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Knowledge Attitude and Practice of Pharmacovigilance Among Doctors Posted at Peripheral Health Centers in a District of West Bengal: A Cross-sectional Study

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ABSTRACT
Pharmacovigilance is the science and activities related to the collection, detection, assessment, understanding, monitoring and prevention of adverse drug reactions (ADRs). Adequate monitoring of ADRs is necessary to prevent the rising mortality and morbidity related to an increased number of ADRs. For this purpose, most countries worldwide including India have started their national Pharmacovigilance programs. Involvement of health care professionals (HCPs) of all levels, most importantly the doctors in this program can render its success by regular reporting of ADRs. In India, several ADR Monitoring Centres (AMCs) are set up in different tertiary healthcare centres throughout the country under the Pharmacovigilance Program of India (PvPI) with its National Co-ordinating Centre at Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh. However the contribution of India towards the Uppsala Monitoring Centre, Sweden (Collaborating centre of WHO for international monitoring of ADRs) is very low. The most important cause of this is the under-reporting of ADRs by the HCPs, which may be due to their deficit of proper knowledge and practice of regular reporting of ADRs. So our study is to assess the knowledge, attitude and practices (KAP) regarding Pharmacovigilance among the doctors posted at different levels of government rural health centres of a district in the eastern part of India. This was a cross-sectional study carried out using a pretested self-administered questionnaire. It was designed to assess the KAP regarding Pharmacovigilance. The study population was the doctors posted at different levels of government rural health centres of a district in the eastern part of India. The questionnaires were distributed to them after proper informed consent and the answers were collected from them after two weeks. The data received from the participants were entered and analyzed by Microsoft Excel spreadsheet in MS Office 10. The response rate of the participants was 90% (126 out of 140). 76.92% didn't know the correct definition of Pharmacovigilance or awareness about PvPI. 61.54% didn't know the Website used for reporting ADRs or about the International Collaborating Centre of Pharmacovigilance. But most of the participants agreed or strongly agreed that all health centres should have the Toll-free number for reporting any unwanted drug reaction (61.54%), or have adequate facilities for reporting the same (84.61%). The majority also agreed that ADR reporting should be made mandatory for all doctors of rural health services (92.31%) and all should have the proper knowledge and actively participate in PvPI (76.92%). The majority of the participants have not reported any ADR to any higher authority (84.62%), but are eager to gain proper knowledge regarding PvPI (92.3%) or attend any training or workshop regarding the same (100%). Knowledge regarding PvPI and its practical implications should be present in doctors of all levels. Adequate participation of all doctors can improve the benefits of this program.

INTRODUCTION

According to the World Health Organization (WHO), Pharmacovigilance is the pharmacological science and activities related to the collection, detection, assessment, understanding, monitoring and prevention of adverse effects or any other drug-related problem, mainly long-term or short-term side effects of pharmaceutical products[1]. One of the most important reasons for worldwide morbidity and mortality is Adverse Drug Reactions (ADRs)[2-5]. The rising number of ADRs also has a major impact on social and public health[6]. So, adequate monitoring of ADRs is very necessary. To identify the drugs causing ADRs, it has been recommended that all countries start their pharmacovigilance programs[7]. Therefore, most countries worldwide have established formal procedures to encourage healthcare professionals to report suspected ADRs encountered in their daily clinical practice to the respective national drug regulatory authority[8].

The collaborating centre of WHO for international monitoring of adverse drug reactions is situated in Uppsala, Sweden (UMC) which has the international database of suspected adverse drug reaction reports from all over the world[9]. The Pharmacovigilance Program of India (PvPI) was launched in July 2010 by a combined venture of the Central Drugs Standard Control Organization (CDSCO), New Delhi, MoHFW, Government of India with All India Institute of Medical Sciences (AIIMS) as the National Coordinating Centre (NCC), under which 22 ADR monitoring centres (AMCs) were formed all over India for monitoring ADRs. To increase the speed and implementation of the program, the NCC was shifted to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, U.P. from AIIMS[10].

