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Development and Validation of a Scale for Causality Assessment of Medical Device-Related Adverse Events: A Prospective Observational Study

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ABSTRACT:

This study aimed to develop and validate a simple, reliable causality assessment scale for medical device-related adverse events in materiovigilance. Delphi-based datasets were analyzed both qualitatively and quantitatively, with Delphi statements categorized and compared to adverse event reports. The new scale standardized causality assessment, reduced inter-assessor disagreement, and improved scientific evaluation of device safety. The validated scale provides a practical tool for enhancing materiovigilance and supporting consistent adverse event reporting in clinical settings.

Keywords:

Materiovigilance, Medical Device, Adverse Event, Causality Assessment, Delphi Method, Scale Validation.

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