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RESEARCH ARTICLE

Pharmacovigilance: How aware are the prescribers?

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ABSTRACT

Background: Adverse drug reactions (ADRs) is one of the important factors contributing to morbidity and mortality among patients and is a major public health burden. Spontaneous ADR reporting plays an important role in detection of ADRs, reducing their incidence and improving patient safety. India has one of the lowest ADR reporting rates in the world. **Aim and Objective:** The aim of the study was to assess the knowledge, attitude and practice (KAP) of doctors towards pharmacovigilance. **Materials and Methods:** A KAP questionnaire validated by subject experts was given to the doctors outside the teaching profession within 50 km of Government TD Medical College, Alappuzha, who consented to be a part of the study. The questions were structured to obtain the demographic details of the doctors, their KAP toward pharmacovigilance. No identifiable information regarding the participants was collected and the participants were assured of their confidentiality. A week's time was given to the participants to answer the questions. **Results:** During the period of 1 year from June 2019 to May 2020, a total of 121 doctors responded to the questionnaire. The respondents aged from 26 to 67 years with the mean age being 37.31 ± 14.15 years. 94 (77.7%) thought that anyone could report an ADR while 16 (13.2%) thought that only doctors could report ADRs. Only 76 (62.8%) were aware of the existence of National Pharmacovigilance Centre in India. Ninety-eight (81%) did not know how to submit the ADR form to the nearest pharmacovigilance center. A vast majority 99 (81.8%) thought that ADRs to drugs of any system of medicine could be reported, while 20(16.5%) felt that only ADRs to modern medicines need to be reported. Among the factors discouraging doctors from reporting ADRs, lack of training to report an ADR 99 (81.8%) and lack of time during practice 83 (68.5%) were cited as the common reasons. A vast majority 116 (95.9%) had not received any formal training on ADR reporting and 114 (94.2%) opined that they would like to receive a formal training on the same. **Conclusion:** Doctors were largely aware of pharmacovigilance but had lack of KAP of reporting ADRs and filling up an ADR form. It emphasizes the need for regular mandatory education and training on ADR reporting among healthcare workers, and also the need to run continuous awareness campaigns on spontaneous reporting of ADRs to enhance reporting rate.

KEY WORDS: Knowledge; Attitude; Practice; Adverse Drug Reactions; Pharmacovigilance; Doctors

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INTRODUCTION

Pharmacovigilance is defined as the sum of activities related to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) caused by drugs. ADR monitoring and reporting systems were put in place post the thalidomide tragedy. This event also led to the World

Health Organization (WHO) starting its International Drug Monitoring Program and since 1968 it has been operating from the Uppsala Monitoring Centre in Sweden.[1]

A formal drug safety monitoring system was proposed for the 1st time in India in 1986. This was followed by the establishment of the National Pharmacovigilance Centre at the All India Institute of Medical Sciences. The National Pharmacovigilance Program sponsored by the WHO and funded by the world bank was launched on January 1, 2005. The primary objective of the program was involving the healthcare professionals in the process of ADR reporting by inculcating a culture of reporting ADRs. To encourage the spontaneous reporting of drugs, many peripheral pharmacovigilance centers were established under the Pharmacovigilance Program of India (PvPI) and on July 18, 2017, WHO designated India as one of the six countries in the world as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programs and Regulatory Services. Spontaneous reporting of ADRs is the easiest to run and the cheapest to implement.[2] It also contributes the highest volumes and therefore health-care professionals play a crucial role in pharmacovigilance. A fear of punitive action also strongly deters the reporting of ADRs. Although many countries have set up spontaneous reporting systems, the rate or reporting is still less than desired. Despite repeated measures to improve pharmacovigilance in India, the rate of spontaneous reporting ADRs is abysmally low. There are many factors that have been linked to under reporting of ADRs.[3] Inman has called these characteristics as the "*seven deadly sins*." His description of the sins were want of *financial incentives* (rewards for reporting), *legal aspects* (fear of litigation or enquiry), *complacency* (the belief that serious ADRs have already been documented by the time the drug has been marketed), *diffidence* (to report an ADR only if you are very sure that it has been caused by the particular drug), *indifference* (a single case that the individual doctor observes will not contribute to medical knowledge), *ignorance* (one needs to report only serious or unexpected ADRs), and *lethargy* (a lack of interest, unable to source a reporting form and other excuses).[4]

The increased contribution of health-care professionals toward spontaneous reporting of ADRs can be a force multiplier with respect to the PvPI. A data analysis of VigiBase data indicates that in 2018, physicians contributed to 57% of individual case safety reports submitted and majority of them were reported from South zone.[5] Hence, this study is undertaken with a view to assess the current knowledge, attitude, and practice (KAP) of ADR reporting among the prescribers outside the teaching profession.