To increase the safety of patients from unwanted drug reactions, an attempt to include pharmacovigilance activity in practices has been taken, for which more numbers of AMCs are being set up across the country under PvPI[11].

Despite such efforts, the contribution of India to UMC (Sweden) is very little (1%) regarding ADR reporting compared to worldwide contribution (5%)[12,13]. Health Care Professionals, especially doctors show less interest in considering ADR reporting as a part of their routine professional practice[14]. Many studies have revealed that underreporting of ADRs is mostly due to a deficiency in adequate knowledge and attitude among healthcare professionals[15,16].

Although several studies in India have evaluated the Knowledge, Attitude and Practice of Pharmacovigilance among doctors working in different teaching hospitals and corporate setups, the same among doctors working at peripheral rural setups has not been done adequately to date[12,15-22]. So the objective of our study is to evaluate the Knowledge, Attitude and Practice regarding ADR monitoring and contribution towards PvPI among Doctors posted in peripheral rural hospitals of a district in the Eastern part of India.

MATERIALS AND METHODS

Study Setting: The study was conducted throughout the government health centres located in the peripheries of a district in the southern part of West Bengal, India. It included the Primary and Upgraded Primary Health Centres, Block Primary Health Centres and Rural Hospitals, where the doctors posted should have a minimum qualification of MBBS. The study was conducted for 3 months (May 2022 to July 2022). Before the study, approval for the same was taken from the Institutional Ethical Committee [ESIC/77/IEC (JOKA)/2022].

Study Design and Population: The study was a cross-sectional questionnaire-based study, which was a field-based descriptive online survey. The participants were the doctors of modern medicine posted in all of the 30 Primary and Upgraded Primary Health Centres, 9 Block Primary Health Centres and 10 Rural Hospitals located in the peripheries of a district in the southern part of West Bengal. There was a total of 140 such doctors who took part in this study.

Inclusion and Exclusion criteria: All the doctors posted in the peripheral health centres as mentioned above, bearing minimum MBBS degree and provided informed consent to participate in this study were included. Those doctors who didn't bear a degree in modern medicine (e.g. AYUSH Medical Officers) and those not willing to take part in the study or did not give informed consent for participation were not included in the study.

Study Tool: A suitable self-administered KAP survey questionnaire was developed from the literature review based on the knowledge, attitude and practices of medical practitioners regarding the understanding of pharmacovigilance activities and ADR reporting[12,15,17,18,21-24]. The pre-designed questionnaire consisted of a total of 21 questions. Out of them, 8 questions were related to 'knowledge', 7 were related to 'attitude' and 6 were related to the 'practice' aspects.

Data Collection: The self-administered structured questionnaire was distributed to the doctors in the study via email after contacting them personally. The responses were collected from the participants after 2 weeks as entirely anonymous and voluntary.

Statistical Analysis: The data from the questionnaires received from the participant doctors was entered and analyzed by Microsoft Excel spreadsheet in MS Office 2010.

RESULTS

Among the 140 doctors to whom the questionnaires and consent form were distributed, 126 (Response rate = 90%) doctors gave consent to participate in the study and submitted the filled questionnaires to the investigators.

Knowledge: 76.92% of total participant doctors gave incorrect responses regarding the definition of the term pharmacovigilance (Fig. 1). The same number of them were unaware of the existence of the Pharmacovigilance Program of India (Fig. 2). About 38.46% of the participant doctors answered correctly regarding the location of the International Collaborating centre for Pharmacovigilance and the website used for reporting an ADR. 30.77% responded with the correct answer regarding the location of the head office of PvPI. Only 15.39% of the participant doctors could answer correctly the name of the scale followed internationally to assess an ADR (Fig. 1). 69.23% of them answered that Doctors are only responsible for reporting ADRs, whereas 15.39% said it is the nurses and 15.38% said it is the patients who are responsible for ADR reporting (Fig. 3). Unfortunately, none of the participant doctors had any information regarding the national Toll-free number for reporting ADRs.

