Infectious Diseases Clinical Controversies Series

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UT Tyler College of Pharmacy; UNT System College of Pharmacy

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November 7-10, 2019 | Grapevine, Texas
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To enter the Q&A and polling questions for this activity, go to ascp.com/qa and click on the title of this activity, as seen below.
Speaker Information – Jonathan Cho

- PharmD from UOP
- PGY1/PGY2 in ID at Lee Health
- Associate Professor at UT Tyler COP
- Infectious Diseases Clinical Pharmacist at Longview Regional Medical Center
- Board Certified Infectious Diseases Pharmacist

Speaker Information – Crystal Howell

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- Infectious Diseases Clinical Pharmacist at Medical City Dallas Hospital
- Board Certified Infectious Diseases Pharmacist
Disclosure – Jonathan Cho and Crystal Howell

• The speakers have no conflicts of interest to disclose.

Learning Objectives

• Analyze the advantages and disadvantages of antimicrobial therapy for use in *Clostridioides difficile* infection.

• Given a patient case, analyze the advantages and disadvantages of antimicrobial therapy use for gram-positive infections.

• Given a patient case, analyze the advantages and disadvantages of antimicrobial therapy use for gram-negative infections.
Clostridioides difficile infection (CDI)
Prophylaxis and Probiotics

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Poll: Which CDI prevention strategies do you currently use at your institution?

To access the polling questions, go to this link: ascp.com/qa and select the “Infectious Diseases Clinical Controversies Series” activity, as seen below.
Poll: Which CDI prevention strategies do you currently use at your institution?

A. Probiotics
B. Metronidazole prophylaxis
C. Vancomycin prophylaxis
D. Fidaxomicin prophylaxis

• \textit{Clostridium difficile} was renamed to \textit{Clostridioides difficile}
• “>20% of all CDIs identified in 2011 had onset in LTCFs”
Clinical Controversy – CDI

Guideline Options to Prevent Recurrence:
• Tapered and pulsed regimen
• Fecal microbiota transplantation (FMT)

Other Proposed Methods to Prevent Recurrence:
• Bezlotoxumab
  • Not discussed today
• Probiotics
  • Guidelines do not make a recommendation
• Prophylaxis
  • Not mentioned in guidelines

Probiotics – Pro

• Primary obj: “assess efficacy and safety of probiotics for the prevention of C. difficile-associated diarrhea (CDAD) in adults and children.”
• Details:
  • 31 RCTs, 4492 patients
  • 23 studies indicate effectiveness of probiotics
• Pertinent Results:
  • CDAD reduced by 64% when given with antibiotics
  • NNT = 29 patients
  • Would prevent 35 CDAD per 1000 patients treated
  • LOS was 0.32 days lower
  • RR for adverse effects was 0.8 (95% CI 0.68-0.95)
### Probiotics – Pro

<table>
<thead>
<tr>
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| Pattani R, Palda VA, Hwang SW, Shah PS. Probiotics for the prevention of antibiotic-associated diarrhea and *Clostridium difficile* infection among hospitalized patients: systematic review and meta-analysis. Open Med 2013; 7:e56–67. | SR and MA of 16 trials | • RR of antibiotic associated diarrhea 0.61 (95% CI 0.47 – 0.79)  
• RR of CDI 0.37 (95% CI 0.22 – 0.61)  
• NNT = 11 |
| Johnson S, Maziade PJ, McFarland LV, et al. Is primary prevention of *Clostridium difficile* infection possible with specific probiotics? Int J Infect Dis 2012; 16:e786–92. | MA of 11 trials | • RR of CDI = 0.39 (95% CI 0.19 – 0.79)                                                |

### Probiotics – Pro Conclusion

*There is sufficient data to suggest that probiotics are both safe and effective as prevention of CDAD with concomitant antibiotic use.*
Probiotics – Con

• Guidelines: insufficient data to support probiotic use!
• Greater benefit shown when studies with CDI incidence 7-20x higher in placebo arms than normally expected were included
  • Baseline risk ranged from 0-40%; differences in CDI definition
• Post-hoc subgroup analysis based on baseline CDAD risk
  • Low (0-2%) $\rightarrow$ RR 0.77 (95% CI 0.45 to 1.32, n = 5845) [P=0.34]
  • Mod (3-5%) $\rightarrow$ RR 0.53 (95% CI 0.16 to 1.77, n = 373) [P=0.70]
  • High (>5%) $\rightarrow$ RR 0.30 (95% CI 0.21 to 0.42, n = 2454) [P<0.01]
• Which probiotic do you use? What dose? How long?

