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Prospective Randomized Double-blinded Trial Comparing 2 Anti-MRSA Agents With Supplemental Coverage of Cefazolin Before Lower Extremity Revascularization

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Abstract

Objective—To compare with antibiotics with methicillin-resistant microbial coverage in a prospective fashion.

Background—Current antibiotic prophylaxis for vascular procedures includes a first generation cephalosporin. No changes in recommendations have occurred despite changes in reports of incidence of MRSA related surgical site infections. Does supplemental anti-MRSA prophylactic coverage provide a significant reduction in Gram-positive or MRSA infections?

Methods—Single center prospective double blinded randomized study of patients undergoing lower extremity vascular procedures from 2011 to 2014. One hundred seventy-eight (178) patients were evaluated at 90 days for surgical site infection. Infections were categorized as early infections less than 30 days of the index procedure and late after 90 days.

Results—Early vascular surgical site infection occurred in 7(8.24%) of patients in the Vancomycin arm, and 11 (11.83%) in the Daptomycin arm ($P = 0.43$). Gram-positive related infections and MRSA infections occurred in 1(1.18%)/0(0%) of Vancomycin patients and 9 (9.68%)/1 (1.08%) of Daptomycin patients, respectively ($P < 0.02$ and $P = 1.00$). Readmissions related to surgical site infections occurred in 4(4.71%) in the Vancomycin group and 11 (11.8%) in the Daptomycin group ($P = 0.11$). Patients undergoing operative exploration occurred in 5 (5.88%) in the Vancomycin group and 10 (10.75%) of the Daptomycin group ($P = 0.17$). Late infections were reported in 3 patients, 2 of which were in the combined Daptomycin group. Median hospital charges related to readmissions due to a surgical site infection was $50,823 in the combination Vancomycin arm and $110,920 in the combination Daptomycin group; however, no statistical significance was appreciated ($P = 0.11$).

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Conclusions—Vancomycin supplemental prophylaxis seems to reduce the incidence of Gram-positive infection compared with adding supplemental Daptomycin prophylaxis. The Incidence of MRSA-related surgical site infections is low with the addition of either anti-MRSA agents compared with historical incidence of MRSA-related infection.

Keywords

antibiotics; lower extremity; MRSA; randomized trial; surgical site infection

Surgical site infection results in significant morbidity after vascular reconstructions. Historical studies have demonstrated a reduction in surgical site infection with the use of antibiotic prophylaxis in vascular surgery.[1] Over the following several decades' comparisons, second- and third-generation cephalosporins have been made with Cefazolin, a first generation cephalosporin, with mixed results in differences in surgical site infection.[2,3] Clearly the acquisition costs are greater with advanced generation cephalosporin's, with unclear advantages in reduction of postoperative infections.

Undoubtedly in the 21st century an evolving bacterial climate has occurred with resistant bacteria accounting for a consistent proportion of wound infections in the vascular patient.[4] The University of South Florida reported in a cohort of 34 patients with complicated extra-cavity vascular surgical site infections nearly 1/2 had methicillin resistant (44%) isolates at the time of antibiotic bead implant procedures and less than 25% of sites producing Gram-negative isolates. This is in contrast to work from our institution that demonstrated nearly opposite isolate findings with respect to methicillin-resistant organisms and Gram-negative organisms with approximately 25% and 40%, respectively.[5] These differences are dramatic and may be related to local regional differences in bacterial colonization or other geographical differences.

Nevertheless, the proportion of Gram-positive organisms with resistance to first generation cephalosporins has skyrocketed. Fifteen years ago a direct comparison of a glycopedide (teicoplanin) with Cefazolin was made with no apparent reduction in incidence of surgical site infection.[6] With this evolving microbial climate, we attempted to address this question several years ago with a prospective randomized trial comparing Cefazolin alone to Cefazolin with the addition of either vancomycin or daptomycin.[7] The infection rate was lowest in those receiving a combination of Cefazolin and Daptomycin; however, sample size was small and other methodological issues were identified. With the increasing incidence of methicillin-resistant *Staphylococcus aureus* (MRSA) infections[4,5] compared with historical series, in addition to a single center design and enrollment challenges we felt a third arm with the current standard of care would be difficult to fulfill patient enrollment in a reasonable time frame. Therefore we sought to evaluate patients undergoing vascular operations with lower extremity incisions and directly compare whether one anti-MRSA agent was superior to the other in a prospective double-blinded fashion.

