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Original Research Article

Knowledge and awareness about ADR reporting and pharmacovigilance among medical undergraduates

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Abstract

Aim: The present questionnaire survey was conducted with an aim of assessing the knowledge, attitude, and awareness related to pharmacovigilance among the final year students of MBBS and BDS in a teaching hospital.
Materials and Methods: To assess the knowledge and awareness about pharmacovigilance and adverse drug reaction (ADR) reporting; a predesigned, structured, close-ended 10 item questionnaire was used.
Results: A total of 180 questionnaires were distributed among the health-care professionals. It was found that only 28.88% students comprising 53.8% medical and 46.1% dental students were aware regarding the existence of pharmacovigilance program of India. While, only 47.77% students felt that ADR monitoring centre should be established in every hospital.
Conclusion: The results of our study indicate that the majority of the students had a poor knowledge and attitude about pharmacovigilance. It has been advised that all the students (medical and dental) should be trained properly on ADR reporting to improve the current scenario in the pharmacovigilance program of the country.
Keywords: Adverse drug reactions, adverse drug reactions reporting, undergraduate students, pharmacovigilance.

1. Introduction

Two major concerns about a drug are safety and efficacy. The efficacy of a drug can be quantified; the same cannot be said about safety. This is because, there are adverse effects of a drug which may be uncommon (but very serious), and many patients may be affected by these adverse effects even before the relationship with the drug is established.[1-2] According to Barker, there are three possible actions of drug: The one you want, the one you don't want, and the one you don't know about.[3]

Drugs have caused and will continue to cause harm people's lives alongside many benefits. Adverse Drug Reactions (ADRs) is defined by the World Health Organization (WHO) as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function." are a major problem and are one of the leading causes of mortality and morbidity.[4] It is one of the significant bases of hospitalization varying between 5% and 20%.[5-6] These drug-related problems are different in different countries and also in the different regions within countries. This can be because of the differences in diseases, prescribing practices, genetics, dietary habits and use of herbal remedies which may pose specific toxic problems.

Because these adverse drug reactions are never reported or their reporting is so less that we never come across the exact burden of the drug related adverse drug reactions.

Under-reporting of adverse drug reactions (ADRs) is very common and is estimated to be only 6–10% of all the ADRs that are reported.[7] There is a considerable increase in awareness about the issues related to drug safety among healthcare providers, healthcare institutions and the public. The term pharmacovigilance has evolved to recognize the importance for monitoring and improving the safe use of medicines.

Postmarketing pharmacovigilance provides data that enhance the rational and safe use of medications. In particular, the safety profile of drugs is dynamic; new information is continually assessed regarding use and outcomes. Among postmarketing surveillance methods, national voluntary reporting systems are an important conduit for the collection of information about specific adverse events involving medications. Because these national reporting programs depend upon voluntary participation, they are

limited by under-reporting and a variance in the quality of the reports received.[8]

World Health Organization defines pharmacovigilance as "the science and activities relating to the detection, evaluation, understanding, and prevention of adverse reactions to medicines or any other medicine-related problems". The Uppsala Monitoring Centre (UMC) located in Uppsala, Sweden, is the field name for the World Health Organization Collaborating Centre for International Drug Monitoring. In India, the Central Drugs Standard Control Organization (CDSCO) is coordinating the pharmacovigilance programme. The pharmacovigilance centres collect, communicate and disseminate ADR data by linking with hospitals as well as practitioners.

The aim of the present study was to assess the knowledge and awareness of ADRs reporting and pharmacovigilance system among medical undergraduates in ACPM Medical College, Dhule.

2. Materials and Methods

A cross-sectional questionnaire survey was conducted in ACPM Medical college dhule. The required information for the study was obtained from all the final year students of MBBS and BDS. The study was conducted for a period of 2 months.

A questionnaire was developed to obtain information on the knowledge and awareness of pharmacovigilance and adverse drug reactions reporting and documentation of ADRs. A total 180 questionnaires were circulated to 97 MBBS students and 83 BDS students.

The questionnaire was a predesigned, structured, close-ended 10 item questionnaire, which had been designed based on the primary objective of the study to assess the knowledge of pharmacovigilance, attitudes toward pharmacovigilance, and ADR reporting.

3. Results

All the participants had heard of the term "pharmacovigilance" prior to the study. 40 (77.7%) of the students reported that pharmacovigilance and ADR reporting was in their curriculum. When asked to define pharmacovigilance using a standard definition such as that of the World Health Organization (WHO), 35 (19.4%) defined it correctly, 27 (15%) gave wrong definitions while 16 (8.8%) gave incomplete definitions. Some of the participants, 21 (11.6%), claimed to have seen the form used in reporting ADR, but when asked for the colour of the form, only 4 participant (2.2%) got the colour right. Likewise, no participant was aware of the WHO causality classification of ADR. 37 (20.5%) of the students who took part in the study had personally experienced ADR prior to the study. The ADRs experienced include urticarial, nausea and vomiting, severe headache, pain in abdomen and loose motions.

4. Discussion

Students in the final year showed deficiency in knowledge on pharmacovigilance activities since less than one quarter of the participants (19.4%) could define pharmacovigilance correctly according to the World Health Organisation definition**.** None of the participants in the study had used a copy of the ADR-reporting form prior to the study. All the participants agreed that they do not know how to go about processing and documenting ADR report. This lack of adequate knowledge could translate to inadequate or lack of participation of these students in reporting ADR when they eventually become doctors. Nonetheless, poor knowledge in pharmacovigilance activities is not restricted to medical students, even physicians might not be having proper knowledge about pharmacovigilance activities and ADR reporting as the number of ADRs that are reported annually are very less.

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