

#2 Diagnosing DFI Correctly

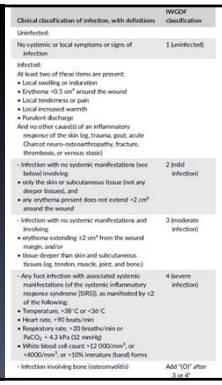


Clinical classification of infection, with definitions	IWGDF classification
Uninfected:	
No systemic or local symptoms or signs of infection	1 (uninfected)
Infected:	
At least two of these items are present:	
• Local swelling or induration	
• Erythema >0.5 cm* around the wound	
• Local tenderness or pain	
• Local increased warmth	
• Purulent discharge	
And no other cause(s) of an inflammatory response of the skin (eg, trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, or venous stasis)	
- Infection with no systemic manifestations (see below) involving • only the skin or subcutaneous tissue (not any deeper tissues), and • any erythema present does not extend >2 cm* around the wound	2 (mild infection)
- Infection with no systemic manifestations and involving: • erythema extending ≥2 cm* from the wound margin, and/or • tissue deeper than skin and subcutaneous tissues (eg, tendon, muscle, joint, and bone.)	3 (moderate infection)
- Any foot infection with associated systemic manifestations (of the systemic inflammatory response syndrome [SIRS]), as manifested by ≥2 of the following: • Temperature, >38 °C or <36 °C • Heart rate, >90 beats/min • Respiratory rate, >20 breaths/min or $PaCO_2$ < 4.3 kPa (32 mmHg) • White blood cell count >12 000/mm³, or <4000/mm³, or >10% immature (band) forms	4 (severe infection)
- Infection involving bone (osteomyelitis)	Add "(O)" after 3 or 4*

- Be precise and consistent when diagnosing, and describing the severity of, infection

7

#3 Exclude noninfectious causes of foot inflammation



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- Infection involving bone (osteomyelitis)	Add "(O)" after 3 or 4*

- These include trauma, gout/pseudogout, Charcot neuro-osteoarthropathy, fracture, phlebothrombosis, and venous stasis

8

Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update) *Diabetes Metab Res Rev. 2020;36(S1)*

- In a person with diabetes and suspected osteomyelitis of the foot, we recommend using a combination of the **probe-to-bone test**, **the erythrocyte sedimentation rate** (or C-reactive protein and/or procalcitonin), and **plain X-rays** as the initial studies to diagnose osteomyelitis.

9

Lam K, van Asten SA, Nguyen T, La Fontaine J, Lavery LA.
Diagnostic accuracy of probe to bone to detect osteomyelitis in the diabetic foot: a systematic review.
Clin Infect Dis. 2016;63:944-948.

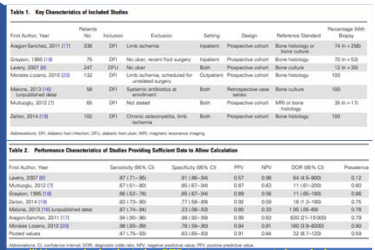


Table 1. Key Characteristics of Included Studies

First Author, Year	Patients No.	Inclusion	Exclusion	Setting	Design	Reference Standard	Percentage With Biopsy
Aragon-Sanchez, 2011 [17]	238	DFI	Limb ischemia	Inpatient	Prospective cohort	Bone histology or bone culture	74 (n = 256)
Grayson, 1995 [18]	75	DFI	No ulcer, recent foot surgery	Inpatient	Prospective cohort	Bone histology	70 (n = 53)
Lavery, 2007 [6]	247	DFU	No ulcer	Both	Prospective cohort	Bone culture	12 (n = 30)
Morales Lozano, 2010 [23]	132	DFI	Limb ischemia, scheduled for unrelated surgery	Outpatient	Prospective cohort	Bone histology	100
Malone, 2013 [16] (unpublished data)	58	DFI	Systemic antibiotics at enrollment	Both	Retrospective case series	Bone culture	100
Mutluoglu, 2012 [7]	65	DFI	Not stated	Both	Prospective cohort	MRI or bone histology	35 (n = 17)
Zelon, 2014 [19]	102	DFI	Chronic osteomyelitis, limb ischemia	Both	Prospective cohort	Bone histology	100

Abbreviations: DFI, diabetic foot infection; DFU, diabetic foot ulcer; MRI, magnetic resonance imaging.