METHODS

Patient Selection and Randomization

The study was conducted from March 2011 to May 2014. Patients referred to the West Virginia University Department of Surgery: Division of Vascular and Endovascular Surgery Charleston Division with indications for a groin or lower extremity vascular procedure were offered the opportunity to participate voluntarily in the research. Explanation of the research study was discussed with the patient by the vascular surgeon. Patients were included if they were 18 years of age undergoing a groin or lower extremity procedure or elective arterial revascularization. Patients were excluded if they had an allergy to Cefazolin, Daptomycin, or Vancomycin; Penicillin; or were being treated for an active infection; or enrolled in another IRB-approved biomedical study.

A sample size of 100 per treatment arm was determined for a total of 200 patients. This is based on Cohen's *d* formula with a significance of 0.05, 95% power and a greater than medium effect size. Because neither combination antibiotic group has been adequately evaluated for studied endpoint of lower extremity surgical site infection. Therefore, we used a Cohen's *d* coefficient as the effect size. We choose to use the coefficient for a medium effect size, which is 0.3.

Patients were randomized to either the cefazolin plus vancomycin arm or the cefazolin plus daptomycin arm. A randomization schedule was prepared using a statistical program. Patients were randomized to study drug A or drug B where only the pharmacy was aware of the drug designated as such. The antibiotics had similar appearing bags and sizes used, and were labeled study drug A or B for the initial administration and the 12-hour administration. The randomization schedule was given to the pharmacy, which prepared the antibiotic. The pharmacy kept a record of patients that corresponded to the randomization schedule. During the study period, 200 patients were randomized for a total of 100 in each arm.

Antibiotic Administration

The pharmacy prepared the antibiotic to be administered by anesthesia before the procedure according to the Surgical Site Infection Program protocol. Cefazolin of 1 gram was supplied in a syringe. Cefazolin 2 gram was supplied in a 100 mL bag. All patients got Cefazolin based on their weight. Patients in the Vancomycin arm received this drug in a 500 cc bag accompanied by a 50 cc bag of normal saline. At 12 hours, they were redosed and received the drug in a 500 cc bag. For patients randomized to receive Daptomycin, they received the drug in a 50 cc bag and this was accompanied by a 500 cc bag of normal saline. At 12 hours, the patient would receive a 500 bag of normal saline. All patients were redosed with Cefazolin at 3 hours during the operation. All patients received Cefazolin and the combination drug within 60 minutes of incision.

Standardization of Practice in the Operating Theatre

All participants in the surgical procedure used a 6-minute scrub with chlorhexidine gluconate 4% hand scrub. All patients were prepped with alcohol-based skin preparation chlorhexidine gluconate 2%w/v and Isopropyl Alcohol 70% v/v. In addition all patients had

occlusive skin drapes over the intended surgical site. At the conclusion of the procedures, all incisions were covered with a dressing cover-roll with stickers instructing not to remove for 48 hours after the procedure. All patients had hair removal by clipping and no patients were shaved. Patients did not routinely undergo nasal swab for MRSA before the procedures to detect colonization. None of the providers were tested for colonization. Intraoperative temperature control was carried out by the anesthesia team and temperatures were maintained 36–37.5 degrees Celsius by means of a bear hugger in all patients. During the operation serum glucose measurements were carried out hourly and intervention with humulin R for measurements of 150 mg/dl by institutional sliding scale.

Study Monitoring

The study employed a prospective double-blinded randomization design. The physicians were blinded throughout the study as to the antibiotic the patient received. Only the Outcomes Research Department and the Pharmacy knew the randomization schedule. Outcomes Research prepared the schedule and pharmacy prepared the antibiotic that the patient received. A dedicated research coordinator from the Clinical Trials Center coordinated the trial and Outcomes Research Department managed the data and conducted the analysis. The study was approved by the Institutional Review Board. Patients scheduled follow up included a visit within 30 days of the procedure and then at 6 months and again at 12 months. All patients who did not expire during the perioperative period achieved compliance with follow-up regimen.

