The VANCO Trial Findings Are Generalizable to a North American Trauma Registry

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Purpose: The VANCO trial generated internally valid evidence that intrawound vancomycin powder reduces the risk of deep surgical site infection in high-energy tibial plateau and pilon fractures. To support the off-label use of intrawound vancomycin powder in routine practice, we investigated the generalizability of the VANCO trial findings to a North American trauma registry sample of the intended target population.

Methods: We conducted a generalizability analysis using the VANCO trial sample of adult patients with a tibial plateau or pilon fracture enrolled from January 2015 to June 2017. We selected a comparator target population of VANCO-eligible patients from Trauma Quality Programs (TQP) research data admission year 2019. We estimated the average treatment effects of intrawound vancomycin powder on deep surgical site infection and gram-positive deep surgical site infection within the VANCO-eligible target population TQP patient sample by calculating a propensity score for probability of trial participation and weighting the VANCO trial participants using inverse probability weights.

Results: The 980 patients in the VANCO trial were highly representative of 31,924 TQP VANCO-eligible patients (Tipton generalizability index 0.96). We estimated that intrawound vancomycin powder reduced the odds of deep surgical infection by odds ratio (OR) =0.46 (95% confidence interval [CI] 0.25-0.86) and gram-positive deep surgical infection by OR = 0.39 (95% CI 0.18-0.84) within the TQP sample of VANCO-eligible patients. For reference, the trial average treatment effects for deep surgical infection and gram-positive deep surgical infection were OR = 0.60 (95% CI 0.37-0.98) and OR = 0.44 (95% CI 0.23-0.80), respectively.

Conclusion: The estimated treatment effects of intrawound vancomycin powder on reducing deep surgical site infection and gram-positive deep surgical site infection in high-energy tibial plateau and pilon fractures in a sample of VANCO trial-eligible patients from the TQP database appear similar, perhaps greater, than the effects observed in the trial.

Table 1. Baseline covariates of individuals in the Trauma Quality Programs (TQP) and VANCO Trial.

Covariate	TQP N = 31,924	VANCO Trial N = 980
Age, years, mean (SD)	49 (16)	46 (14)
Sex, female, n (%)	13,268 (42%)	363 (37%)
Race/Ethnicity, n (%)		
Non-Hispanic White	20,737 (65%)	685 (70%)
Non-Hispanic Black	5,331 (17%)	148 (15%)
Hispanic	3,788 (12%)	107 (11%)
Other	2,068 (6%)	40 (4%)
Insured, n (%)	28,210 (88%)	797 (81%)
Work-related injury, n (%)	1,892 (6%)	100 (10%)
Body mass index, kg/m^2, median (IQR)	28 (24 - 33)	29 (25 - 33)
Current smoker, n (%)	8,806 (28%)	383 (39%)
Alcohol abuse, n (%)	1,585 (5%)	30 (3%)
Diabetes, n (%)	4,214 (14%)	80 (8%)
Open fracture, n (%)	5,643 (18%)	191 (19%)
Fracture location, n (%)		
Plateau	23,616 (74%)	497 (51%)
Pilon	8,308 (26%)	483 (49%)