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KNOWLEDGE, ATTITUDE AND PRACTICES OF PHARMACOVIGILANCE AMONG DOCTORS AT A TERTIARY CARE TEACHING HOSPITAL BIRGUNJ, NEPAL

Singh Smita,[1*] Sarraf Deependra Prasad,[2] Singh Prabin,[3] Poudyel Pragati [4]

[1] Department of Pharmacology, National Medical College, Birgunj
[2] Department of Clinical Pharmacology and Therapeutics, B.P. Koirala Institute of Health Sciences, Dharan
[3] Department of Pediatrics, Narayani Sub-Regional Hospital, Birgunj
[4] Department of Physiology, People's Dental college and Hospital, Kathmandu, Nepal

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Correspondence to:
Dr. Singh Smita, MD
Department of Pharmacology, National Medical College, Birgunj
Email: ssktm3@gmail.com, Cell: 9852056346

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ABSTRACT

Introduction: *Pharmacovigilance helps in the detection and prevention of adverse effects of drugs. For effectiveness of this program, health care professionals should report adverse drug reactions considering it as their moral and professional obligation. The objective of this study was to assess the knowledge, attitude and practices of the doctors towards pharmacovigilance in a tertiary care teaching hospital situated in Province two.*

Materials and Methods: *A cross sectional study was carried out using self-administered questionnaire consisting of four parts; first part included demographic profile of participants, second part consisted of ten questions for the assessment of the knowledge about pharmacovigilance, third part comprised of six questions on attitude and forth part consisted of five questions on practice. The results were depicted in the form of percentage for each questionnaire.*

Results: *The response rate of participants was 88.51%. Pharmacovigilance was correctly defined by 52%. Department of drug administration is the responsible body for monitoring adverse drug reactions in Nepal which was correctly answered by 80% of the participants. Only 8% had reported adverse drug reactions though 62% had encountered it in their clinical practice.*

Conclusion: *The study revealed poor knowledge, attitude and practices of pharmacovigilance among practicing doctors, thus educational intervention is needed for the proper functioning of this program.*

Keywords: *Attitude; Knowledge; Pharmacovigilance; Practices*

INTRODUCTION

Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem".[1] It helps in ensuring that the patient receives safe drugs as adverse drug reactions(ADRs) are considered as one of the major reasons of mortality and morbidity in the world.[2]

Phase IV clinical trial (Post marketing surveillance) includes safety surveillance (Pharmacovigilance) where uncommon/idiosyncratic ADRs, unexpected drug interactions, reactions in special groups like children, pregnant/lactating women, patients with renal/hepatic diseases, chronic toxicity can be detected by collection of different types of ADRs reporting forms used in different countries.[3]

The reasons for underreporting of ADRs vary from countries to countries but major causes include lack of awareness about the existence of pharmacovigilance program, negative attitude towards ADR reporting and unavailability of ADR reporting forms. Health care professionals should fill the ADR forms as it is their moral and professional obligation.[4] In Nepal, the Department of Drug Administration was established as National Centre for Pharmacovigilance in the year 2004; however, it's still in infancy stage due to lack of awareness, function and benefits of this program among healthcare professionals.[5] For strengthening the program several strategies such as awareness, trainings, inclusion of program in curriculum, expanding the program to community level can be implemented. Knowledge, attitude and practices (KAP) of the healthcare professionals about pharmacovigilance have been assessed by different studies conducted

abroad; however, few studies have been conducted in Nepal.[6] Therefore, the objective of the present study was to evaluate the KAP of pharmacovigilance among practicing medical doctors at National Medical College Teaching Hospital, Birgunj, Nepal.

MATERIALS AND METHODS

A cross-sectional study was conducted among doctors at National Medical College and Teaching Hospital (NMCTH) Birgunj, Nepal from January to March 2021. NMCTH is one of the largest teaching hospitals in Narayani zone. Clinical doctors working in NMCTH were enrolled in the study whereas the doctors who did not give consent were excluded. For the calculation of sample size, the prevalence of good knowledge of ADRs reporting among doctors was taken 34.3% from the study conducted among the health care professionals in Kathmandu.[9]

The sample size was calculated as follow,

$n= z^2xp \times q/d^2$

$= 3.84x34.3\ (100-34.3)/\ (7)^2$

$= 176$

where, n = minimum sample size, p = prevalence, 34.3%, q = 100-p, e = margin of error, 7%

Therefore, the calculated sample size was 176.