Definitions

Surgical site infections were defined as infections by either cellulitis adjacent to a recent surgical site or purulent discharge from a surgical site. This was categorized to depth of involvement previously by Szilagyi et al.[8] The timing of the documented infection was also determined and classification of early infection as those occurring within 30 days of the procedure, 30–90 days intermediate, and late if documented > 90 days after the vascular procedure. A clinical coordinator followed the patient during the hospitalization to document any diagnosis of a surgical site infection and monitored all follow-up visits and readmissions to document an adverse event in the enrolled patients.

Statistical Analysis

The first level of analysis included descriptive statistics and univariate statistics. Comparison of groups was done using a *t* test for continuous data and a χ^2 for categorical data. Analysis involving data with small number included Fisher's χ^2 and χ^2. Differences are considered significant between the 2 groups if the *P* value is less than 0.05.

RESULTS

Patient Population

Two hundred (200) patients meeting the inclusion criteria were consented and randomized to receive Cefazolin plus Vancomycin and or Cefazolin plus Daptomycin during their surgical procedure. Twenty-two patients were excluded from the analysis for the following reasons: procedure cancelled for 9 patients after consent and randomization; 2 patients

received only 1 dose of Vancomycin; 3 patients screened failed before the procedure; and 8 patients died within 30 days after the procedure. None of the 8 patients who died after the procedure developed an infection. One-hundred and seventy-eight (178) patients are included in the analysis; 93 in the Cefazolin plus Daptomycin arm, and 85 in the Cefazolin plus Vancomycin arm.

Table 1 includes a description of the patient population. There were no differences between the patients in either study arm with respect to age, sex, race/ethnicity, co-morbid conditions, or perioperative risk factors. Risk factors included home oxygen use, current lower extremity wound, hospitalization in the last 30 days, a history of MRSA, and laboratory parameters.

Surgical Site Infections

Twenty-one (11.8%) of the 178 patients developed a surgical site infection. Three patients had superficial infections only and did not require surgical exploration for surgical site infection therefore no bacteria was isolated from there surgical site, with cellulitis only and received oral antibiotics only and thus far have not required admission for a surgical site infection. Eighteen patients developed an infection within 30 days of the procedure and 3 patients greater than 90 days post procedure. Thirteen (13) of the 93 patients (14%) in the Cefazolin plus Daptomycin and 8 of the 85 patients (9%) in the Cefazolin plus Vancomycin arm developed an infection including both early and late infections.

In the combination Daptomycin arm: Gram-positive infections with or with concomitant Gram-negative bacteria occurred in 10/13 patients with infections. This included 2 patients with MRSA: 1 early and 1 late. In the combination Vancomycin arm 2 patients developed an early Gram-positive infection (*Staphylococcus hominis*) and a polymicrobial Gram-positive anaerobic infection (*Actinobacter* and Vancomycin-resistant *enterococus*) and 1 in the late period for 3 total Gram-positive infections; however, no MRSA infections occurred and none containing *S. aureus*. In the Daptomycin combination group, 10 patients required re-exploration for infection 10.7% versus 4 patients in the Vancomycin cohort 5.88%; however, this was not statistically significant ($P = 0.17$). The total mean charges for patients requiring an infection related readmission was $50,823 in the combination Daptomycin arm and $110,920 in the combination Vancomycin group; however, no statistical significance was appreciated likely secondary to the wide range of costs per infection readmission $P = 0.948$ (Table 2).

Three infections (1.69%) were categorized as class I, with cellulitis only 2 of which were documented in the combination vancomycin arm within 90 days of surgery and 1 in the daptomycin arm as a late infection greater than 90 days from the index surgical procedure.

Early Infections (<30 days)

In the combination vancomycin arm, a total of 7 (8.24%) of patients developed an infection including 2 superficial infections Szilagi Class 1, resulting in 5(5.88%) Szilagi 2/3 infections. *S. aureus* was not isolated from any patients in the vancomycin cohort but 3 Gram-positive species were isolated from 2 surgical sites including, Vancomycin-resistant

Enterococcus/Actinobacter and *S. hominis* from early infections. Of the 7 infections, 4 (4.71%) required a repeat admission within 90 days of the procedure. Including 5 patients total requiring operative re-exploration for documented surgical site infection, 1 of these 5 patients exploration occurred during the admission of the initial procedure for evacuation of a hematoma and cultured *Klebsiella pneumonia*. At the surgical site, 6 of the 7 (85.7%) infections occurred at the groin incision and 4 of the 7 had an autologous reconstruction at the surgical site with infection with the remaining 3 patients having a prosthetic implant at the time of the index procedure.

