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Original Research Article

Knowledge, attitude and practice toward adverse drug reaction reporting among practicing clinicians at a tertiary care hospital

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ABSTRACT

Background: Pharmacovigilance has evolved as an important tool for dealing with Adverse Drug Reactions (ADRs) both in pre-marketing and post-marketing scenario. Underreporting of ADRs at our Adverse drug reaction Monitoring Centre (AMC) led us to conduct this study to assess Knowledge, Attitude and Practice (KAP) of the practicing clinicians at our tertiary care Pt. J.N.M. Medical College associated Dr. B.R.A.M. Hospital, Raipur, Chhattisgarh, India, towards ADRs reporting.

Methods: This was a cross-sectional study using pretested questionnaires consisting of 29 questions related to KAP of the practicing clinicians at Pt. J.N.M. Medical College associated Dr. B.R.A.M. Hospital, Raipur towards ADRs reporting. The percentage of responders for each question was calculated. All statistical analysis was performed in Microsoft Office Excel 2007.

Results: Out of 135 questionnaires distributed only 100 were considered for analysis, so the overall response rate was 74.07%. We calculated the result from the 100 responders. Overall 77% responders were aware of existence of ADR monitoring system in India, while only 40% were aware of its existence at their hospital. Only 8% responders had reported ADRs to the National Pharmacovigilance Centre and 10% to the Adverse drug reaction Monitoring Centre (AMC) at their hospital. Lack of knowledge about where, how and whom to report ADRs, lack of time, inability to decide what to report (known or unknown ADRs) and unavailability of ADR reporting form were the important factors discouraging them reporting ADRs.

Conclusions: Creating awareness regarding ADR reporting through CMEs among practicing clinicians and early sensitization at medical undergraduate level for medical students may improve the current ADR reporting rate.

Keywords: Awareness, Cross-Sectional Studies, India, Pharmacovigilance, Surveys and Questionnaires

INTRODUCTION

Adverse drug reaction is defined by World Health Organisation (WHO) as a response to a drug which is noxious and unintended, and which occurs at dose normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.[1] ADRs are major cause for morbidity and mortality worldwide. The percentage of hospital admissions due to ADRs in some developed countries is more than 10%. About 15-20% of their hospital budget is lost dealing with drug complications. Whereas limited information is available on cost of ADR management in developing countries like ours.[2]

Pharmacovigilance (PV) has emerged as a new science for early detection and prevention of possible drug-related morbidity and mortality. The WHO defines Pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions or other drug related problems.[3]

WHO established its Programme for International Drug Monitoring in response to the Thalidomide disaster detected in 1961. Together with the WHO Collaborating Centre for International Drug Monitoring, Uppsala, WHO promotes PV at country level. In India, the ADRs are monitored by Indian Pharmacopeia Commission.[3]

The information collected during the pre-marketing phase of drug development is inevitably incomplete about possible ADRs as they are done in a controlled environment. Post-marketing surveillance potentially detect less common, but sometimes very serious ADRs. PV covers both the clinical trial and the post-marketing phases.

Alert and observant practicing clinicians have played important role in PV to prevent the development of drug morbidity and mortality by timely reporting suspected ADRs, resulting in the withdrawal of dangerous drugs from the market or in restriction of their use. Selective inhibitors of COX-2 Rofecoxib and Valdecoxib were withdrawn from market in 2007 because of increased risk of myocardial infarction and athero-thrombotic involvements.[4] Similarly, the restrictions to the use of Rosiglitazone are based on data of ADR reports which shows an elevated risk of heart attacks in patients treated with it. The decision to restrict access to Rosiglitazone was made on September 23, 2010 US-FDA. This was possible because of active involvement of practitioners in ADR reporting.[5]

Various Studies have shown that 462 medicinal products were withdrawn between 1953-2013 due to ADR reporting.[6] After the launch of the Pharmacovigilance Programme of India (PvPI) in 2010, Indian Pharmacovigilance has progressed tremendously, but a lot more has to be done to make the country truly pharmacovigilant. Under PvPI, Adverse drug reaction Monitoring Centre (AMC) set up in Medical colleges and Multispecialty Hospitals play a major role in collection and follow-up of ADR reports from healthcare professionals. At present, there are 150 AMCs under this programme. Among Asian countries, India is the only country having more than 1 lac Individual Case Safety Reports (ICSRs) in Vigibase. But this is only 2% of the UMC'S global drug safety database as per 2013 records.[7] We are the 2nd largest population in the world and must contribute more ADRs.

