dose and nephrotoxicity was infrequently encountered. Limitations include the frequent use of additional, potentially active antimicrobials and difficulty in assessment of clinical success and AKI in patients after discharge.

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439. Iclaprim Use for Acute Bacterial Skin and Skin Structure Infection (ABSSSI) is Not Associated with Hyperkalemia: Phase 3 REVIVE Studies

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Background. Trimethoprim inhibits sodium channels in the distal portion of the renal tubule, thereby impairing renal potassium excretion. Trimethoprim has been associated with a greater risk of hyperkalemia compared with other antibiotics (amoxicillin, nitrofurantoin, cefalexin, ciprofloxacin). An analysis of Phase 3 studies was conducted to determine whether iclaprim, under development for ABSSSI and also a selective bacterial dihydrofolate reductase inhibitor like trimethoprim, is associated with hyperkalemia, relative to vancomycin, an antibiotic not associated with hyperkalemia.

Methods. A post-hoc safety analysis was conducted on pooled results of two Phase 3, double-blind, randomized (1:1), active-controlled trials (REVIVE-1/-2) in patients with ABSSSI. These trials compared iclaprim 80 mg fixed doses with vancomycin 15 mg/kg; both administered intravenously every 12 hours for 5–14 days. Hyperkalemia was defined as serum potassium (K) ≥5.5 mmol/L, if normal at baseline, while on study drug. Hyperkalemia was compared between treatment groups and stratified subgroup comparisons were performed.

Results. Demographics and baseline disease characteristics were similar between the pooled iclaprim and vancomycin groups (table). Hyperkalemia occurred during treatment in 1.5% (9/592) and 2.5% (15/599) of patients treated with iclaprim and vancomycin, respectively. Of the patients with hyperkalemia, one patient in each treatment group had moderate to severe renal impairment (creatinine clearance [CrCl] 15–59 mL/minute). Among patients with moderate to severe renal impairment on any RAS, KSD or K supplements, hyperkalemia occurred in 1/16 and 0/16 patients in the iclaprim and vancomycin groups, respectively, and in 2/83 and 0/46 patients with mild to no renal impairment. No patients with hyperkalemia experienced adverse events of palpitations, chest pain, myalgia, muscular weakness or fatigue.

Conclusion. No differences in hyperkalemia were seen between the iclaprim and vancomycin groups in the Phase 3 REVIVE studies. In general, few cases of hyperkalemia occurred among patients with renal impairment treated with concomitant angiotensin-converting enzyme inhibitors and angiotensin-receptor blockers treated with iclaprim.

Table. Demographics and baseline disease characteristics of patients in the REVIVE studies.

Characteristics, n (%)	Iclaprim (n=592)	Vancomycin (n=599)
Age (years)		
<65	519 (87.7)	506 (84.5)
>=65	73 (12.3)	93 (15.5)
Gender		
Male	379 (64.0)	365 (60.9)
Chronic comorbidities		
Diabetes mellitus	56 (9.5)	70 (11.7)
Ischemic heart disease	18 (3.0)	16 (2.7)
Cardiac failure	19 (3.2)	14 (2.3)
Hypertension	120 (20.3)	145 (24.2)
Baseline creatinine clearance (mL/min)		
≥60	559 (94.4)	559 (93.3)
15-59	25 (4.3)	27 (4.6)
Exposure to RAS, KSD and/or K supplements		
None	488 (82.4)	483 (80.6)
One	82 (13.9)	95 (15.9)
Two	22 (3.7)	18 (3.0)
Three	0	3 (0.5)
Serum K ≥5.5 mmol/L	9 (1.5)	15 (2.5)
Normal renal status	6 (1.0)	10 (1.7)
Mild renal impairment	2 (0.3)	3 (0.5)
Moderate/severe renal impairment	1 (0.2)	1 (0.2)
Missing	0	1 (0.2)

K=potassium; KSD=potassium sparing diuretics; RAS=agents acting on the renin-angiotensin system.

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440. Necrotizing Soft-Tissue Infections Involving *Actinomyces* Species

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Background. *Actinomyces sp.* are associated with numerous clinical diseases in humans; however, there are few case reports of necrotizing soft-tissue infections (NSTIs) involving these organisms. Their role in NSTIs has not been well described. At our medical center, we noted an increase in *Actinomyces sp.* isolated from the tissue specimens of patients with NSTIs, prompting further evaluation.

