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Erratum Article

DEVELOPMENT AND VALIDATION OF A NOVEL METHOD FOR CAUSALITY ASSESSMENT USING SUSPECTED ADVERSE DRUG REACTIONS TO ANGIOTENSIN-CONVERTING ENZYME INHIBITORS

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ABSTRACT

Objectives: The study has been designed to develop, test reliability, and construct validity of a novel versatile causality assessment tool (VCAT) method.

Methods: The study included 427 literature case reports of angiotensin-converting enzyme inhibitors with suspected adverse drug reactions from 1990 to February 25, 2016. The causality of these cases was assessed independently by 3 raters in 3 phases of the study. Kappa (*k*) and intra-class correlation Intraclass Correlation Coefficient (ICC) were used to test reliability and validity of the VCAT method.

Results: Intra-rater reliability was high between Phase I and Phase III (k=0.84–0.93; % agreement: 92.3–96.3%). Inter-rater agreement was good in Phase I (k=0.87–0.89, % agreement: 93.7–94.1%, ICC: 0.975) and Phase III (k=0.85–0.89, % agreement: 93–94.4%, ICC: 0.973). Validity was proved by the high agreement observed between Phase I and Phase II (k=0.78–0.94; % agreement: 89.7–97.2%; p<0.001); and between Phase II and Phase III (k=0.8–0.9; % agreement: 90.2–94.8%; p<0.001).

Conclusion: VCAT method is a standardized causal assessment tool that gives valid and reproducible results. It has shown good agreement with the expert judgment method. This method may overcome the limitations enthralled with existing methods of causality assessment.

Keywords: Angiotensin-converting enzyme inhibitors, Adverse drug reaction, Causality, Method, Rater.

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Old Table-

Table 1: VCAT parametric table

Parameters/Condition	Favorable (Yes)	Unfavorable (No)	Unknown	Score
TTO	6	0.1	1	
D	1.5	1	1	
L	1.25	1	1	
C	1.25	1	1	
DR	1.25	1	1	
LD	1.25	0.5	1	
R	4	0.75	1	
DDI	0.5	1	1	
H	0.75	1	1	
CD	0.75	1	1	
Total score (by multiplication of all individual scores): TTO x D x L x C x DR x LD x R x DDI x H x CD				

TTO: Time to onset; D: Dechallenge; L: Evidence in literature; C: Class effect; DR: Dose dependency/response; LD: Lab data/biopsy results supporting the event; R: Rechallenge; DDI: Drug-drug interactions; H: Medical history; CD: Confounding drugs. VCAT: Versatile causality assessment tool

New Table-

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