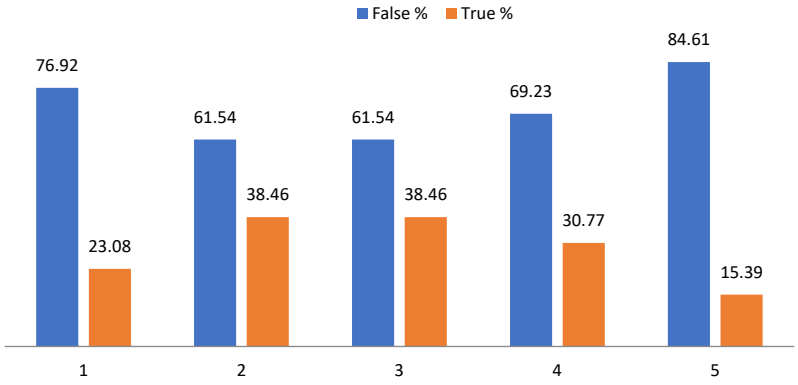

Fig. 1: The parameters numbered 1 to 5 given below each bar diagram have been detailed in the adjacent box), 1: Every Govt. Health centres of all levels should have adequate facilities for reporting any unwanted event caused by a drug, 2: Proper knowledge regarding ADRs of drugs reduces the burden of medical expenses for patients and HCPs, 3: ADR reporting becomes a burden to regular clinical duties, 4: Reporting any ADR to be made mandatory for all doctors posted in Rural health services, 5: HCPs of all levels should have the proper knowledge and actively participate in the Pharmacovigilance program, 6: National Toll-free numbers for reporting ADRs should be displayed in rural health centres of all levels