MATERIALS AND METHODS

It is a descriptive study among doctors outside the teaching profession within 50 km of Government TD Medical College, Alappuzha. The study was initiated after getting the Ethics Committee Approval. A KAP questionnaire validated by subject experts of two different medical colleges with respect to content and time was given to the participants who consented to be a part of the study. The questions were structured to obtain the demographic details of the doctors, 13 questions to assess their knowledge and seven questions to learn about their attitude and practices toward pharmacovigilance and suggestions to improve ADR reporting. No identifiable information regarding the participants was collected and the participants were assured of their confidentiality. A week's time was given to the participants to answer the questions.

Ethical Consideration

The study was initiated after getting the Ethics Committee Approval. (IEC No-13/2016) No identifiable information regarding the participants was collected and the participants were assured of their confidentiality.

Statistical Analysis

The data were analyzed using Microsoft excel 2010 and descriptive data are expressed as frequencies and percentages.

RESULTS

During the period of 1 year from June 2019 to May 2020, a total of 121 doctors responded to the questionnaire. The response rate was 100% as all the questionnaires were returned. The mean age was 37.31 ± 14.15 years (26–67 years) and majority of the respondents were in the age group of 30–40 years (n = 52, 43%). The mean years of practice were 11.48 ± 9.39 years (1–36 years). Detailed demographics are shown in Table 1.

Respondents when asked who could report ADRs, 94 (77.7%) replied that anyone could report an ADR while 16 (3.2%) thought that only doctors could report ADRs and the rest six thought that any medical professional could report it. Only 76 (67.2%) were aware of the existence of National Pharmacovigilance Centre in India. To the open ended question on where the nearest Pharmacovigilance center was, 82 (67.8%) knew Government T D Medical College, Alappuzha, was the nearest pharmacovigilance centre while 38 (31.4%) replied it was Government Medical College, Kottayam, and one respondent did not know the answer. Even though majority of the participants 116 (95.9%) had come across ADRs during clinical practice 60 (49.6%) never knew that it had to be reported, 86 (71.1%) neither knew from where to procure an ADR form nor how to fill up one.

Ninety-eight (81%) did not know how to submit the ADR form to the nearest pharmacovigilance centre. 82 (62%) felt that all ADRs to all drugs need to be reported, while the rest

Table 1: Demographic descriptions of participants

Variable	*n* (%)
Age group	
<30 years	25 (20.7)
31–40 years	52 (43.0)
41–50 years	26 (21.5)
51–60 years	15 (12.4)
>60 years	3 (2.5)
Gender	
Male	56 (46.3)
Female	58 (47.9)
Not mentioned	7 (5.8)
Sector of practice	
Government	87 (71.9)
Private	28 (23.1)
Not mentioned	6 (5)
Years of practice	
<5 years	39 (32.2)
5–10 years	29 (24.0)
11–15 years	15 (12.4)
16–20 years	19 (15.7)
>20 years	18 (14.9)

(39) opposed the statement. When asked about the criteria for selecting an ADR for reporting, 91 (75.2%) thought that preference in reporting should be given for severe ADRs, 64 (52.9%) for rarely seen ADR, 57 (47.1%) for labeled reactions, and 45 (37.2%) thought reporting needs to be done only for certain ADRs, only 24 (19.8%) opined that it should be only for new drug [Figure 1].

A vast majority 99 (81.8%) thought that ADRs to drugs of any system of medicine could be reported, while 20 (16.5%) felt that only ADRs to modern medicine need to be reported and the rest thought that only ADRs related to Ayurvedic drugs need to be reported. Majority of the participants opined that they had multiple sources of information for ADRs of which Continuing Medical Education programs 58 (47.9%) and peer discussion 49 (40.1%) topped the list as shown in Table 2.