Table 2. Performance Characteristics of Studies Providing Sufficient Data to Allow Calculation

First Author, Year	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	DOR (95% CI)	Prevalence
Lavery, 2007 [6]	.87 (.71–.96)	.91 (.86–.94)	0.57	0.98	64 (4.5–900)	0.12
Mutluoglu, 2012 [7]	.67 (.51–.80)	.85 (.67–.94)	0.67	0.63	11 (.61–200)	0.60
Grayson, 1995 [18]	.66 (.52–.78)	.85 (.67–.94)	0.69	0.56	11 (.65–180)	0.66
Zelon, 2014 [19]	.63 (.73–.90)	.77 (.58–.89)	0.92	0.59	16 (1.3–190)	0.75
Malone, 2013 [16] (unpublished data)	.87 (.74–.94)	.23 (.08–.53)	0.90	0.33	1.95 (.05–69)	0.76
Aragon-Sanchez, 2011 [17]	.94 (.90–.96)	.86 (.82–.89)	0.99	0.63	630 (21–19,000)	0.79
Morales Lozano, 2010 [23]	.96 (.93–.98)	.76 (.59–.90)	0.94	0.91	160 (9.9–4000)	0.90
Pooled values	.87 (.75–.93)	.83 (.65–.93)	0.91	0.84	32 (6.1–120)	0.59

Abbreviations: CI, confidence interval; DOR, diagnostic odds ratio; NPV, negative predictive value; PPV, positive predictive value.

"We conclude that the PTB test can accurately rule in diabetic foot OM in the high-risk patients and rule out OM in low-risk patients."

10

Lawrence A Lavery 1, Junho Ahn, Easton C Ryan, Kavita Bhavan, Orhan K Oz, Javier La Fontaine, Dane K Wukich
What are the Optimal Cutoff Values for ESR and CRP to Diagnose Osteomyelitis in Patients with Diabetes-related Foot Infections?
Clin Orthop Relat Res 2019 Jul;477(7):1594-1602.

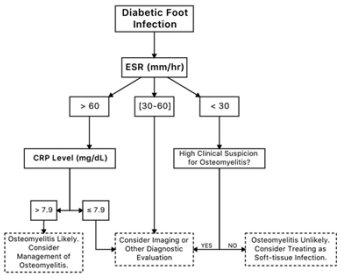
- What are the optimal cutoff values for ESR and CRP to differentiate osteomyelitis from soft-tissue infection in patients with DFIs?
- Methods
- 1842 patients diagnosis of diabetes mellitus, moderate or severe infection
- ESR and CRP values within 72 hours of admission
- 353 patients were included in the study
  - 176 patients with osteomyelitis
  - 177 with soft-tissue infection

11

Lawrence A Lavery 1, Junho Ahn, Easton C Ryan, Kavita Bhavan, Orhan K Oz, Javier La Fontaine, Dane K Wukich
What are the Optimal Cutoff Values for ESR and CRP to Diagnose Osteomyelitis in Patients with Diabetes-related Foot Infections?
Clin Orthop Relat Res 2019 Jul;477(7):1594-1602.

Results

An ESR of 60 mm/h and a CRP level of 7.9 mg/dL were determined to be the optimal cutoff points for predicting osteomyelitis



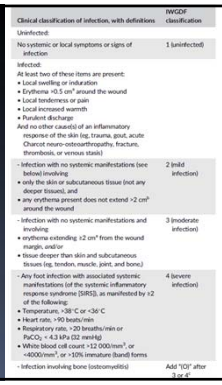
12

#4 Identify causative pathogens

- Send samples of tissue (not swabs) and preferably bone (for suspected osteomyelitis)
- Review results of any previously obtained cultures
- Attempt to differentiate pathogens (requiring treatment) from colonizing or contaminating organisms

13

#5 Differentiate between soft-tissue and bone infection



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- Infection involving bone (osteomyelitis)	Add "(O)" after 3 or 4†

- This helps in making decisions with respect to medical versus surgical, urgency of, and duration of, treatment.

14

Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update)
Diabetes Metab Res Rev. 2020;36(S1)

- In a person with diabetes and suspected **osteomyelitis** of the foot, in whom making a definitive diagnosis or determining the causative pathogen is necessary for selecting treatment, collect a **sample of bone (percutaneously or surgically)** to culture clinically relevant bone microorganisms and for histopathology

15

Couturier A, Chabaud A, Desbiez F, et al. ***Comparison of microbiological results obtained from per-wound bone biopsies versus transcutaneous bone biopsies in diabetic foot osteomyelitis: a prospective cohort study.*** *Eur J Clin Microbiol Infect Dis. 2019;38: 1287-1291*

- Evaluate the reliability of per-wound bone biopsy (PWB) cultures by comparing them with concomitant Transcutaneous bone cultures obtained through healthy skin
- Two bone biopsies were performed on each consenting patient:
  - TCB through a cutaneous incision in healthy skin
  - Per-wound bone biopsy (PWB)
- 46 paired cultures
  - 16 (42%) of the PWB and TCB pairs had identical culture results
  - PWB revealed all microorganisms found in the transcutaneous specimen in 26/38 samples (68.5%)

In patients with DFO, the culture results of specimens taken by per-wound biopsies did not correlate well with those obtained by TCB.