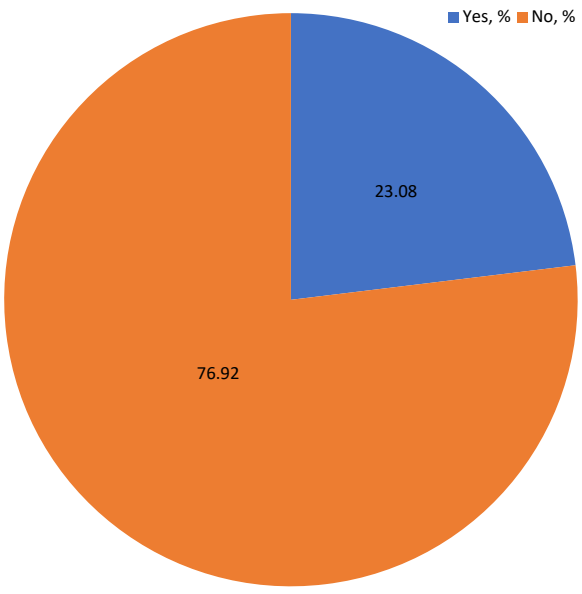

Fig. 2: Awareness of Pharmacovigilance program in India

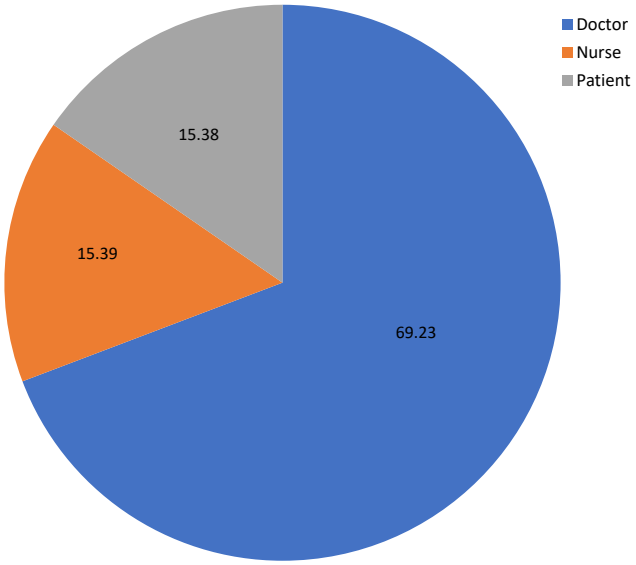

Fig. 3: Personnel responsible for reporting ADR

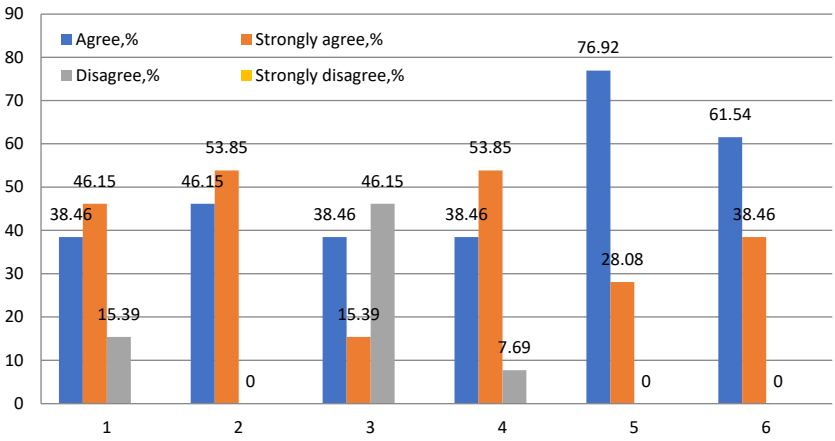

Fig. 4: Attitudes of the Participants towards the programme, 1: Every Govt. Health centres of all levels should have adequate facilities for reporting any unwanted event caused by a drug, 2: Proper knowledge regarding ADRs of drugs reduces the burden of medical expenses for patients and HCPs. 3: ADR reporting becomes a burden to regular clinical duties. 4: Reporting any ADR to be made mandatory for all doctors posted in Rural health services. 5: HCPs of all levels should have the proper knowledge and actively participate in the Pharmacovigilance program. 6: National Toll-free numbers for reporting ADRs should be displayed in rural health centres of all levels

Attitude: About 87.18% of participant doctors agreed with the fact that each and every unwanted reaction from a drug should be reported. 38.46% of them agreed, whereas 46.15% strongly agreed that every government health setup of all levels should have adequate facilities for reporting any unwanted event caused by a drug. All the participants agreed (53.85% out of them strongly agreed) with the fact that proper knowledge regarding adverse drug reactions related to a drug can reduce the burden of medical expenses for both the patient and Healthcare Providers (HCPs). There was mixed feedback from the participants regarding ADR reporting as a burden to regular clinical duties (38.46% Agreed, 15.39% strongly agreed, but 46.15% disagreed). However, most of them strongly agreed (53.85%) that reporting any ADR should be made mandatory for all doctors in rural health services.76.92% of participants agreed and 28.08% strongly agreed that all healthcare professionals up to the grass root level (e.g. Staff Nurses, Laboratory technicians, Auxiliary Nurse Midwives, ASHAs, Trained Birth Attendants). All participants agreed with the fact that the Toll-free number of Pharmacovigilance should be displayed in the rural health centres at all levels (Fig. 4).