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| Saltzman T, Fazzari M, Chung S, et al. The effect of probiotics on the incidence of *Clostridium difficile*. Poster presentation at: IDWeek 2018; October 3-7, 2018; San Francisco, CA. Poster 514. | Retrospective cohort study | • Higher correlation of probiotic use and number of antibiotics taken  
  • RR of CDI 1.88 (95% CI 1.1 – 3.16) [P=0.02]  
  • After adjustment, positive correlation still, but not signif. |
| Box MJ, Ortwine KN, Goicoechea M. No impact of probiotics to reduce *Clostridium difficile* infection in hospitalized patients: a real-world experience. Open Forum Infect Dis. 2018 Dec 13;5(12):ofy192. | Retrospective cohort study | • Healthcare facility-onset CDI 1.8% vs 0.9%; P=0.16 |
Probiotics – Con

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• Elderly, colitis and immunocompromised were at increased risk  
• Saccharomyces most frequent |
• Patients w/enteral nutrition had increased noninfectious complications |

Probiotics – What Do We Think?

Our Thoughts

- Alternatives
- Evidence Quality
- Cost vs. Benefit
- ADE
- Which one?

Cost vs. Benefit

Evidence Quality

ADE
Prophylaxis – Pro

• Purpose: “examine the efficacy and safety of fidaxomicin as prophylaxis against CDAD” in Hematopoietic Stem Cell Transplant (HSCT) patients receiving fluoroquinolone prophylaxis during neutropenia

• Details:
  • RCT, double-blind, placebo controlled, multi-center
  • Intervention: fidaxomicin 200mg or placebo daily

• Pertinent Results:
  • Confirmed CDAD incidence was 4.7% vs 10.7% (p = 0.0026)
  • NNT = 17


Prophylaxis – Pro Conclusion

The use of vancomycin 125mg PO bid or Fidaxomicin 200mg PO daily can be used to prevent CDI

Prophylaxis – Con

• Show me the data?!  
  • The doses and durations use vary drastically  
  • Long-term benefit of secondary prophylaxis is unknown  
• Physician practice varies:  
  • 54.2% use in patients with history of CDI recurrence  
  • 29.9% use in patients with history of CDI receiving antibiotics  
• No prospective, randomized studies evaluating secondary prophylaxis to provide guidance  
• Is there outcomes data?!  
• Cost vs. benefit
Prophylaxis – Con

- More patients not receiving prophylaxis were on metronidazole before and after HSCT
  - 30-days before: 0% vs. 7%, P=0.02
  - 30-days after: 7% vs. 16%, P=0.09
- No differences in outcomes:
  - Median length of stay 29 vs. 28 days; P=0.22
  - 1-year estimated rate of overall survival (HR 0.60; 95% CI 0.32–1.12; P=0.11)
  - Non-relapse mortality (HR 0.72; 95% CI 0.29–1.83; P=0.49).
  - Graft vs Host Disease (GVHD)-free, relapse-free survival rates (38.2% vs. 45.6%, respectively; P=0.39)

