The prevention of catheter-related bloodstream infection (CRBSI) has been an area of intense research, but the heterogeneity of endpoints used to define catheter infection makes the interpretation of randomized controlled trials (RCTs) problematic" Grooth et al (2019).

Abstract:

BACKGROUND: The prevention of catheter-related bloodstream infection (CRBSI) has been an area of intense research, but the heterogeneity of endpoints used to define catheter infection makes the interpretation of randomized controlled trials (RCTs) problematic.

OBJECTIVES: To determine the validity of different endpoints for central venous catheter infections.

DATA SOURCES: 1) Individual-catheter data from 9428 catheters from four large RCTs. 2) Study-level data from 70 RCTs identified with a systematic search. For each RCT the prevalence rates of CRBSI, quantitative catheter tip colonization, catheter-associated infection (CAI) and central line-associated bloodstream infection (CLABSI) were extracted for each randomized study arm.

STUDY ELIGIBILITY CRITERIA: RCTs published between January 1987 and October 2018 investigating short-term central venous catheters or short-term dialysis catheters.

PARTICIPANTS: Adult patients requiring short-term central venous access.

INTERVENTIONS: Various interventions to reduce catheter infections.

METHODS: CRBSI was used as the gold-standard endpoint, for which colonization, CAI and CLABSI were evaluated as surrogate endpoints. Surrogate validity was assessed as: 1) the individual partial coefficient of determination (individual-pR2) using individual-catheter data; 2) the coefficient of determination (study-R2) from mixed-effect models regressing the therapeutic effect size of the surrogates on the effect size of CRBSI, using study-level data.

RESULTS: Colonization showed poor agreement with CRBSI at the individual-patient level (pR2=0.33 95%CI 0.28-0.38) and poor capture at the study level (R2=0.42, 95%CI 0.21-0.58). CAI showed good agreement with CRBSI at the individual-patient level (pR2=0.80, 95%CI 0.76-0.83) and moderate capture at the study level (R2=0.71, 95% CI 0.51-0.85). CLABSI showed poor agreement with CRBSI at the individual-patient level (pR2=0.34, 95%CI 0.23-0.46) and poor capture at the study level (R2=0.28, 95%CI 0.07-0.76).

CONCLUSIONS: CAI is a moderate to good surrogate endpoint for CRBSI. Colonization and CLABSI should be interpreted with caution they do not reliably reflect treatment effects on CRBSI.

CLINICAL TRIALS REGISTRATION: NCT01479153, NCT00417235, NCT01189682, NCT01629550.

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Reference:

Grooth, H.J., Timsit, J.F., Mermel, L., Mimoz, O., Buetti, N., du Cheyron, D., Oudemans-van Straaten, H.M. and Parienti, J.J. (2019) Validity of surrogate endpoints assessing central venous catheter-related infection: evidence from individual- and study-level analyses. Clinical Microbiology and Infection. October 3rd. doi: 10.1016/j.cmi.2019.09.022. .