The combination cohort with daptomycin a total of 11 infections (11.83%) developed an early surgical site infection. A total of 9 infections contained a Gram-positive isolate. *S. aureus* infections were seen in 7 patients and 1 patient demonstrated a methicillin resistant *S. aureus* species. One additional patient isolated a coagulase negative *staphylococcus* species and another the microorganism *S. pneumonia* was recovered during exploration. A polymicrobial infection was seen in 3/11 (27.3%) including both Gram-positive and negative orgainism. One patient had *Candida* cultured and 1 *Escherichia coli* as the sole organism. The location of the infections occurred in the groin in 3/11 (27.3%), in the thigh or calf incision in 7/11 (63.6%) and 1 in the chest wall after an axillobifemoral bypass. At the site of the vascular surgical site infection, 7/11 (63.6%) had a prosthetic implant and the remaining 4 had an autologous reconstruction at the site of the vascular surgical site infection.

Late Infections by Cohort Greater Than 90 days

A 6-month minimum follow up was carried out in all patients with the longest follow up over 4 years. Late infections occurring greater than 90 days post procedure occurred in 3 patients during the study period. This included 2 in the combination daptomycin and 1 in the combination vancomycin arm (Table 4). The combination daptomycin group, 1 patient developed cellulitis of the groin incision region overlying a seroma that resolved with oral antibiotics only; and a second patient with an infected femoral anastamotic pseudoaneurysm isolated MRSA at the time of surgical repair. In the combination vancomycin cohort *Staphylococcus lugdenensis* was cultured from a late infected seroma after interposition repair of a degenerative femoral aneurysm with polytetrafluroethylene interposition.

The locations of infections, and conduit if used with specific microbiology are listed in Tables 3 and 4.

DISCUSSION

Surgical site infection after vascular reconstruction occurs at varying rates depending on method to calculate the incidence. Using the NSQIP database evaluating 30 day infection rates after lower extremity revascularization the incidence was reported at 11% in 2011.[9] Risk factors for infection include but are not limited to: length of procedure, blood transfusions, type of skin preparation, and location of the surgical procedure.[10] Comorbidities that likely contribute to infection rates include: obesity, diabetes, low preoperative functional status, female sex, and history of smoking. In addition, postoperative hematomas and perioperative statin administration may contribute to risk of surgical site

infection specifically in those with surgery involving a groin incision.[11] The development of postoperative infection results in longer hospital stays, costs, increased risk of conduit failure and limb loss.

Location of surgical site also plays a factor in subsequent risk of surgical site infection. The groin crease and tendency of a moist environment likely contributes to this site resulting in more frequent wound problems than other locations incision sites. All patients in this study had a lower extremity incision with greater than 95% involving the groin specifically. Our previous randomized study permitted multiple surgical site incisions and likely diluted and provided more heterogeneity because neck and arm incisions are less frequently complicated by site infections.[7]

The primary endpoints of the study demonstrated several interesting findings. The incidence of Gram-positive infections after lower extremity incisions for vascular operations were reduced in the combination regimen of cefazolin/vancomycin compared with that of cefazolin/daptomycin 1.18% versus 9.68% $P = 0.02$. Of interest only 2 Gram-positive infections were seen in the combination regimen with Vancomycin less than 90 days of surgery including Vancomycin-resistant *enterococcus* and *S. hominis.* This is clearly less than seen in historical series with Gram-positive organisms accounting for the majority of early vascular surgical site infections.

Specifically evaluating the 2 combination regimens with respect to MRSA infections no advantage was demonstrated. With the cefazolin/vancomycin regimen demonstrating no MRSA infections within 90 days of surgery, the cefazolin/daptomycin regimen group had 1 infection (1.08%). Our series reports MRSA infections far less than contemporary series reporting MRSA as the leading organism from vascular patients with resultant increased morbidity, increased hospital length of stay, and higher implant removal and risk of limb loss.[12]

Late infections were uncommon in both groups with 2 patients in the daptomycin cohort and only 1 in the combination Vancomycin group. Two of the 3 infections involved staphyloccal species of including 1 patient with MRSA. *Staphylococcus epidermidis* has historically been the most common late microbe isolated but was seen in none of our 3 late infections.[13] One patient demonstrated clinical signs of a late infection and was treated for a late suspected infected seroma, and has not at this point demonstrated a recurrent infection.