16

Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update) *Diabetes Metab Res Rev. 2020;36(S1):e3280.*

- Collect an appropriate specimen for culture for almost all clinically infected ulcers to determine the causative pathogens
- For a soft tissue DFI, obtain a sample for culture by aseptically collecting a tissue specimen (by curettage or biopsy) from the ulcer

17

#6 Ensure specialist consultation for most moderate and all severe infections

- Evaluate and individualize treatment options for each patient
- In complex cases, involve specialists (or optimally multidisciplinary teams), especially surgeons

18

Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update)
Diabetes Metab Res Rev. 2020;36(S1)

- Nonsurgeons should urgently consult with a surgical specialist in cases of severe infection or of moderate infection complicated by extensive gangrene, necrotizing infection, signs suggesting deep (below the fascia) abscess or compartment syndrome, or severe lower limb ischemia
- In a patient with diabetes and uncomplicated **forefoot** osteomyelitis, for whom there is no other indication for surgical treatment, **consider treating with antibiotic therapy without surgical resection of bone**

19

#7 Choose an effective antibiotic regimen with the narrowest spectrum

- For empiric, and especially definitive, therapy select an antibiotic regimen based on the likely or proven: causative pathogen(s); their antibiotic susceptibilities; and, evidence of efficacy for DFIs

20

#8 Optimize patient-related effectiveness of antibiotic therapy

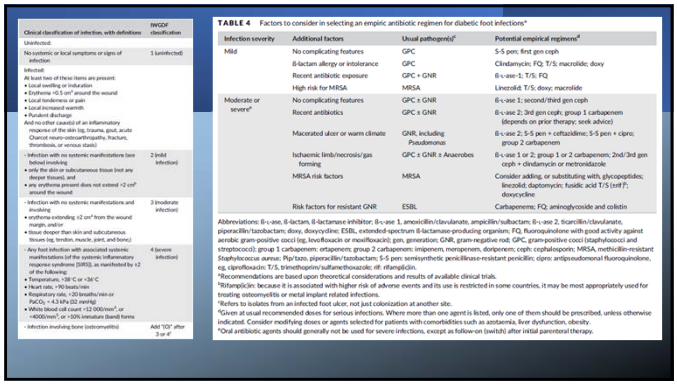
- Evaluate for factors such as adherence to the treatment regimen, impaired gastrointestinal absorption, key comorbidities (obesity, renal failure), and presence of clinically significant peripheral arterial disease in affected limb

21

#9 Medical therapy – as long as necessary and as short as possible

- For most mild and moderate **soft tissue infections 1–2 weeks** of therapy is sufficient
- For **osteomyelitis with residual infected bone, prescribe no more than 6 weeks** of antibiotic therapy. Consider shorter treatment durations if infection resolves quickly

22



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- Infection involving bone (osteomyelitis)	Add "(O)" after 3 or 4[c]

TABLE 4 Factors to consider in selecting an empiric antibiotic regimen for diabetic foot infections[a]

Infection severity	Additional factors	Usual pathogen(s)[b]	Potential empirical regimens[d]
Mild	No complicating features	GPC	S-S pen; first gen ceph
	ß-lactam allergy or intolerance	GPC	Clindamycin; FQ, T/S; macrolide; doxy
	Recent antibiotic exposure	GPC + GNR	ß-L-ase-S; T/S; FQ
	High risk for MRSA	MRSA	Linezolid; T/S; doxy; macrolide
Moderate or severe[e]	No complicating features	GPC ± GNR	ß-L-ase 1; second/third gen ceph
	Recent antibiotics	GPC ± GNR	ß-L-ase 2; 3rd gen ceph; group 1 carbapenem (depends on prior therapy; seek advice)
	Macerated ulcer or warm climate	GNR, including Pseudomonas	ß-L-ase 2; S-S pen + ceftazidime; S-S pen + cipro; group 2 carbapenem
	Ischaemic limb/necrosis/gas forming	GPC ± GNR ± Anaerobes	ß-L-ase 1 or 2; group 1 or 2 carbapenem; 2nd/3rd gen ceph + clindamycin or metronidazole
	MRSA risk factors	MRSA	Consider adding, or substituting with, glycopeptides; linezolid; daptomycin; fusidic acid T/S (*enf*[f]; doxycycline
	Risk factors for resistant GNR	ESBL	Carbapenems; FQ; aminoglycoside and colistin

