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Knowledge and Perception of Pharmacy Practice Students on Causality Assessment of Adverse Drug Reactions

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Abstract Pharmacy Practice students play an important role in identifying and reporting Adverse Drug Reactions (ADRs). Prior studies focused on knowledge of pharmacy students on reporting ADRs. There are no studies conducted to assess the knowledge and understand the perception of students on causality assessment of ADRs. A web-based cross-sectional study was conducted from October 2019 to April 2020 among the Pharmacy Practice students in various pharmacy colleges across India. Consent form was obtained before filling the questionnaire. The questionnaire was distributed through social media applications and staff of respective colleges. Descriptive analysis was performed to calculate frequencies and percentages of categorical variables. A total of 723 students, 608 responses were received from 30 pharmacy colleges across India. The mean age (SD) of participants was 22.95 (1.61) years. The majority of responses were received from females (70.39). The majority of participants (90.78%) were aware of various causality assessment scales. More than half (58.55%) strongly agreed that there is a need for hands on training on causality assessment of ADRs at college level. Around 80% of the participants strongly agreed that clinical pharmacist is necessary in the healthcare team for causality assessment of ADRs. The knowledge of students on causality assessment of ADRs was found satisfactory. Students believed that having regular workshop on causality assessment of ADRs may help improve their skills in identifying the suspected medications that caused ADRs and helps in better patient care.

Keywords Causality Assessment, Knowledge, Perception, Pharmacy, Adverse Drug Reaction

1. Introduction

According to World Health Organization (WHO), Adverse Drug Reaction (ADR) is defined as a response to a drug which is noxious and unintended. It occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function [1]. ADR is a major cause of morbidity and mortality in patients as well as in healthy individuals. In a prospective study, it was found that the prevalence of ADRs was 12.4% [2] and 7.8% of ADRs were attributed to drug-drug interactions [3]. Therefore, it is also

important to identify the suspected drug and prevent the reaction. Through the causality assessment of ADRs, it is possible to identify the culprit drug(s), strengths and the relationship between the suspected drug and the reaction [4].

In a systematic review, it was found that there are 34 different methods for causality assessment of ADRs. These include Expert Judgment or Global Introspection (WHO and Uppsala Monitoring Centre, Wilhelm), Algorithms (Naranjo, Karch and Lasagna), and probabilistic/Bayesian Approaches (Marshford, Lanctot). However, they concluded that there is no gold standard to perform causality assessment of ADRs [5].

The role of pharmacists widened from traditional medication dispensing practices to identifying, analysing, reporting and communicating of ADRs [6]. Also, pharmacists are involved in providing drug information, medication interventions and counselling for consumers on use and administration of medications [6]. The postgraduate students in pharmacy such as Master of Pharmacy Practice (M. Pharm) and Doctor of Pharmacy (Pharm D) V- and VI-year students play an important role in reporting ADRs as they have a practical exposure to identifying and reporting of ADRs. In this context, the National Coordination Center, Indian Pharmacopeia Commission (IPC) started Pharmacovigilance Programme of India for safe and effective use of medications. Under this program, the IPC had planned to collaborate with the pharmacy institutions in India to increase the reporting culture of ADRs [7].

There are many studies conducted elsewhere to understand the knowledge of pharmacy students on reporting of ADRs and Pharmacovigilance [8], [9]. But to our knowledge, there are no studies conducted in India to understand the knowledge and perception Pharm D and M.Pharm Pharmacy Practice students on causality assessment of ADRs.

Aim of the Study

The aim of this study was to assess the Knowledge and perception of V, VI Pharm D and M. Pharm Pharmacy Practice students on causality assessment of ADRs.

2. Material and Methods

Study Design

A web-based cross-sectional study was conducted from October 2019 to April 2020 among the V, VI Pharm D and M. Pharm Pharmacy Practice students studying in various pharmacy colleges in India. This study was conducted based on guidelines for reporting survey-based research submitted to academic medicine [10].

Development of Questionnaire

A 21-item self-administered questionnaire was developed with the help of the experts in the field of pharmacovigilance. The questionnaire included three domains. The first domain consisted of demographic details of participants such as age, gender, and class of the students. The second and third domain consisted of knowledge (10) and perception (11) related questions respectively. The response to each question in the knowledge domain had “yes” or “no” options. The response “yes” was considered as positive knowledge of students towards causality assessment of ADRs. The response of each question in the perception domain was based on the Likert scale (strongly agree, agree, neutral, disagree and strongly disagree.