Methods. Microbiology databases were utilized to identify patients with clinical cultures growing *Actinomyces sp.* from January 2008 to December 2018. Adult patients admitted to the R Adams Cowley Shock Trauma Center with a diagnosis of NSTI were included for analysis.

Results. Nine patients were identified meeting inclusion criteria, the first in February 2018–none prior. Organisms isolated from culture included *Actinomyces turicensis* (n = 3), *Actinomyces europeaus* (n = 1), and five organisms identified only as *Actinomyces* species. 89% of patients had additional co-pathogens identified in their tissue cultures. Eight patients had NSTIs of the lower extremity (n = 5) and/or the genitourinary area (n = 6), and one had chronic decubitus ulcers. Comorbidities included diabetes mellitus (77%), chronic kidney disease (33%). 44% patients were in septic shock at presentation. Surgical debridement was performed in all patients. Eight patients were discharged on amoxicillin, with a mean treatment duration of 75 days (range 31–90). One patient was treated with ampicillin–sulbactam. Readmission rate at 90 days was 37%; only one was related to the index infection. One death occurred during the index hospitalization, secondary to NSTI. No patients experienced adverse drug reactions during therapy.

Conclusion. We describe one of the largest case series to date of *Actinomyces* sp. associated with NSTI. The startling appearance of *Actinomyces* sp. at our institution directly followed the implementation of matrix-assisted laser desorption/ionization time of flight mass spectrometry in January 2018. *Actinomyces* sp. may act as co-pathogens contributing to the severity of NSTIs, augmenting the virulence of other organisms. As more advanced technology is used in laboratories to identify these organisms, further study is needed to determine pathogenicity and appropriate treatment.

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441. Factors Associated with a Change of Antimicrobial Therapy in Patients with Cellulitis Who Started with Amoxicillin–Clavulanate (A/C) Monotherapy

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Background. Cellulitis is a frequent cause of admission of adult patients to medical wards and A/C monotherapy is commonly used as the initial regimen. Studies evaluating the factors associated with the change of this regimen are lacking.

Methods. Data were extracted from a prospective and observational study of 606 adult patients with cellulitis admitted to several Spanish hospitals. Comorbidities, microbiological, clinical, lab, diagnostic, and treatment data were analyzed and compared according to the continuation/change of A/C. Multiple logistic regression modeling was performed to determine the variables independently associated with A/C switching.

Results. Overall 259 (42.7%) patients started A/C monotherapy, 56 (21.6%) of which were switched to other antimicrobials. Patients switched from A/C developed sepsis (19.6% vs. 8.4%, P = 0.02) and underwent imaging methods (P < 0.01) more commonly than those kept on A/C. These A/C switched patients had higher serum glucose (P = 0.04), creatinine (P < 0.0001), leukocyte (P = 0.006) and neutrophil counts (P < 0.0001). Regarding microbiological data, patients switched from A/C had more frequently pus (P < 0.0001) and blood cultures (P = 0.002) available, a microorganism identified (P < 0.0001) and higher rates of Gram-negative bacilli infections (P = 0.003). Patients switched from initial A/C had also longer hospitalization stays (10.5 vs. 5.2 days, P < 0.00019, longer duration of IV (10.0 vs. 4.3 days, P < 0.0001), and overall antibiotic treatment (16.5 vs. 10.4 days, P < 0.0001) and needed more frequently surgical treatment (25.0 vs. 4.9%, P < 0.0001), specialized follow-up after discharge (36.4 vs. 17.3%, P = 0.0009) and combination therapy after discharge (35.9% vs. 1.1%, P < 0.0001).The variables independently asociated with A/C switch in the multivariate analysis were higher serum creatinine (P = 0.03), neutrophil counts (P = 0.003), days on IV antibiotics (P < 0.0001) and the needed for surgical treatment (P = 0.004)

Conclusion. Patients switched from the initial A/C regimen do not have differences in the predisposing factors, but seem to have more serious cellulitis, characterized by higher neutrophil counts and serum creatinine, needing extended IV antibiotic therapy and additional surgical debridement.

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