Citation

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<tr>
<td>Carignan A, Poulin S, Martin P, et al. Efficacy of secondary prophylaxis with vancomycin for preventing recurrent <em>Clostridium difficile</em> infections. Am J Gastroenterol. 2016 Dec;111(12):1834-1840.</td>
<td>Retrospective cohort study</td>
<td>Decreased risk for recurrent CDI (AHR, 0.47; 95% CI, 0.32-0.69; P&lt;0.0001) but not for initial episodes (AHR, 0.91; 95% CI, 0.57-1.45; P=0.68)</td>
</tr>
<tr>
<td>Splinter LE, Kerstenetzky L, Jorgenson MR, et al. Vancomycin prophylaxis for prevention of <em>Clostridium difficile</em> infection recurrence in renal transplant patients. Ann Pharmacother. 2018 Feb;52(2):113-119.</td>
<td>Retrospective cohort study</td>
<td>No significant difference in CDI recurrence (0% [0/12] vs 8% [2/24], P = 0.54)</td>
</tr>
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</table>
Increased doses throughout therapy if diarrheal episodes |
Prophylaxis – What Do We Think?

Cost vs. Benefit
Specific Patients (HSCT)
Dose? Duration?
Our Thoughts

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Gram Positive Infections

Linezolid for bacteremia and double coverage for MRSA

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Poll: Which of the following would you use to treat MRSA bacteremia?

A. Linezolid
B. Vancomycin
C. Daptomycin + ceftaroline
D. Vancomycin + cefazolin
Clinical Controversy - Linezolid for Bacteremia

- There are no bacteremia guidelines
- **MRSA** bacteremia mortality 20-30%
- **MRSA** guidelines recommend vancomycin or daptomycin

**Linezolid for Bacteremia – Pro**

- **SR and MA** to compare daptomycin and linezolid for vancomycin resistant *Enterococcus* (VRE)
- Details:
  - 13 studies; 1188 patients (532 daptomycin, 656 linezolid)
- Pertinent Results:
  - **Mortality OR 1.46 with daptomycin** compared to linezolid (95% CI 1.02-2.09)
  - Microbiologic relapse OR 2.65 with daptomycin (95% CI 1.03-6.78)
Linezolid for Bacteremia – Pro

• Open-label, multicenter, non-inferiority study of patients with catheter-related bloodstream infection (CRBSI) randomized to linezolid or vancomycin

• Details:
  • 294 patients needed for a power of 80%-> 393 completed treatment

• Pertinent Results:
  • Microbiologic success in 66.7% of linezolid patients and 66.7% of vancomycin patients (95% CI -19 to 19)
  • MRSA: linezolid 79.2% vs 76.2% (95% CI -21.4 to 27.4)


Linezolid for Bacteremia – Pro

• Prospective cohort study of propensity score matching patients (2:1) with *Staphylococcus aureus* bacteremia (SAB)

• Purpose: efficacy and safety of completing SAB treatment with oral linezolid in low risk patients

  • Low risk: **clinically stable**, **appropriate source control**, **negative follow up blood cultures**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Oral Linezolid (n =45)</th>
<th>Standard Treatment (n = 107)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 day relapse</td>
<td>1 (2.2)</td>
<td>4 (3.7)</td>
<td>1.00</td>
</tr>
<tr>
<td>30 day mortality</td>
<td>1 (2.2)</td>
<td>17 (15.9)</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>LOS after 1st culture</strong></td>
<td><strong>8 (7-10)</strong></td>
<td><strong>19 (15-32)</strong></td>
<td>&lt; 0.01</td>
</tr>
</tbody>
</table>

Linezolid for Bacteremia – Pro Conclusion

Linezolid can be used for MRSA bacteremia

Linezolid for Bacteremia – Con

- Bacteriostatic
- Data for treatment of serious infections are extremely limited
- Would not use for extended period of time
  - Increase risk for thrombocytopenia
- Some data show benefit of linezolid vs. daptomycin for VRE
  - Limitations: variable case definitions, small sample size, variations in outcome measures, insufficient daptomycin dosing
Linezolid for Bacteremia – Con

• Multicentered, retrospective cohort study evaluating linezolid vs daptomycin for treatment of VRE-BSI
  • Results are even more impressive as daptomycin dose was 6 mg/kg
  • Linezolid had ↑ risk of treatment failure (RR 1.37; 95% CI 1.13-1.67; P = 0.001)
  • After adjusting for confounding factors treatment failure persisted (adjusted RR 1.15; 95% CI 1.02-1.30; P = 0.026)
  • Higher 30-day mortality (42.9% vs 33.5%; RR, 1.17; 95% CI, 1.04-1.32; P = 0.014)
  • Higher microbiologic failure rates (RR, 1.10; 95% CI, 1.02-1.18; P = 0.011)


