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Extent of under reporting of adverse drug reactions (ADRS) in India: Evaluation using logistic regression analysis (LRA) model

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Abstract

Objective:

1. To determine statistically, the knowledge, awareness/attitude and perception/practice (KAP) related risk factors / variables significantly responsible for under reporting of ADRs in India, using logistic regression analysis (LRA) Model,
2. Use the LRA model to estimate the extent of under reporting of ADRs if the current levels of KAPs of Medical Practitioners (MPs) in India continue to prevail and
3. To recommend corrective measures for implementation at National level to improve KAP related risk variables in order to reduce the risk of underreporting of ADRs

Methods: The results of survey on KAPs of MPs in India towards under reporting of ADRs were published earlier by same authors. In the same KAP survey, there was an option in questionnaire to provide the information on

1. number of ADRs observed during medical practice and
2. The number of ADRs reported to relevant authorities like Pharmacovigilance (PV)/ADR monitoring centers.

116 MPs out of 870 MPs who participated in the survey provided the above information. All MPs who reported less than 25% of ADRs were assumed to contribute to the underreporting of ADRs prevailing in India. Hence, in respect of these MPs the status of "underreporting" was categorized as "Yes" and in the others as "No". Thus, dependent/outcome variable (status of underreporting of ADRs) was measured on binary/dichotomous scale as Yes (0)/No (1). Similarly, six independent/predictor variables were also measured on a binary/dichotomous scale as "present" or "absent". Using these data, Six 2x2 contingency tables were prepared with "status of underreporting of ADRs as outcome variable and each of the 6 independent/predictor variables. These 2x2 contingency tables revealed that each independent variable was significantly associated with "underreporting of ADRs". However, 2x2 contingency table has a major limitation as it assumes the levels of all other independent variables except the one used in preparing 2x2 contingency tables, to be the same in all other respondents. This assumption is not realistic hence, 2x2 contingency tables fail to estimate the true odds ratio to express risk of underreporting of ADRs. 2x2 contingency table is prepared using one risk factor/ variable at a time, from many other independent variables. Hence it is possible that all or some of the remaining independent variables may be confusing the relationship between independent variables and the dependent variable - underreporting. This is known as confounding. Hence, to account for any confounding, if present, the data were analyzed using logistic regression analysis (LRA). Logistic regression analysis is a powerful tool for assessing the relative importance of factors that determine the outcome.

Results: Data from 116 out of 870 who provided information number of ADRs observed and the number of ADRs reported to Govt. ADR monitoring/PV centers were used to generate 2x2 contingency tables. Underreporting of ADR was used as the outcome variable and the each of the other variables were measured on binary/dichotomous scale (as Yes/No). The odds ratio in favor of under reporting was found to be statistically significant with each of the six variables. Logistic Regression Analysis (LRA) model uses statistical techniques to get statistically significant variables responsible for underreporting after adjusting for confounding variables unlike in 2x2 contingency tables. Stepwise logistic regression analysis when applied to data from 116 MPs, picked up 4 variables out of 6 as statistically significant ($P<0.05$) variables after adjusting for confounding variables as responsible for observed underreporting in India.

Conclusion: Thus, results suggest that at the current level of the following KAP related factors/variables of MPs, there is high probability of continuing the problem of "underreporting of ADRs" for some more time in India:

1. Proc_diff = Difficult procedure
2. Proc_knowledge = Knowledge of ADR reporting procedure
3. ADR attributable to Medicine
4. Govt ADR centers useful

If the shortcomings in the current levels of KAPs of MPs are eliminated/removed, it may be possible to resolve successfully the issue of underreporting of ADRs in India. The shortcomings in KAP levels of MPs can be removed by developing appropriate training modules at National level to create awareness among all healthcare professionals and MPs and by designing simple ADR forms and procedures for reporting of ADRs to PV/ADR monitoring centers.

Key Words: Adverse drug reactions, pharmacovigilance, ADR reporting, logistic regression analysis (LRA), odds ratios (ORs).