Convenience sampling method was used. A semi-structured questionnaire was developed after reviewing previously published articles related to this field and consent for the questionnaire from authors who have contributed in this field was undertaken.[7,8] The questionnaire was divided into four parts; first part included demographic profile of the participants, second part consisted of ten questions on knowledge of pharmacovigilance, third part comprised of four questions on attitude of pharmacovigilance and the fourth part consisted of six questions on practice of pharmacovigilance. Both attitude and practice were assessed by Yes or No response. Ethical clearance was obtained from Institutional Ethics Committee, NMCTH (F-NMC/511/077/078). After taking the consent from the participants, the questionnaires were directly distributed to the doctors in their respective departments and collected after 20 minutes. Anonymity of the participants was maintained. The collected data proforma were checked for their completeness and those having missing/unfilled data were discarded. The data were entered in Microsoft Excel 2007. The distributive statistics like mean, frequency and percentage were calculated and the data were depicted in the form of tables.

RESULTS

Out of 209, a total of 185 participants responded and seven incomplete Proforma were discarded giving a response rate of 88.51%. Majority of the participants were male (61.24%), assistant professor (34.27%). Most of the participants (57.3%) were in the age group of 31 to 40 years (Table 1).

Table 1. Sociodemographic characteristics of the participants (n=178)

Variables		Frequency	Percentage
Gender	Male	109	61.24
	Female	69	38.76
Age in years	21 – 30	41	23.03
	31 – 40	102	57.30
	More than 40	35	19.66
Desig-nation	Medical officer	33	18.54
	Postgraduate student	49	27.53
	Assistant professor	61	34.27
	Associate professor	11	6.18
	Professor	24	13.48

Table 2 shows the knowledge of the pharmacovigilance among the participants. Only 52.81% participants gave the correct definition of Pharmacovigilance while 80.34% participants responded correctly that Department of Drug Administration is responsible for monitoring ADR in Nepal. More than half of the participants (64.04%) agreed that reporting of ADR in Nepal is voluntary (Table 2).

Table 3 shows the responses of the participants towards attitude of pharmacovigilance. One hundred and sixty six participants (93.26%) believed that reporting ADR of drugs is necessary. Ninety four (52.81%) participants thought pharmacovigilance should be taught in detail to healthcare professionals. One hundred and sixty eight (94.38%) participants agreed that establishment of ADR monitoring center in every hospital is essential (Table 3).

Table 4 shows the responses of the participants towards practice of pharmacovigilance. One hundred and seventy (95.51%) participants had never reported an ADR case. Only eleven (6.18%) participants had got training on pharmacovigilance (Table 4). The factors discouraging the participants from reporting ADR was lack of time in 78%, incentives in 66%, misconception that single reporting doesn't have any impact in 64%, lack of confidence that ADR has occurred in 34% and availability of ADR form in 29%.

Table 2. Knowledge of the pharmacovigilance among participants (n=178)

S.N.	Questions on knowledge	Correct response (%)	Incorrect response (%)
1.	Pharmacovigilance is the science that relates to the detection, assessment, understanding and prevention.	94 (52.81)	84 (47.19)
2.	The specific aim of Pharmacovigilance is to improve patient safety.	78 (43.82)	100 (56.18)
3.	The scale most commonly used to establish the causality of an ADR is Naranjo algorithm.	65 (36.52)	113 (63.48)
4.	Scale most commonly used to establish the severity of an ADR is Hartwig scale.	67 (37.64)	111 (62.36)
5.	Post marketing Surveillance is the commonly employed by the pharmaceutical companies to monitor ADRs of new drugs after they are launched in the market.	70 (39.33)	108 (60.67)
6.	VigiFlow is the WHO online database for reporting ADR by member countries.	41 (23.03)	137 (76.97)
7.	In Nepal, the national center responsible for monitoring ADRs is Department of Drug Administration.	143 (80.34)	35 (19.66)
8.	Doctors, nurses and pharmacists can report an ADR in Nepal.	111 (62.36)	67 (37.64)
9.	Reporting of ADR in Nepal is voluntary.	114 (64.04)	64 (35.96)
10.	Form used to report ADR in Nepal is ADR reporting form.	59 (33.15)	119 (66.85)

Table 3. Attitude of the pharmacovigilance among participants (n=178)