Vancomycin for surgical prophylaxis has previously been shown to have favorable outcomes compared with cephalosporin therapy alone. Unlike our series where we used a combination of cefazolin with Vancomycin, Maki et al compared cefazolin, cefamandole, and vancomycin in cardiac and vascular operations. With over 300 patients, the incidence of surgical site infections was lowest in the vancomycin group 3.7% versus 12%, and 11% in with cefazolin and cefamandole, respectively. However, in the group of only 86 vascular operations were enrolled therefore superiority was not possible; however, vancomycin patients incurred only 1/3 the number of infections as those receiving a cephalosporin.[14]

Another glycopeptide teicoplanin has been studied and did not perform as good as vancomycin. The theoretical benefit to vancomycin is less side effects related to a longer

half-life. Marroni compared 238 patients with either abdominal or lower extremity prosthetic vascular surgery and reported no reduction in either wound infection or graft infections with a glycopeptide compared with 1st generation cephalosporin, with wound and graft infection rates of 4.2%/1.7% and 1.7%/0% in the Cefazolin group ($P = 0.195$). Cost saving favored the use of a 1st generation cephalosporin in this report. Again this series differs from ours in several aspects, no 1st generation cephalosporin comparison, only prosthetic implant patients in their series and autologous or no implant in our cohort, and over 60% in both groups on Marroni series having abdominal aortic aneurysm repair without lower extremity incisions.[6]

Although this series sheds some light on the impact of combination regimens in contemporary elective vascular surgery patients with lower extremity incisions, several clear limitations are appreciated. First and utmost is the lack of comparison with the current recommended prophylactic agent alone, ie, Cefazolin. Although we potentially underpowered this study we still detected a significant difference in Gram-positive infections between the 2 arms. With a single center investigation and with a decreasing number of open surgical reconstructions, a 2-arm study was carried out. We also suggested from our previous series that Ancef and Daptomycin might be superior to either Cefazolin alone or in combination with Vancomycin. Future studies should again include a Cefazolin only arm compared with combination with vancomycin. Although the evolving climate of bacteria has shifted to higher resistant bacteria proportions, we are unable to ascertain the impact against the current standard of care. Second, although the addition of an anti-MRSA microbial agent may reduce the rate of Gram-positive infections are we simply shifting the flora to more Gram-negative microbes that are potentially even more difficult to manage?

CONCLUSIONS

The role of antibiotic prophylaxis is to provide coverage against the most common organisms resulting in postoperative infections. With the shifting resistant trend of microbes, prophylactic regimens will likely need changed to continue to provide appropriate spectrum needed. This small series demonstrates that addition of anti-MRSA agents to the current standard of care antimicrobial can limit the incidence of methicillin resistant infections in the early postoperative period.

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TABLE 1

Description of the Population

	Cefazolin + Daptomycin (n = 94)	Cefazolin + Vancomycin (n = 92)	*P*
Age	62.60 ± 11.8 (23–92)	63.94 ± 10.7 (35–89)	0.4226
Sex (male)	41 (43.62%)	40 (43.48%)	0.9848
Race/ethnicity (white)	7 (92.55%)	90 (97.83%)	0.1692
Comorbidities			
DM	30 (31.91%)	23 (25.00%)	0.2962
CHF	12 (12.77%)	10 (10.87%)	0.6889
COPD	27 (28.72%)	29 (31.52%)	0.6774
CAD	49 (52.13%)	46 (50.00%)	0.7716
PVD	85 (90.43%)	80 (86.96%)	0.4548
Hyperlipedemia	72 (76.60%)	74 (80.43%)	0.524
Hypertension	84 (89.36%)	77 (83.70%)	0.2573
Current_smoker	55 (58.51%)	59 (64.13%)	0.4314
Past_smoker	33 (35.11%)	23 (25.00%)	0.133
Patients on oxygen	3 (3.23%)	5 (5.43%)	0.4602
Patients with open wound	15 (16.13%)	11 (11.96%)	0.4142
Patients with hospitalization in last 30 days	32 (34.41%)	32 (35.16%)	>0.999
Patients with MRSA history	8 (8.51%)	3 (3.26%)	0.1291
Hemoglobin	12.88 ± 1.8 (8.2–17.7)	13.2 ± 2.0 (7.8–17.7)	0.272
White count	8.12 ± 2.1 (3.8–14.1)	8.68 ± 2.93 (3.7–18.5)	0.1421
Glucose in 24 h	112.3 ± 27.21 (76–221)	122.0 ± 51.96 (35–389)	0.1212
ICU LOS	2.10 ± 1.5 (0–9)	2.3 ± 2.0 (0–12)	0.3546