Abbreviations: ß-L-ase, ß-lactam, ß-lactamase inhibitor; ß-L-ase 1, amoxicillin/clavulanate, ampicillin/sulbactam; ß-L-ase 2, ticarcillin/clavulanate, piperacillin/tazobactam; doxy, doxycycline; ESBL, extended-spectrum ß-lactamase-producing organism; FQ, fluoroquinolone with good activity against aerobic gram-positive cocci (eg, levofloxacin or moxifloxacin); gen, generation; GNR, gram-negative rod; GPC, gram-positive cocci (staphylococci and streptococci); group 1 carbapenem: ertapenem; group 2 carbapenem: imipenem, meropenem, doripenem; ceph: cephalosporin; MRSA, methicillin-resistant *Staphylococcus aureus*; Pip/tazo, piperacillin/tazobactam; S-S pen: semisynthetic penicillinase-resistant penicillin; cipro: antipseudomonal fluoroquinolone, eg, ciprofloxacin; T/S, trimethoprim/sulfamethoxazole; rif: rifampicin.

[a]Recommendations are based upon theoretical considerations and results of available clinical trials.

[b]Rifampicin: because it is associated with higher risk of adverse events and its use is restricted in some countries, it may be most appropriately used for treating osteomyelitis or metal implant related infections.

[c]Refers to isolates from an infected foot ulcer, not just colonization at another site.

[d]Given at usual recommended doses for serious infections. Where more than one agent is listed, only one of them should be prescribed, unless otherwise indicated. Consider modifying doses or agents selected for patients with comorbidities such as azotaemia, liver dysfunction, obesity.

[e]Oral antibiotic agents should generally not be used for severe infections, except as follow-on (switch) after initial parenteral therapy.

23

#10 Surgical treatment – can limit need for antibiotic therapy

- Draining abscesses and resecting infected bone can limit the duration of antibiotic therapy required

24

Spellberg B, Lipsky BA.
Systemic antibiotic therapy for chronic osteomyelitis in adults.
Clin Infect Dis. 2012;54:393-407.

Table 2—Factors potentially favoring selecting either primarily medical or primarily surgical treatment for diabetic foot osteomyelitis

Medical	
	Patient is too medically unstable for surgery
	Poor postoperative mechanics of foot is likely (e.g., with mid- or hindfoot infections)
	No other surgical procedures on foot are needed
	Infection is confined to small, forefoot lesion
	No adequately skilled surgeon is available
	Surgery costs are prohibitive for the patient
	Patient has strong preference to avoid surgery
Surgical	
	Foot infection is associated with substantial bone necrosis
	Foot appears to be functionally nonsalvageable
	Patient was already nonambulatory
	Patient is at particularly high risk for antibiotic-related problems
	Infecting pathogen is resistant to available antibiotics
	Limb has uncorrectable ischemia (precluding systemic antibiotic delivery)
	Patient has strong preference for surgical treatment

25

Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update)
Diabetes Metab Res Rev. 2020;36(S1)

- Administer antibiotic therapy initially by the parenteral route to any patient with a severe DFI.
- Switch to oral therapy if the patient is clinically improving and has no contraindications to oral therapy and if there is an appropriate oral agent available.
- Treat patients with a mild DFI and most with a moderate DFI, with oral antibiotic therapy, either at presentation or when clearly improving with initial intravenous therapy
- We suggest not using any currently available topical antimicrobial agent for treating a mild DFI
- Administer antibiotic therapy to a patient with a **skin or soft tissue DFI** for a duration of 1 to 2 weeks
- Consider continuing treatment, perhaps for up to 3 to 4 weeks, if the infection is improving but is extensive and is resolving slower than expected or if the patient has severe peripheral artery disease
- If evidence of infection has not resolved after 4 weeks of apparently appropriate therapy, re-evaluate the patient, and reconsider the need for further diagnostic studies or alternative treatments.