In this scenario, the ADRs reporting rate from our tertiary care Pt. J.N.M. Medical College and associated Dr. B.R.A.M. Hospital, Raipur (C.G.) is yet to pick up. Between June 2014- May 2015 only 26 ADRs were reported from our AMC as shown by a study done by Agrawal M et al.[8] Though there was increase in reporting rate to about 180 cases (unpublished data) of ADRs between June 2015- May 2016, it was still very less as compared to other AMCs in India. So, we tried to assess knowledge, attitude and practice among practicing clinicians toward suspected ADR reporting at our tertiary care teaching hospital to improve the reporting rate of ADRs by taking necessary steps.

METHODS

This was a cross-sectional, observational, questionnaire based study. The questionnaire was prepared based on previous studies which were modified as per our requirements.[9-13] The practicing clinicians at Pt. J.N.M. Medical College and associated Dr. B.R.A.M. Hospital, Raipur (Chhattisgarh) participated in the study. Prior permission was obtained from institutional ethical committee.

A total of 135 questionnaires were distributed to practicing clinicians during April 2016 and May 2016. The completion of the questionnaire by responders was taken as their consent to participate in the study. Those who were reluctant to participate or did not return the questionnaire within the given time were excluded from the study. 5 responders were reluctant to participate and returned the questionnaire unfilled, and 30 responders did not return the questionnaire, hence only 100 were taken into consideration.

Each questionnaire consisted of 29 questions related to Knowledge, Attitude and Practice towards suspected ADRs reporting of the practicing clinicians with minimum qualification MBBS and 5 questions related to their demographic profile. Provision was made for suggestions on possible ways to improve ADR reporting. In order to preclude any potential, bias the disclosure of the name of the responder was made optional. The information was recorded and analyzed using Microsoft Excel worksheet (Microsoft Office 2007). In the statistical analysis, the percentage of responders for each response was calculated from the total number of participating clinicians in the study.

RESULTS

Only 100 out of 135 responders filled and returned the questionnaires giving the overall response rate of 74.07%. Out of the 100 responders 64% (n=64) were male and 36% (n=36) were female.

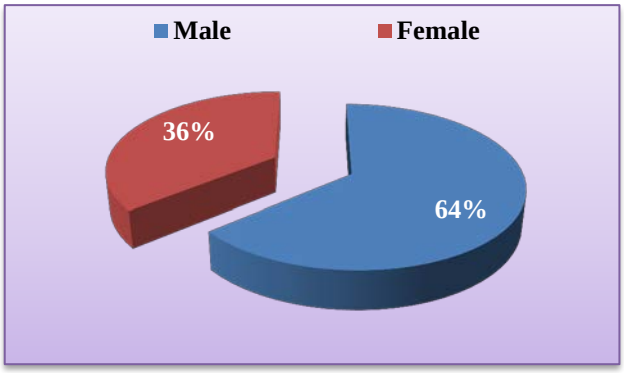

Figure 1: Gender-wise distribution.

90% (n=90) responders fell in the age group <50 years and 7% (n=7) fell in the age group 50-60 years, while only 3% (n=3) were >60 years of age. 46% (n=46) responders belonged to medicine speciality, 26% (n=26)

belonged to surgical speciality and 28% (28) were MBBS (graduate) doctor.

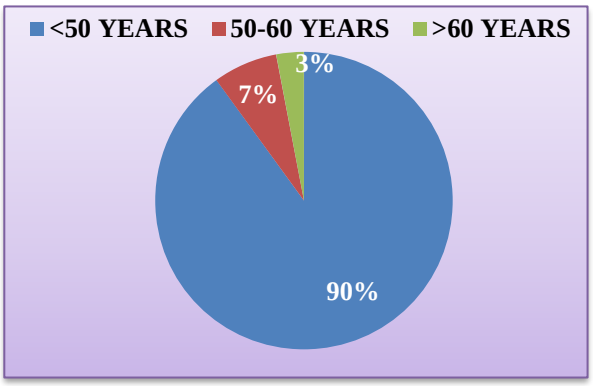

Figure 2: Age group-wise distribution.

80% (n=80) responders agreed that all healthcare personnel should think reporting ADRs their responsibility and 90% (n=90) of them agreed its useful for their profession to report suspected ADRs for patients' safety. Only 30 % (n=30) responders favoured the role of AMC at their hospital for spreading awareness regarding voluntary reporting of suspected ADR. Figure 1 and Figure 2 show the distribution of responders based on gender and age-groups respectively.

Nearly 70% of them agreed that Creating awareness about ADR reporting and monitoring system through CMEs or WORKSHOPs will be helpful. Almost 50% agreed that making reporting compulsory to all healthcare professionals, making the patients aware to report ADR to clinicians, electronic reporting of ADR, posting of trained staff to report ADR and making the form easy to fill will improve the reporting rate. 26% agreed incentives for reporting ADR will motivate reporting.

