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Development and validation of a modified Naranjo scale for better causality assessment of adverse events

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Background: Correct causality assessment of Adverse Drug Reactions is extremely important in day-to-day medical practice. It assumes even greater significance during clinical development of a drug because of paucity of prior information available about a drug's safety profile. The existing algorithms such as Naranjo scale used for causality assessments are inadequate due to improper distribution of weightage to vital questions. Therefore, a modified Naranjo scoring system for causality assessment of adverse events (AE) was developed.

Methods: We modified the Naranjo scale by (a) changing the weightage given to certain responses in the existing Naranjo scores (b) expanding few questions allowing greater clarity for causality assessment (c) modifying the cut-off scores for classification of AEs as definite, probable, possible, doubtful and not related. We then validated the modified Naranjo scale against the existing scale in 19 random cases at a tertiary care cancer hospital using physician's opinion as gold standard.

Results: Nineteen cases were used for validating the modified Naranjo scale. Of these, 6 cases were described by treating physician as 'unrelated' AEs and 13 as 'related' to the drug in question. The number of cases fallen into doubtful, possible, probable and definite categories using Naranjo scale are 1, 6, 7 and 5 respectively. Using modified algorithm, number of cases fallen into not related, doubtful, possible, probable and definite categories are 1, 5, 4, 8 and 1 respectively. Categories of 'possible-definite' are considered 'related', and 'doubtful-not related' are considered 'unrelated'. Thus, the modified algorithm had 100% concordance with physician's opinion whereas the Naranjo scale had only 73.7% concordance. Five out of 6 cases (83%) were misclassified by Naranjo as 'related' when they were actually 'unrelated'.

Conclusion: The Naranjo scale showed a huge bias towards classifying AEs as 'related' to drugs. The modified algorithm gives better sensitivity and specificity for the causality assessment of AEs.

Biography

Manjunath Nookala Krishnamurthy has completed his Super-specialization course in Clinical Pharmacology & Toxicology and working as Assistant Professor in the Department of Clinical Pharmacology Tata Memorial Centre, Mumbai, India. He is involved in management of early phase clinical trials (phase 1) and a biosimilar trial. He is also an Active Member in the Data safety monitoring committee playing a key role in the assessments of the adverse drug reactions. He is also involved in the clinical studies involved in collecting the adverse drug reaction data in oncology in renal cancer, hepatocellular cancer, lung and prostate cancer. He has publications in the PubMed indexed journals.

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