Linezolid for Bacteremia – Con

• Prospective, single-centered, observational study evaluating linezolid vs. lipopeptide for treatment of persistent MRSA bacteremia
• Duration of persistent bacteremia (median 16 days vs. 10 days; P = 0.008) was longer in linezolid-based salvage group
• 30-day mortality (11% vs. 25%; P = 0.08)
• Adverse reactions were not followed
• No significant difference in outcomes between the two groups

Linezolid for Bacteremia – What Do We Think?

Great for transitions of care (TOC)
Evaluate risk factors for persistent bacteremia
Adverse drug reactions

Our Thoughts

Clinical Controversy – Double Coverage of MRSA

- CDC considers MRSA a serious threat
- MRSA bacteremia mortality 20-30%
- Beta lactamase
- mecA
- Thick cell wall
- vanA

Double Coverage for MRSA – Pro

• Details:
  • Open-label prospective RCT of adults with MRSA bacteremia
  • All patients had an ID consult
  • Randomized to either:
    • Daptomycin 6 – 8 mg/kg/day + ceftaroline 600mg IV q8h
    • Monotherapy with either vancomycin dosed by pharmacy or daptomycin 6 - 8 mg/kg/day
  • Pertinent Results:
    • Trial stopped early to significant mortality benefit in the combination arm
    • Combination arm 0% vs 26% in monotherapy arm (p = 0.029)


Double Coverage for MRSA – Pro

• Details:
  • Case series of 7 patients with persistent MRSA bacteremia
  • Sources: endocarditis, abscess, and unknown
  • 1st line therapy: vancomycin
  • 2nd line therapy: daptomycin
    • Daptomycin doses ranged from 6-10 mg/kg
  • Pertinent Results:
    • When an anti-staphylococcal β lactam was added, blood cultures cleared within 24 hrs
  • Theory:
    • Anti-staphylococcal β lactams reduce the surface charge of the bacteria which enhances daptomycin binding

Double Coverage for MRSA – Pro Conclusion

*Dual coverage should be used to treat MRSA infections, especially bacteremia*

Is double coverage considered standard of practice for most infections?

Most guidelines recommend monotherapy
  - Skin and skin structure infections
  - Respiratory infections
  - Urinary tract infections

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<td>Wargo KA, McCreary EK, English TM. Vancomycin combined with clindamycin for the treatment of acute bacterial skin and skin-structure infections. Clin Infect Dis. 2015 Oct 1;61(7):1148-54.</td>
<td>Retrospective cohort study</td>
<td>3.7 ± 1.5 days vs 4.0 ± 2.0 days, <em>P</em> = 0.192, combination and monotherapy, respectively</td>
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### Double Coverage for MRSA – Con

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<td>LaVie KW, Anderson SW, O’Neal HR Jr, et al. Neutropenia associated with long-term ceftaroline use. Antimicrob Agents Chemother. <strong>2015</strong> Oct 26;60(1):264-9.</td>
<td>Retrospective cohort study</td>
<td>• Mean duration of 27 days for ceftaroline • 7/39 (18%) developed neutropenia with majority have an ANC&lt;500 cells/mm³</td>
</tr>
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### Double Coverage of MRSA – What Do We Think?

- Persistent bacteremia?
- Endovascular source? Endocarditis?
- Different dosing and education
- Adverse drug reactions
- Our Thoughts

$$\text{A}$$
Gram Negative Infections
Double coverage and the treatment of ESBLs and Amp-Cs

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Poll: Which of the following would you use to treat bacteremia due to an ESBL-producing organism?

To access the polling questions, go to this link: ascp.com/qa and select the “Infectious Diseases Clinical Controversies Series” activity, as seen below.
Poll: Which of the following would you use to treat bacteremia due to an ESBL-producing organism?