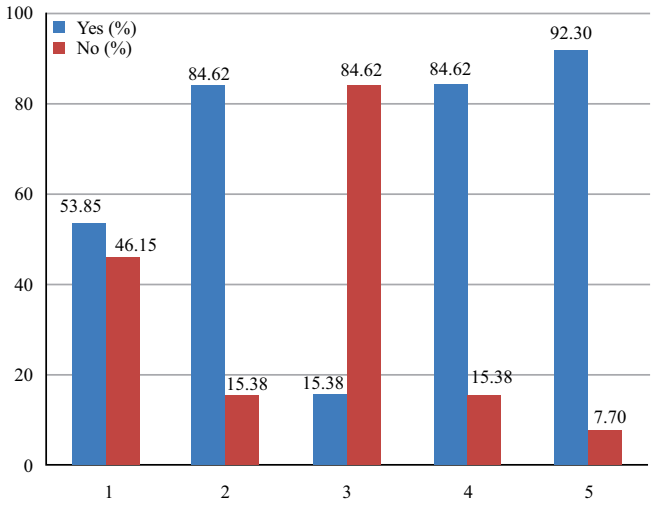

Fig. 5: Response towards pharmacovigilance program related to practice, 1: Encounter of any ADR in clinical practice, 2: Aware of the contraindications or possible side effects of a drug before prescribing it to a patient, 3: Ever reported any ADR to any higher authority or AMC?, 4: Eager to make proper arrangements in the respective health centre for reporting and tackling the consequences of any encountered ADR, 5: Eager to gain proper knowledge regarding the Pharmacovigilance Program of India (PvPI)

Practice: Among all participants, 53.85% have encountered an ADR at least once in their clinical practice. 84.62% of the participants said that they are aware of the possible side effects and contraindications of a drug before prescribing it to a patient, but a very small number of them (15.38%) have reported them to any higher authority or AMCs. 84.62% of participants have agreed to make proper arrangements in their health centre for reporting any encountered ADR and tackling the consequences due to those ADRs. Almost all the participants have shown eagerness to gain proper knowledge regarding PvPI and attend any Workshop or training program on Pharmacovigilance if arranged by the Department of Health and Family Welfare (Fig. 5).

DISCUSSION

Pharmacovigilance deals with the detection, assessment, understanding and prevention of any adverse reaction or any unwanted events associated with a drug. Once a new drug is released in the market for clinical use in society, the role of pharmacovigilance is to ensure the safety of the patient along with the rational use of the drug[25]. The most important outcome of pharmacovigilance is to prevent unnecessary negative consequences of pharmacotherapy on patients[26]. Reporting ADR by the spontaneous reporting system is an important component of the pharmacovigilance program.

However, the most important reason for the low success rate of this program is the under-reporting of ADRs. Various studies including those on Knowledge, Attitude and Practices on Pharmacovigilance have shown the under-reporting of ADRs by doctors of different hospitals as the main cause of the failure of this program[21,27-30].

In the present study, the participants were the doctors posted in the peripheral rural health centres. The response rate of participation was 90%, which is highly significant for a survey response if compared to other studies on the same issue[31-34]. The knowledge regarding Pharmacovigilance and the programs related to the same, National and international Controlling authorities of the program and website for reporting the ADRs is not correct among the majority of the subjects, which is nearly similar to a few other previous studies[30,35-37].

In the present study, proper attitude regarding ADR reporting was found among the participant doctors and it was considered important, lack of both adequate knowledge and proper practice regarding the same led to under-reporting of unwanted drug reactions encountered, if any. A similar scenario has also been found in a few other studies[22,38].

The positive outcome of our study is that the participant doctors were eager to gain proper knowledge regarding Pharmacovigilance if any arrangement is made for the same. They have also shown interest in equipping their respective healthcare centres with regular and proper ADR reporting facilities and also in tackling any situation related to unwanted drug reactions if encountered.

CONCLUSION

Knowledge regarding Pharmacovigilance and its practical implication should not be limited only to

the doctors working at corporate or tertiary care health centres located in urban or suburban regions, but also among those posted at peripheral rural health centres like primary and secondary health centres. Adequate reporting of unwanted reactions related to any drug will not only help in its post-marketing surveillance but also helps in reducing the economic burden of both patients and the health centres. Proper participation of doctors of all levels along with other health care professionals can improve the benefits of the Pharmacovigilance program in a country.

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