When asked whether ADR reporting is a professional obligation, 92 (76%) where in affirmation while 16 (13.2%) replied they did not know the answer and the rest denied the statement. However, only 65 (53.7%) refuted the statement that they would report an ADR only if it is mandatory, while the rest agreed to it. Among the factors discouraging doctors from reporting ADRs, lack of training to report an ADR 99 (81.2%) and lack of time during practice 83 (63.6%) were cited as the common reasons followed by fear that the report may be wrong 74 (61.2%) or the fear of medicolegal implications following reporting 64 (52.9%), the belief that a single reported ADR is unlikely to make a difference

Table 2: Sources of knowledge about ADR

Source	*n* (%)*
CMEs	58 (47.9)
Peer discussion	49 (40.1)
Journals	44 (36.4)
Internet	35 (28.9)
Medical representatives	3 (2.4)

*Single participant opted multiple choices, ADR: Adverse drug reactions

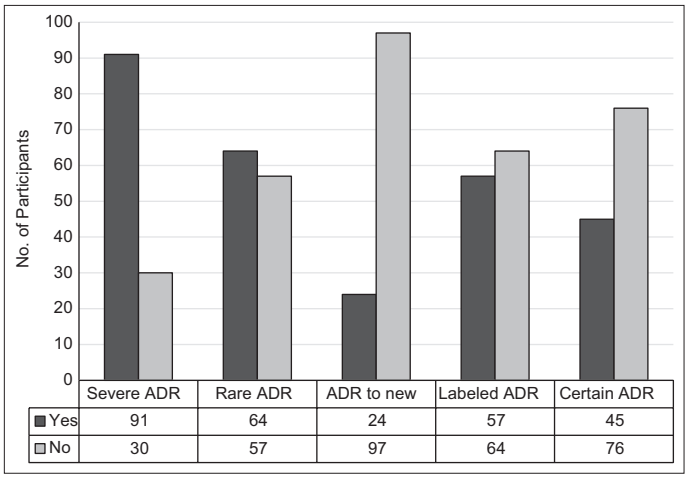

Figure 1: Factors determining selection of an adverse drug reaction to report

55 (45.5%) or there is no need to report an established ADR 43 (35.5%) and lack of incentives 29 (24%) as shown in Table 3. On eliciting opinion about the choice to report a hypothetical ADR, 103 (85.1%) said that they would report Phenobarbitone induced Stevens Johnsons Syndrome and 83 (68.6%) said that they would report INH induced hepatotoxicity. Only a minority opined that they would report Aspirin induced gastritis 18 (14.9%), Lisinopril-induced cough 29 (24%) or Heparin-induced thrombocytopenia 59 (48.8%) as shown in Figure 2.

A vast majority 116 (95.9%) had not received formal training on ADR reporting and 114 (94.2%) opined that they would like to receive a formal training on the same. The suggestion to improve ADR reporting culture included initiation of training programs on pharmacovigilance 118 (97.5%), dissemination of more educational materials and handouts 112 (92.6%), reminders in the form of emails and short messaging services 99 (81.8%), and making ADR reporting a mandatory activity 99 (81.2%).

DISCUSSION

Despite the continuous efforts of the Government of India to foster the culture of spontaneous reporting of ADRs, underreporting remains a major issue within the doctor community. The recent pandemic with the accelerated approval of "repurposed" medicines for COVID-19 highlights

Table 3: Factors discouraging ADR reporting

Factor	Agree (%)	Disagree (%)
Lack of training to report an ADR	99 (81.2)	22 (18.8)
Lack of time during practice	83 (63.6)	38 (26.4)
Fear that the report may be wrong	74 (61.2)	47 (38.8)
Fear of medicolegal implications following reporting	64 (52.9)	57 (47.1)
Single reported ADR is unlikely to make a difference	55 (45.5)	66 (54.5)
No need to report an established ADR	43 (35.5)	78 (64.5)
Lack of incentives	29 (24)	92 (76)

ADR: Adverse drug reactions

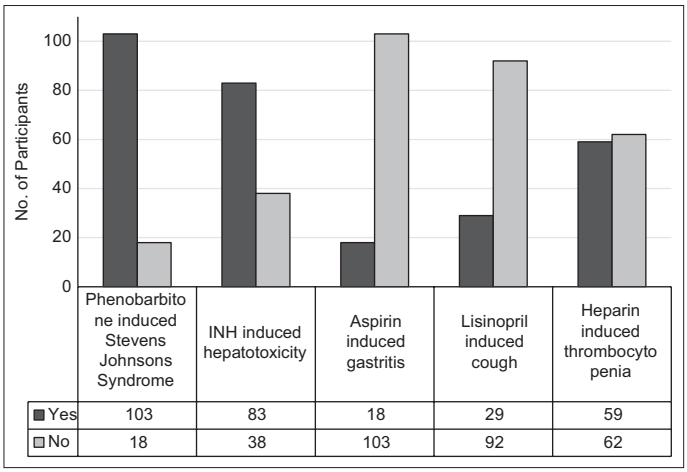

Figure 2: Reporting a hypothetical adverse drug reaction

the importance of safety monitoring of medicines and vaccines during public health emergency. Spontaneous reporting of ADRs is the cornerstone of National Pharmacovigilance system.[6] This study was done in the district of Alappuzha. The 121 respondents surveyed were practitioners of modern medicine (government and private sector) outside of teaching institutions. The majority of the doctors surveyed were from the government sector. The respondents aged from 26 to 67 years. 94 (77.7%) thought that anyone could report an ADR while 16 (3.2%) thought that only doctors could report ADRs. The study tested the KAP of various aspects of pharmacovigilance among the stakeholders.

