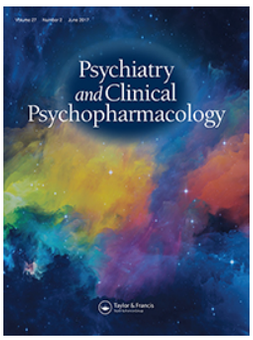

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LETTER TO THE EDITOR

Adverse drug reactions and causality: the Turkish version of Naranjo Adverse Drug Reactions Probability Scale

To the Editor,

Early recognition of adverse drug reactions is crucial in the medication management of psychiatric disorders. Several diagnostic assessment tools have been proposed to evaluate and manage adverse drug reactions and determine the likelihood of drug involvement. The qualities required for an objective diagnostic assessment tool are reproducibility and validity. Reproducibility implies different users reaching the same ratings despite differences in time and place of administration and is important when comparing results at baseline and during or after the experimental procedure. Validity, in this context, means that the method is able to distinguish between cases who are drug-induced or related and cases who are not. Use of clinical judgement in evaluating alternative etiological explanations is also crucial. To improve objectiveness, consistency, and accuracy for the causality assessment of adverse drug reactions, several different clinical instruments have been proposed [1]. The Naranjo Adverse Drug Reactions Probability Scale (NADRPS) was developed for the assessment of adverse drug reactions [2]. The principal advantages of the Naranjo Adverse Drug Reaction scale are simplicity, not being time-consuming, and a wide range of applicability. The Naranjo criteria classify the probability that an adverse event is related to drug treatment based on a list of weighted questions, which examine factors such as the temporal association of drug administration and event occurrence, alternative causes for the event, drug levels, dose–response relationships, and previous patient experience with the medication. The adverse drug reactions are assigned to a probability category from the total score as follows: definite if the overall score is 9 or greater, probable for a score of 5–8, possible for 1–4, and finally unlikely if the score is 0. The weightings of criteria might differ among different adverse reactions to take into account the singularities of each therapeutic problem. The Naranjo scale asks for a confirmation of the adverse drug reaction using objective evidence. The Naranjo criteria also do not take into account any drug–drug interactions. Drugs are evaluated individually for causality, and points deducted if another factor may have resulted in the adverse event, henceforth weakening the causal association.

When we review the case reports submitted to medical journals, we came to realize that a case report would most likely be rejected by the reviewers when authors stated that they did not use any objective assessment tool for adverse drug reactions. While reporting a an adverse drug reaction, clinicians should identify and record data from the patients and present this information using a structured reporting form, which includes demographic data, a detailed clinical history including underlying diseases and treatment, the presence of risk factors such as alcohol or substance use or pregnancy, temporal relationship between the administration of the suspected drug and the onset of adverse reaction, and between the withdrawal of the drug and the course of the adverse reaction, exclusion of alternative causes, and finally the outcome of the reaction. To the best of our knowledge, while the Adverse Reaction Submission Form prepared by the Turkish Pharmacovigilance Center can provide a demographic data for adverse drug reactions for the clinicians, no instruments like the NADRPS is available in Turkish. Here, we provide a Turkish version of the NADRPS, following the Brislin's established guidelines [3]. The NADRPS has been translated into Turkish by Samet Kose, and back-translated into English by Ercan Akin, who was blinded to the original items. After establishing semantic equivalence of the NADRPS items, the content equivalence of all items was examined, and no items were excluded as being irrelevant. We encourage the application of the NADRPS in the causality assessment of any suspected drug-induced adverse reactions for case reports submitted for publication from Turkey.

The NADRPS appears to be reliable and reproducible and could be of considerable clinical value in assessing complex patients in clinical practice and also in research settings. Furthermore, the scale can be useful in routine clinical practice to recall the parameters that need to be systematically addressed in cases of suspected adverse reactions so that clinical evaluation and management can be improved and become more consistent. We conclude that systematic application of the NADRPS would improve the quality of the assessment

of adverse drug reactions in a variety of clinical situations.

Naranjo Advers İlaç Reaksiyon Olasılık Ölçeği	Evet	Hayır	Bilinmiyor	Puan
1. Daha önce bu advers reaksiyon ile iligili *ikna edici* bir rapor bildirildi mi?	+1	0	0	
2. Advers reaksiyon, şüpheli ilaç verildikten sonra mı ortaya çıktı?	+2	−1	0	
3. Advers etki, ilaç kesildikten ya da *specifik* bir antagonist uygulandıktan sonra düzeldi mi?	+1	0	0	
4. İlaç yeniden uygulandığında advers reaksiyon yeniden ortaya çıktı mı?	+2	−1	0	
5. Advers reaksiyona yol açabilecek ilaç dışında alternatif nedenler var mıydı?	−1	+2	0	
6. Plasebo verildiğinde advers reaksiyon yeniden ortaya çıktı mı?	−1	+1	0	
7. Kanda (ya da diğer sıvılarda) tespit edilen ilaç toksik olarak kabul edilen konsantrasyonlarda mıydı?	+1	0	0	
8. Advers reaksiyon ilacın dozu artırıldığında daha şiddetlli, azaltıldığında daha az şiddetli miydi?	+1	0	0	
9. Hasta *daha önce* aynı ya da benzer bir ilaca maruz kaldığında benzer bir advers reaksiyon sergiledi mi?	+1	0	0	
10. Advers reaksiyon herhangi bir objektif kanıt tarafından teyit edildi mi?	+1	0	0	
			Toplam	

Disclosure statement

No potential conflict of interest was reported by the authors.

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