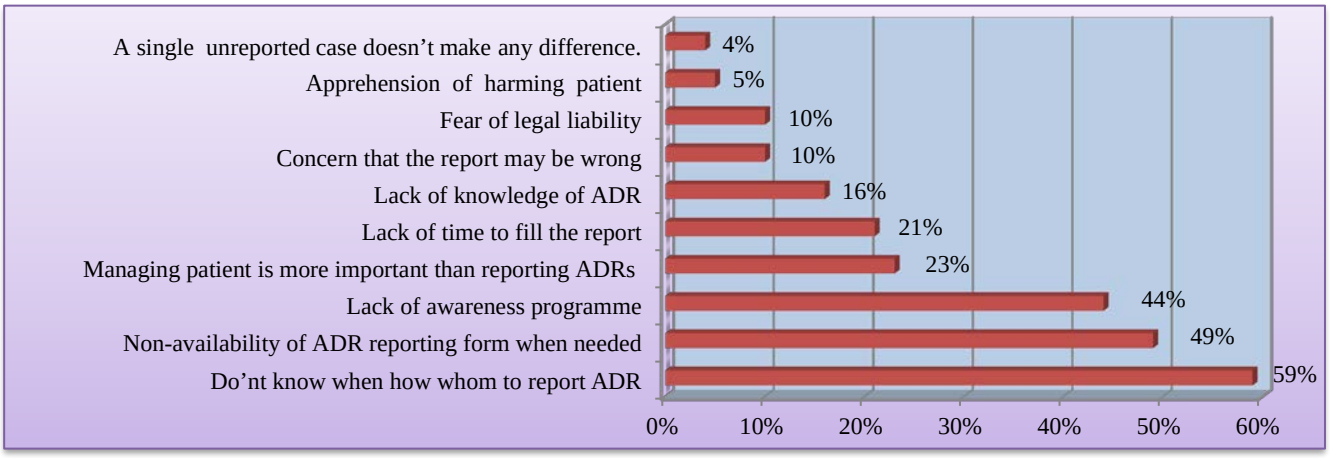

Figure 3: Factoring discouraging ADRs reporting.

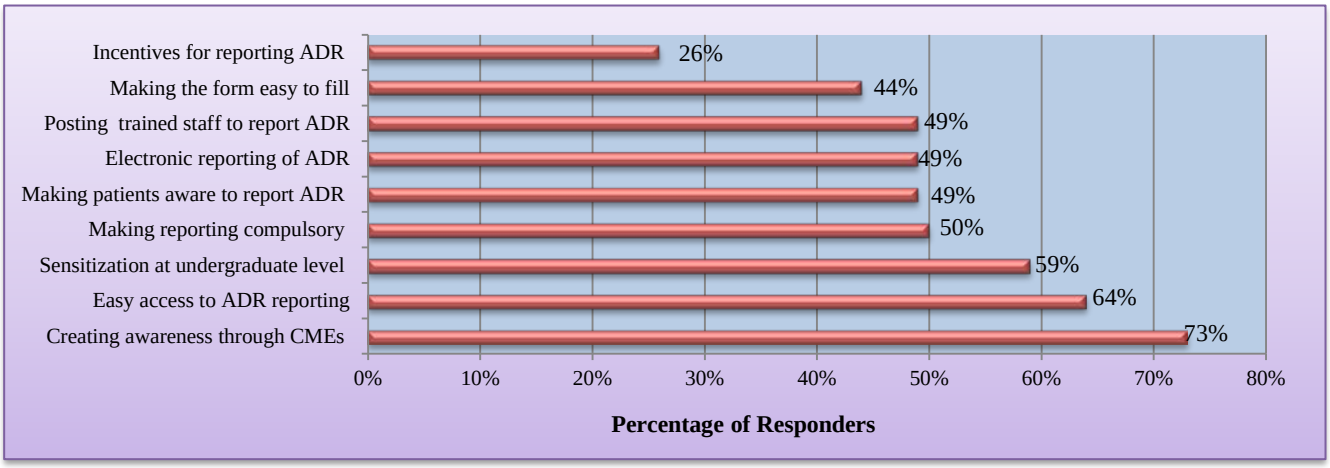

Figure 4: Factors that may improve ADR reporting rate.