A. Meropenem  
B. Piperacillin/tazobactam  
C. Cefepime  
D. Levofloxacin

Clinical Controversy – Double Coverage of Gram Negative Organisms

- Efficacy
- Feasibility
- Mortality
- Safety
- Clearance
- Cost
- Clearance
Double Coverage of Gram Negative Organisms – Pro

Details:
- SR and MA of patients with multi-drug resistant *Acinetobacter baumannii*
- 25 studies, 2379 patients

Pertinent Results:
- Combination therapy with colistin compared to monotherapy with colistin increased microbiologic clinical cure (RR 1.21, 95% CI 1.1 – 1.34)
- Combination therapy with colistin significantly decreased all-cause mortality (RR 0.58, 95% CI 0.35 – 0.96)


Double Coverage of Gram Negative Organisms – Pro

Details:
- Retrospective cohort of 41 patients with *Klebsiella pneumoniae* carbapenemase (KPC)
- Treatments:
  - Combination: carbapenem + (colistin/polymixin B or tigecycline)
  - Monotherapy: colistin/polymixin B or tigecycline

Pertinent Results:
- 28 day crude mortality OR was 0.07 when combination therapy was used compared to monotherapy (95% CI 0.009 – 0.71)

Double Coverage of Gram Negative Organisms – Pro Conclusion

Combination therapy improves mortality in multi-drug resistant gram negative infections

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Double Coverage of Gram Negative Organisms – Con

• Retrospective, single-center study comparing β-lactam monotherapy with β-lactam/fluoroquinolone combination
• Primary outcome: 28 day mortality
  • Critically ill (25.6% [23 of 90] versus 27.8% [22 of 79]; adjusted HR, 0.87; 95% CI, 0.47 to 1.62; P = 0.660)
  • Less-critically ill (4.2% [9 of 214] versus 8.8% [28 of 319]; adjusted HR, 0.44; 95% confidence interval [CI], 0.20 to 0.98; P = 0.044)
    • However, way more patients with bacteremia from a urinary source (P<0.01)
• No safety data collected (e.g. adverse reactions, QTc prolongation)

### Double Coverage of Gram Negative Organisms – Con

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• 69.4% (95% CI, 59.1-81.6) vs. 73.5% (95% CI, 68.4%-79.0%) |
| Vardakas, KZ, Tansarli GS, Bliziotis IA, et al. β-Lactam plus aminoglycoside or fluoroquinolone combination versus β-Lactam monotherapy for *Pseudomonas aeruginosa* infections. Int J Antimicrob Agents. 2013 Apr;41(4):301-10. | Meta-analysis | • No mortality difference for β-lactam monotherapy either as definitive (RR 0.97, 95% CI 0.77-1.22) or empiric (RR 1.02, 95% CI 0.78-1.34) |
| Chamot E, Boffi El Amari E, Rohner P, et al. Effectiveness of combination antimicrobial therapy for *Pseudomonas aeruginosa* bacteremia. Antimicrob Agents Chemother. 2003 Sep;47(9):2756-64. | Retrospective cohort study | • ↑ mortality with monotherapy empiric (adjusted HR, 3.7 [95% CI, 1.0–14.1]), but no significant difference for definitive (adjusted HR, 0.70 [95% CI, .30–1.7]) |

### Key Points
- **Multi-national, open-label, randomized controlled trial** from 2014-17 evaluating meropenem/vaborbactam vs. best available therapy (BAT)
- mCRE-MITT population, cure rates were 65.6% (21/32) and 33.3% (5/15) [P = 0.03] at End of Treatment and 59.4% and 26.7% [P = 0.02] at Test of Cure
- Day-28 all-cause mortality was 15.6% and 33.3%
- Treatment-related AEs and renal-related AEs were 24.0% and 4.0% for meropenem-vaborbactam vs 44.0% and 24.0% for BAT
- Monotherapy for CRE infection was associated with increased clinical cure, decreased mortality, and reduced nephrotoxicity
Double Coverage of **Gram Negative** Organisms – What Do We Think?