*Statistically significant.

TABLE 2

Infections Occurring in Less Than 30 Days

	Cephazolin + Daptomycin (n = 93)	Cephazolin + Vancomycin (n = 85)	*P*
MRSA	1 (1.08%)	0	1.00
Gram-positive (including MRSA)	9 (9.68%)	1 (1.18)	0.02
Total Infections	11 (11.83%)	7 (8.24%)	0.43
Re-explored surgery	10 (10.75%)	5 (5.88%)	0.17
Readmission related to infection	11 (11.83%)*	4 (4.71%)**	0.11
Total charges due to readmission related to infection Mean/Median (Range)**	50823.39/41937.27 (8399.72–94346.38)	110920.67/45450.17 (21691.13–331091.20)	0.948

* One readmitted for wound dehiscence, cultured obtained and negative pressure wound dressing applied at bedside and no operative exploration.

** Two infections were cellulitis of incision before discharge and placed on antibiotics @ discharge without subsequent readmission, 1 patient developed a wound infection before discharge and was explored before discharge.

TABLE 3

Surgical Site Infections Combination Vancomycin 8: Daptomycin 13

Site	Conduit	Procedure	Microorganism(s)	Timing
Groin	Dacron	Aorto-bifem	None-cellulitis only	Early
Groin	Bovine	CFA endart.	None-cellulitis only	Early
Groin	Vein	Femoral-tibial	*Pseudomonas, Escheria coli, Staphylococcus Hominis*	Early
Groin	Vein	Femoral-tibial	*(Actinobacter/VRE)*[*]	Early
Calf	Vein	Femoral-tibial	*Enterobacter Clocae*[*]	Early
Groin	PTFE	Femoral-tibial	*Morganella Morganii*[*]	Early
Groin	Vein	Femoral-tibial	*Klebseilla pneumonia*	Early
Groin	PTFE	Femoral interp	*S. Lugdenensis*	Late
Calf	PTFE	Femoral-popliteal	*S. Aureus, E. coli, Serratia*[*]	Early
Calf	PTFE	Femoral-popliteal	*S. aureus*	Early
Groin	PTFE	Femoral-Femoral	*Streptococcus Pneumonia*	Early
Thigh	PTFE	Femoral-pop	*E. coli*	Early
Thigh	PTFE	Femoral-pop	*S. aureus*	Early
Chest	PTFE	Axillo-bifem	*S. aureus*	Early
Calf	vein	Femoral-tibial	*S. aureus/E. coli*	Early
Groin	vein	Femoral popliteal	*Staphylococcus coagulase*	Early
Thigh	vein	Femoral popliteal	*Candida*	Early
Groin/calf	PTFE	Femoral tibial	MRSA, *E. cloacae*[*]	Early
Thigh	vein	Femoral-tibial	*S. Aureus/Enterobacter Aerogenes*[*]/Beta hemolytic *Streptococcus*	Early
Groin	PTFE	Femoral-popliteal	MRSA	Late
Groin	PTFE	Femoral-poplitalcellulitis	Only	Late

[*] Resistant to cefazolin.

TABLE 4

Infections Occurring Less Than or Greater Than 90 Days

	Cephazolin plus Daptomycin (n = 93)	Cephazolin plus Vancomycin (n = 85)	*P*
Infection < 90 d	11 (11.83%)	7 (8.24%)	0.43
Infection > 90 d	2 (2.15%)	1 (1.18%)	1.00