DISCUSSION

All healthcare providers (physicians, pharmacists, nurses, dentists and others) should report ADRs as part of their professional responsibility, even if they are doubtful about the precise relationship with the given medication. However, various studies have emphasized the practicing clinicians are in the best position to report on suspected ADRs observed in their everyday patient care.[9,10,12-15]

In present study, male responders were in majority 64% compared to females 36%. This difference was due to the fact that 60% faculty in our institute were males and only 40% females. Therefore, this study showed that both males and females had participated in equal ratio and gender had no role in awareness level. The average age of the responders was 35.42 and maximum (90%) were below 50 years. This means they had minimum 10 years of experience as practitioners and could identify and differentiate ADRs. Similar findings were seen in the study done by Kiran LJ et al.[16] We also found that physicians constituted 46% which was almost double of surgeons 26% and MBBS graduate doctors were 28% among our responders.

77% of the responders were aware of existence of ADRs monitoring system of India, which is like the study by Adedeji et al. in Nigeria where 71.4% were aware of existence of national PV centre.[17] However, only 40% of the responders were aware of existence of AMC at our hospital. In a study by Aithal et al, only 23% were aware of ADR centre in their hospital.[18] This, increased awareness at our AMC is due to aggressive sensitization workshops among clinicians. And in near future with continued sensitization at undergraduate level, para-medical staff and for practitioners, we hope 100% will be aware about ADR reporting.

Overall attitude of responders towards ADR reporting was very good. 80% of them agreed that all healthcare personnel should think reporting ADRs their responsibility and 90% of them agreed that reporting suspected ADRs is useful for their profession as it increases patient's safety which is in agreement to findings of Debasis et al.[19] Inspite of this positive attitude 40% responders admitted that they had seen ADRs at the hospital but only 8% had reported ADRs to the National Pharmacovigilance Centre while 10% had reported to the AMC at their hospital. Kharkar et al, and Pimpal Khute et al, had similar finding.[12,20] This gap in the attitude and reporting suggests that newer methods must be developed so that reporting becomes a reality and not just mere thought process.

We have pasted posters in front of all OPD's and wards with national help line no.18001803024 of PvPI and the contact number of our AMC. The contact number is also printed on the OPD slip. We have also sensitised the nursing staff to report any unexpected response to drug therapy to their treating doctors. But these efforts have not yielded any positive results.

In this study, few important factors discouraging practicing clinicians to report ADRs and asked the responders whether they agreed or disagreed with those. Figure 3 depicts the entire finding where (59%) responders responded positively with the fact that don't know where, how and whom to report ADRs and (49%) agreed with non-availability of ADR reporting form when needed, while (44%) agreed with lack of awareness programmes. Lack of time to fill the report, lack of knowledge of ADR, concern that the report may be wrong, fear of legal liability, apprehension of harming patients were some other reasons for discouraging them to report ADRs. A mindset that a single unreported case does not make a difference is the major culprit for not reporting ADRs though only 4% agreed with this. Similar reasons have been published in other studies.[21,22]

We also offered certain measures to the responders for improving ADRs reporting and asked them whether they agreed with those or not. (73%) of them agreed with creating awareness about ADR reporting and monitoring system through CMEs or workshops and (64%) were agreed with making easy access to ADR reporting form. (59%) agreed with early sensitization at undergraduate level while almost (50%) agreed with making reporting compulsory to all healthcare professionals. It is mandatory to report all ADRs by pharmaceutical companies but not for practitioners for whom it is voluntary. Electronic reporting of ADRs, posting of trained staff to report ADRs and making the patients aware to report ADRs to clinicians will also improve ADR reporting. Similar measures were suggested in other studies for improving ADRs reporting.[23-25] This implies that facilitating the reporting process and developing accessible tools like mobile applications/short service messages will motivate clinicians to report ADR. Incentives in the form of public appreciation or giving certificates to those who report maximum ADRs in a year will boost the pharmacovigilance programme.

Motivated by such responses of the practicing clinicians we have started sensitization at the undergraduate level by hands on training how to fill up the ADR reporting form. Repeated verbal reminders to clinicians, mentioning the number of ADRs reported by their colleagues and small incentives given like giving them appreciation in front of whole class have helped to improve ADR reporting. Our AMC has organized workshops at different department of the hospital. With the effort of our enthusiastic AMC technical associate we have got the national PV helpline number printed in the OPD slips of our tertiary care teaching hospital so that patient can directly report. Yet a lot of work has to be done at local as well as central level to improve the ADR reporting rate.

In present study, though the participants were aware of the importance of voluntary reporting of suspected ADRs, lacunae in the knowledge and practices were the main reasons for underreporting. Filling those lacunae through repeated CMEs or Workshops and early sensitisation at undergraduate level might bring positive results in ADR reporting rate among practicing clinicians. Patients awareness through social media will compel them to come back to their clinicians which in turn will motivate ADR reporting.

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