Only 67.8% of those surveyed were aware that the nearest pharmacovigilance center was Government T D Medical college, Alappuzha. The majority of the doctors who took part in the study had come across ADRs in their practice but nearly half (49.8%) of them were unaware that they have to be reported. This finding is supported by similar studies done on doctor populations elsewhere. In a study done on paediatricians in Odisha, though 95% participants encountered ADR in their practice, only 50% reported them.[7] Interestingly in a cross-sectional questionnaire-based study among physicians, pharmacists, and nurses working in tertiary care public hospitals of Lahore, Pakistan, 79.5% physicians and 58.4% nurses stated that they did not report any ADR, while 67.6% of the pharmacists stated that they reported ADRs in their workplace.[8] ADR reporting in developing countries is significantly low, given that developing countries account for about 80% of the global disease burden but are responsible for < 1% of the total ADR reports.[9] This shows that despite a long running National Pharmacovigilance program, a lot still needs to be done to get the message across. The study also highlights the lack of knowledge about where to procure and how to fill an ADR reporting form (71.1%). This compares with a meta-analysis study done on ADR reporting in India which found that more than 50% of the sample were not aware of PvPI and around 32% thought that all drugs available in market were safe (modern medicine, herbal/traditional) and 67% did not know where to obtain ADR reporting forms.[10] The majority of the prescribers surveyed in our study (81.8%) agreed that ADRs against drugs under all systems must be reported. This is important as a South Asian association for regional cooperation study had estimated more than 4246 registered herbal drugs are available as over the counter sans any restrictions on its sale.[11] A nationwide program Ayushsuraksha has been launched by the Ministry of AYUSH, New Delhi, to establish and generate system wise database of ADRs to improve clinical safety of Ayurveda, Siddha, Unani, and Homeopathic Drugs.[12] Seriousness of reaction is the most common factor that encourages prescribers to report an ADR. Lack of training, fear of medicolegal action, lack of time, and the belief that reporting of a single ADR would not make a difference were some of the notable factors that discouraged ADR reporting. This observation was similar to a study performed in Turkey where the most common reason for not reporting was not being sure if it is an ADR (29.6%), followed by not knowing where to report (27.2%).[13] Interestingly 24% said that a lack of incentive as one of the reasons not to report. The anonymous nature of submission of ADR data should be stressed as it will then remove the fear of medicolegal action. As shown by the study, respondents did not give importance to the more common and expected ADRs. Hence, the message that should be conveyed is that every ADR should be reported.

Three-fourths of the doctors surveyed opined ADR monitoring as a professional obligation, but barring a few none had received any formal training on pharmacovigilance and the majority welcomed such an initiative. CMEs and peer discussion played very important roles followed by journals and the internet in expanding knowledge about ADRs. A core group related to pharmacovigilance should be set up at every state IMA (Indian Medical Association) headquarters from where periodic information regarding ADR monitoring should be disseminated right up to the level of an individual at the local branches. Doctors who report ADRs should be duly acknowledged so as to increase participation. The reason being that motivation and initiative play a huge role in spontaneous reporting and this ultimately reflects in the numbers of ADRs reported.[14]

One limitation of the study is that this is a study of a single district and does not claim to represent the whole of the state of Kerala. Data from multiple districts need to be collected. There is no non responder bias in the study as the response rate recorded was 100% and all areas of the district of Alappuzha was represented.

CONCLUSION

This study helped in identifying the gaps related to pharmacovigilance among primary and secondary health-care prescribers in the district of Alappuzha. Lack of awareness about the fact that ADRs need to be reported and the need to provide quality training to all the stakeholders is one major outcome of this study. The essentiality of a sustained campaign on pharmacovigilance till spontaneous reporting of ADRs becomes a routine activity, especially in view of the fact that a majority of doctors consider ADR reporting as a professional obligation needs to be worked on further. A feedback information to reporters along with an acknowledgment will go a long way in promoting a culture of ADR reporting.

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