S.N.	Questions on attitude	Responses	
		Yes (%)	No (%)
1	Do you think reporting an ADR of drugs is necessary?	166 (93.26)	12 (6.74)
2	Do you think pharmacovigilance should be taught in detail to healthcare professionals?	94(52.81)	84(47.19)
3	Do you think it is necessary to report only serious and unexpected reactions?	109(61.24)	69(38.76)
4	Do you think of establishment of ADR monitoring center in every hospital?	168(94.38)	10(5.62)

Table 4. Practice of the pharmacovigilance among participants (n=178)

S.N.	Questions on practice	Responses	
		Yes (%)	No (%)
1	Have you reported ADR cases?	8 (4.49)	170 (95.51)
2	Have you been trained to report ADR form?	11 (6.18)	167 (93.82)
3	Have you ever experienced ADR in your patients during practice?	109 (61.24)	69 (38.76)
4	Have you ever seen ADR reporting form?	56 (31.46)	122 (68.54)
5	Have you ever yourself experienced ADR?	98 (55.06)	80 (44.94)
6.	Have you ever read an article related to prevention of ADR?	98(55.06)	80(44.94)

DISCUSSION

In the present study, KAP about pharmacovigilance(PV) was assessed among doctors at a tertiary health care center, Birgunj. PV plays a pivotal role in withdrawing the drug from the market after its launch where practicing doctors play a major role in supporting this program. In the present study, 53% gave correct definition of PV which was similar to study conducted in South India by Gupta et al where this percentage was 62.4%.[10] Only about 43% knew about the aim of PV which was similar with the study conducted by Kharadi et al (46%).[11] About 80% of doctors knew about location of national pharmacovigilance center which is in accordance with the study done by Palaian et al in Nepal where 60.7% of the healthcare professionals were aware about the location of the regional pharmacovigilance center.[4] The correct response to the question who can report ADRs was 62% which was higher than that of the study done by Meher et al (40%)[12] and Kharadi et al (50%).[11] Naranjo algorithm is used for the assessment of causality where as Hartwig scale is used for severity which categorizes ADRs

into mild, moderate and severe. In this study, only 36% knew about the scale used to measure causality where as 37% knew about Hartwig scale which is near to that of study done by Palaian et al where 30% were aware about Naranjo scale and 28% about Hartwig scale.[4]

Relating to attitude towards reporting, 93% agreed that ADRs reporting was necessary, 52% thought pharmacovigilance should be taught in detail to health care professionals, 94% thought of establishment of ADRs monitoring center in every hospital. Similar results were obtained from different studies done at different places.[10,12] Though doctors had experienced ADRs in 61% of their patients only 4% of them had reported it which is quite less than the study done by Palaian[4] but similar to that of study done by Meher et al.[12]

Different studies have shown different reasons for underreporting but the major causes are lack of knowledge about reporting procedure and existence of reporting system, unavailability of ADR forms, belief that these ADR are already known, lack of time, ignorance towards reporting, inability to decide ADRs, legal issues etc.[4] In the present study, the major reasons for under-reporting are lack of training about how and where to report (93%), lack of time (78%), not coming across the ADRs (61%) which is in accordance with the study done by Gupta et al where 85% of doctors were unaware about procedure of reporting and lack of time in 73%.[13]

Overall, our study suggests that clinical sessions, trainings, workshops should be conducted to train the practicing doctors regarding ADRs which will increase their awareness and strengthen their confidence towards reporting as reporting is their moral and professional obligation. Studies have also shown that educational intervention has a pivotal role regarding improvement in reporting.[14] Katekhaye et al suggested some measures that can improve the PV and ADR reporting such as implementation of feedback system, active participation of monitoring committee, publicity of the reporting, mandatory reporting, establishment of separate PV Outpatient department and ADR specialist in every department.[15] These measures can also be implemented in Nepal for the improvement of PV which is still in its early stage.

Though the present study might delineate a new pathway for the promotion and development of PV at national level, it has few limitations. Only doctors were included in the study; other healthcare professionals like nurses and pharmacists weren't included. This study was conducted in single hospital; hence, it might be difficult to infer the findings to the entire hospitals of the country. Due to high turnover of health professionals, educational intervention and its impact couldn't be carried.

CONCLUSION

The doctors at NMCTH had a relatively limited knowledge, attitude and practice towards pharmacovigilance and reporting of ADRs. Proper trainings should be conducted to promote and improve ADRs and pharmacovigilance.

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