Our Thoughts

Local Resistance

Empiric vs Definitive

Adverse drug reactions

Organism?

$$$$$

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Clinical Controversy – Carbapenem Sparing ESBL and AmpC Treatments

- Enzymatic resistance mechanism most common in **gram negative** organisms
  - Extended Spectrum β-lactamase (ESBL) and AmpC are increasingly common
Carbapenem Sparing Treatment – Pro

• Purpose: compare 30 day mortality of patients with ESBL bacteremia empirically treated with piperacillin-tazobactam vs a carbapenem

• Details:
  - Retrospective cohort study at 2 university hospitals of patients with ESBL E. coli and K. pneumoniae bacteremia.
  - 151 patients (piperacillin-tazobactam 94, carbapenem 57)

• Pertinent Results:
  - 30 day mortality was not statistically different (30.9% vs 29.8%, p = 0.89)
  - Carbapenems had an OR of 3.32 (95%CI 1.12-9.87) as a risk factor for acquiring a multi-drug resistant organism


Carbapenem Sparing Treatment – Pro

• Purpose: “compare clinical outcomes of patients with invasive infections caused by AmpC” treated with cefepime vs meropenem

• Details:
  - Propensity score matched prospective observational cohort
    - Bacteremia, pneumonia, intra-abdominal infections
    - Enterobacter spp, Serratia marcescens, or Citrobacter spp
    - 78 patients (46 cefepime, 32 meropenem)

• Pertinent Results:
  - Primary outcome: 30 day mortality (10 vs 11, p = 0.99)
  - Matched OR for mortality receiving cefepime was 0.6 (95% CI 0.23 – 2.31)

Carbapenem Sparing Treatment – Pro

Conclusion

Piperacillin-tazobactam and cefepime are non-inferior treatment options for ESBL and AmpC producing organisms respectively.

Carbapenem Sparing Treatment – Con

- Single-center study comparing 14-day mortality of piperacillin-tazobactam vs. carbapenems for ESBL bacteremia
- 141 (48%) piperacillin-tazobactam vs. 110 (52%) carbapenems
  - Less immunocompromised patients in piperacillin-tazobactam arm
- Common bacteremia sources:
  - Catheter-related (46%), urinary (21%), intra-abdominal (17%)
- The adjusted risk of death was 1.92 times higher for patients receiving piperacillin-tazobactam (95% CI, 1.07-3.45)

Carbapenem Sparing Treatment – Con

• Non-inferiority, randomized clinical trial comparing piperacillin-tazobactam (188) vs. meropenem (191) for ESBL bacteremia

• Common bacteremia sources:
  • Urinary (54.8% vs 67%), intra-abdominal (18.1% vs 14.7%)

• Piperacillin-tazobactam arm had shorter time to receipt of appropriate antibiotics (5.5 hrs vs 9 hrs)

• Primary outcome: 30 day mortality (12.3% vs. 3.7%, RD 8.6%)

• Adjustment for a urinary tract source and Charlson Comorbidity Index score resulted in little change
  • Unadjusted OR, 3.69 (97.5% CI, 0 to 8.82); adjusted OR, 3.41 (97.5% CI, 0 to 8.38)


Carbapenem Sparing Treatment – Con

• Retrospective chart review of patients treated with carbapenem vs. either cefepime or piperacillin/tazobactam for Enterobacter sp., S. marcescens, C. freundii, Providencia sp., and M. morganii (ESCPM)

• Respiratory infection (53.3%), bacteremia (46.7%)

• E. cloacaе (53.3%), S. marcescens (30%), C. freundii (6.7%)

• All patients: 13.3% vs. 26.8%, P = 0.164

• ICU patients: 9.1% vs. 29.6%, P = 0.046
  • Trend favored carbapenems for those on mechanical ventilation, vasopressor

Carbapenem Sparing Treatment – What Do We Think?

Our Thoughts

- Severity of Infection
- Bacterial Burden
- Adverse drug reactions
- ESBL vs AmpC
- Source and Source Control
- New Drugs as Carbapenem-Sparing?

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Social Q&A

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