A quantitative insight on preclinical and clinical year medical students towards adverse drug reporting and pharmacovigilance in Malaysia

Kingston Rajiah, Mari Kannan Maharajan and Prashanthini Janardanan

Department of Pharmacy Practice, School of Pharmacy, International Medical University, Kuala Lumpur, Malaysia

Abstract

Objective

To investigate the knowledge of medical students and their perception on adverse drug reaction (ADR) reporting and pharmacovigilance.

Methods

Cross-sectional study was carried out on clinical or preclinical year medical students using paper-based questionnaires during their coursework.

Key findings

There were differences between the two groups in responses relating to ADR reporting (preclinical 3.3 versus clinical 3.7; $P < 0.01$) and reasons for not reporting a suspected ADR (preclinical 3.4 versus clinical 3.8; $P = 0.001$).

Conclusions

Medical students from clinical years had higher knowledge of ADR reporting. The perception on ADR reporting by clinical year students was significantly higher. Keywords adverse drug reactions; Malaysia; medical students; pharmacovigilance

Introduction

Many countries have their own Pharmacovigilance Center, as the national pharmacovigilance system is the main way to collect information about the occurrence of adverse drug reactions (ADR) in both the hospital and community settings. In Malaysia, the Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) has expanded its pharmacovigilance efforts in various ways in an attempt to reduce ADR incidents and its associated costs.[1] The activities of MADRAC are coordinated by the Uppsala Monitoring Centre as per the guidelines prescribed by the World Health Organization. Despite the existence of such drug safety monitoring systems, there are several studies explained the under-reporting phenomenon as being due to uncertainty about the drug causing an ADR, difficulty in accessing/compiling the reporting forms and a lack of knowledge of the aim and clinical utility of pharmacovigilance among health professionals.[2–6] Medical schools are critical places for future physicians to learn the professional norms of ADR reporting and pharmacovigilance, yet little is known about how students' perceptions vary during the course of their education and training. Understanding these differences is important, because it can reflect how the medical/clinical school experience influences students towards ADR reporting and pharmacovigilance. In the light of this scientific background, there is a need to study the students' knowledge on pharmacovigilance and ADR reporting, to create awareness on ADR reporting at various levels of their course (preclinical and clinical years). The objective of this study was to investigate the level of ADR reporting knowledge and pharmacovigilance of medical students in their preclinical and clinical years, as well as their perception of ADR reporting at these different stages of their coursework.

Methods

Ethical approval

The study was approved by the International Medical University Joint Committee for Research and Ethics (Reference number: BP I-01/11(27)2014).

Study design and instrument

A cross-sectional study was carried out on preclinical and clinical year medical students in International Medical University, Malaysia (IMU), from July to December 2014 using a validated questionnaire during the coursework. Convenience sampling was performed by applying a single mean formula with alpha set at 0.05, standard deviation (SD) of 1.98 and precision at 0.30. Participants were asked to complete the paper-based questionnaire which had three sections: (1) demographic details, (2) yes/no-type questions pertaining to knowledge on ADR reporting and pharmacovigilance (yes = 1, no = 0) and (3) statements which were designed to evaluate students' perception of ADR reporting and pharmacovigilance using a five-point Likert scale format (Strongly agree = 5 to Strongly disagree = 1). The Cronbach's alpha value was 0.75.

Data analysis

Data were entered and analysed using SPSS (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.). T-test (two-tailed) was used to find out the significant difference between preclinical and clinical year students' knowledge and perception with P-values of <0.05 were judged to be statistically significant at 95% confidence interval.

Results

The demographic details of the respondents participating in the study are shown in Table 1. The number of female respondents was higher than the number of males. The average age of the respondents was 21.6 ± 1.1 years.

Statistically significant differences were observed in two questions which asked about their knowledge of ADR reporting. Clinical students had better knowledge than preclinical students. First, for the question concerning how to report ADR to the relevant authorities in Malaysia (mean responses 0.92 versus 0.51; P = 0.01), and the other question is about how causality assessment of ADR is undertaken in Malaysia (mean responses and 0.93 versus 0.33 respectively; P = 0.001; Table 2).

Statistically significant differences were observed in two statements which assessed about students' perception towards ADR reporting. One related to their preparedness to report any ADR in their future practice (preclinical 3.23 versus clinical 3.74; P = 0.01) and another one was the uncertainty of ADR and its association with drugs is a reason for not reporting a suspected ADR (preclinical 3.4 versus clinical 3.8; P = 0.001; Table 2).

Discussion

The difference between the knowledge of preclinical and clinical year students suggests that the clinical experience may have an impact on students' knowledge regarding ADR reporting and pharmacovigilance, which may lead to better reporting of ADR in the future.[7] The limited knowledge of the preclinical year students in identifying ADR and reporting may be due to minimal exposure to the clinical environment.[8]

Pertaining to the perception towards ADR reporting and pharmacovigilance, there was a significant difference between preclinical and clinical year groups in two aspects. The first

aspect is the perception of preclinical students that they are insufficiently prepared to report any ADR in their future practice. This may be because of lack of training on ADR reporting, or lack of hands-on activities in their coursework.[7,8] On the other hand, clinical students with their present knowledge perceive that they are well inclined to report any ADR in their future practice; this may be due to their exposure to the clinical environment. The second aspect is the perception of preclinical students that they are uncertain about ADR and their association with drugs; hence, they may not report ADR. The reason that preclinical year students may not report a suspected ADR may be due to the precariousness of its connection with the drugs.[9,10] This reveals that the preclinical students need to learn more about the common ADR caused by different drugs and their reporting in their future practice.

Limitations

Studies with larger samples and including students from multiple medical schools should be conducted. Students may have reported strong intentions and positive perception because they knew that reporting ADR is an expected behaviour.

Conclusions

Medical students from the clinical years had a higher level of knowledge on ADR reporting than those in preclinical years. Therefore, there is a need to focus on the curriculum of the preclinical year medical students on pharmacovigilance aspects. The perception of clinical year students in relation to ADR reporting is significantly different from preclinical year students. A future longitudinal study could complement what has been analysed in this study.

Declarations

Conflict of interests

The Authors declare that they have no conflicts of interest to disclose.

Funding

This research is supported by Institute for Research, Development & Innovation, International Medical University, Malaysia. BP I-01-12 (30) 2015.

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Table 1 Demographic summary of preclinical and clinical year students

Students group	*n*	%
Male	78	49.68
Preclinical	42	53.84
Clinical	36	46.15
Female	79	50.31
Preclinical	53	67.08
Clinical	26	26.58

Table 2 *T*-test statistics of medical students' knowledge and perception on adverse drug reaction (ADR) reporting and pharmacovigilance

Items group	Students	*N*	Mean	Std. deviation	Mean difference	Sig.(two-tailed)
I How to report ADR to the relevant authorities in Malaysia	Preclinical	95	0.51	1.06	0.410	0.01
	Clinical	62	0.92	0.94		
II How causality assessment of ADR is undertaken in Malaysia	Preclinical	95	0.33	0.73	0.60	0.001
	Clinical	62	0.93	0.67		
III Preparedness to report any ADR in their future practice	Preclinical	95	3.23	1.06	0.51	0.01
	Clinical	62	3.74	0.85		
IV Uncertainty of ADR and its association with drugs is a reason for not reporting a suspected	Preclinical	95	3.24	0.92	0.59	0.001
	Clinical	62	3.83	0.69		