26

Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update)
Diabetes Metab Res Rev. 2020;36(S1)

- Treat diabetic foot **osteomyelitis** with antibiotic therapy for no longer than 6 weeks
- If the infection does not clinically improve within the first 2 to 4 weeks, reconsider the need for collecting a bone specimen for culture, undertaking surgical resection, or selecting an alternative antibiotic regimen
- Treat diabetic foot osteomyelitis with antibiotic therapy for just a few days if there is no soft tissue infection and all the infected bone has been surgically removed
- For diabetic foot osteomyelitis cases that initially require parenteral therapy, consider switching to an oral antibiotic regimen that has high bioavailability after perhaps 5 to 7 days if the likely or proven pathogens are susceptible to an available oral agent and the patient has no clinical condition precluding oral therapy

27

Stopping antibiotics after surgical amputation in diabetic foot and ankle infections—A daily practice cohort
Anne Rossel, Dan Lebowitz, Karim Gariani
Endocrinol Diab Metab. 2019

- Determine ppropriate duration of antibiotic therapy for diabetic foot infections (DFI) after surgical amputation in toto
- Minimum follow-up was 2 months
- 482 amputated DFI episodes for a median of 2.1 years after the index episode.
- Osteomyelitis in 239 cases (239/482; 50%).
- Surgical amputation
  - Toes (n = 155)
  - Midfoot (280)
  - Hindfoot (47)
  - 178 cases (37%) required revascularization
- After amputation, the median duration of antibiotic administration was 7 days
- 109 cases (25%), antibiotics were discontinued immediately after surgery
- Clinical failure occurred in 90 DFIs (17%), due to the same pathogens in only 38 cases.
- In multivariate analysis, neither duration of total postsurgical antibiotic administration nor immediate postoperative discontinuation altered failure rate
- Conclusion: "According to our clinical pathway, we found no benefit in continuing postsurgical antibiotic administration in routine amputation for DFI. In the absence of residual infection (ie, resection at clear margins), antibiotics should be discontinued"

28

Remission in diabetic foot infections: Duration of antibiotic therapy and other possible associated factors
Karim Gariani, Dan Lebowitz et al
Diabetes Obes Metab. 2019;21:244–251

- Determine the most appropriate duration of antibiotic therapy for diabetic foot infections
- 1018 DFI episodes in 482 patients
  - 392 episodes of osteomyelitis,
  - 626 soft tissue infections
  - 313 cases involved revascularization
- Patients underwent surgical debridement for 824 episodes (81%), of which 596 (59%) required amputation
- The median total duration of antibiotic therapy was 20 days.
- Neither duration of antibiotic therapy nor parenteral treatment affected risk of recurrence
- Neither >3 weeks versus <3 weeks of therapy, nor >1 week versus <1 week of intravenous treatment affected recurrence

Conclusions: "Our analysis found no threshold for the optimal duration or route of administration of antibiotic therapy to prevent recurrences of DFI. These limited data might support possibly shorter treatment duration for patients with DFI."

29

Three versus six weeks of antibiotic therapy for diabetic foot osteomyelitis: A prospective, randomized, non-inferiority pilot trial
Karim Gariani, Truong-Thanh Pham, et al
Infectious Diseases Society of America

- Patients with diabetic foot osteomyelitis (DFO) who underwent surgical debridement,
- Investigated a short (3 weeks), compared with a long (6 weeks) duration of systemic antibiotic treatment is associated with non-inferior results for clinical remission and adverse events (AE)
- Prospective, randomized, non-inferiority, pilot trial
- Patients with DFO after surgical debridement to either a 3-week or a 6-week course of antibiotic therapy. The minimal duration of follow-up after end of therapy was two months
- 44 were randomized to the 3-week arm and 49 to the 6-week arm
- The median number of surgical debridement was 1 (range, 0-2 intervention
- Remission occurred in 37 (84%) of the patients in the 3-week arm compared to 36 (73%) in the 6-week arm
- AE was similar in the two study arms (17/44 vs. 16/49)
- Conclusions. "In this randomized, controlled pilot trial, a post-debridement systemic antibiotic therapy course for DFO of 3-weeks gave similar (and statistically non-inferior) incidences of remission and AE to a course of 6 weeks."

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Take Home Points

- Multi-Specialty Team
- Differentiate Between Soft Tissue and Osseous Infection
- Accurate Diagnosis

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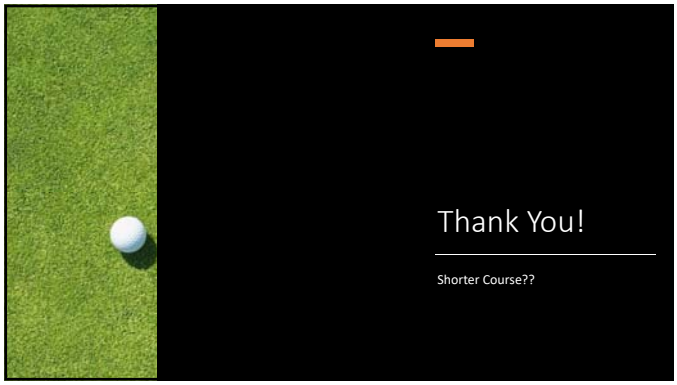

Thank You!

Shorter Course??

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