Validation of the Questionnaire

Firstly, the content and face validation were performed by the subject experts (lecturers and researchers). The questionnaire was revised based on the suggestions given. Later, a pilot study was conducted on 30 randomly selected Pharmacy Practice students to assess the reliability of the questionnaire by using cronbach’s alpha. The alpha value of the questionnaire was 0.72 which was considered as inter-related and unidimensional.

Study Sample

The V, VI year Pharm D and I and II year M. Pharm Pharmacy Practice students from various colleges in India were included in this study. These students were selected because of pharmacy regulations of India. According to Pharmacy Council of India, the students from these two courses are actively involved in providing pharmaceutical care services such as patient counselling, providing drug information, identifying, reporting and minimizing adverse drug reactions. The duration of Pharm D course is six years, which is divided into two phases. The duration of M. Pharm Pharmacy Practice course is two years [11]. The Phase I of Pharm D is again divided into five years. In these five years, students will be taught on various subjects such as Pathophysiology, Pharmacology, Pharmacotherapeutics, Clinical Pharmacy, Hospital Pharmacy, Pharmacoepidemiology, Pharmacoeconomics and the fifth year includes submission of six months project work. The Phase II of Pharm D course lasts for one year in which students will have six months of clinical postings in general medicine unit and speciality unit respectively. In the first year of M. Pharm Pharmacy Practice, students will be taught on subjects such as Clinical Pharmacy Practice, Pharmacotherapeutics I, hospital & Community Pharmacy along with clinical postings. In the second year, students will be taught on Pharmacotherapeutics II, Principles of Quality Use of Medicines, Pharmacoepidemiology and

Pharmacoeconomics along with clinical postings and 12 months of project work [12].

Sample Size

The sample size was calculated by using Raosoft sample size calculator [13]. With 5% margin error, 95% confidence level, for a population size of 20000 and with 50% response distribution the estimated sample size was 377.

Distribution of the Questionnaire

A google form was created with the finalized questionnaire. Responses were collected in MS office Excel spread sheet (Version 2019). The google form was circulated to staff and students of 100 pharmacy colleges across India from an institutional email. Besides, the google form was circulated by the authors via their personal social network accounts such as WhatsApp, Instagram and Facebook to V, VI Pharm D and M. Pharm Pharmacy Practice students. "Limit to one response" option was selected to restrict multiple responses from one student.

Statistical Analysis

Mean and standard deviations was calculated for quantitative data and frequencies and percentages for qualitative data.

Ethical Approval

This study received an exemption from the Institutional Human Ethics committee of JSS College of Pharmacy, Mysuru as it was considered as minimal risk research. However, participants were asked to give voluntary consent to take part in the study.

3. Results

From a total of 723 participants who gave consent to participating in the study, 608 participants from 30 pharmacy colleges were included. The remaining 115 participants responses were not included in the synthesis of data due to incomplete filling of the questionnaire. The mean age (SD) of participants was 22.95 (1.61) years. The majority of responses were received from females [428 (70.39)]. Maximum responses were received form VI PharmD students (49.34%), followed by V PharmD (43.09%), II M. Pharm (4.6%) and I M. Pharm (2.96%) (Table 1).

Table 1. Demographic Details of Participants

Demographics N=608	
Age (Years, Mean (SD))	22.95 (1.61)
Gender (Number (%))	
Male	180 (29.6)
Female	428 (70.39)
Class of the Student (Number (%))	
V Pharm D	262 (43.09)
VI Pharm D	300 (49.34)
I M.Pharm (Pharmacy Practice)	18 (2.96)
II M.Pharm (Pharmacy Practice)	28 (4.6)

Knowledge of Students on Causality Assessment of ADRs

Around 96% of participants heard about causality assessment of ADRs and approximately 94% of participants were aware that the purpose of causality assessment is to find the relationship between the suspected drug and the reaction. Around 92% of participants believed that causality assessment of ADRs is mandatory. The majority of students were aware of various causality assessment scales [552 (90.78)] and 74% of the participants depend on more than one causality assessment scale. Nearly 72% of the participants said that any healthcare professional can perform causality assessment of ADRs. The details of responses on knowledge of pharmacy students on causality assessment of ADRs are presented in table 2.

Table 2. Knowledge of students on Causality Assessment of ADRs (N=608)

Sl. No	Question	Number (%)	
		Yes	No
1	I have heard about the causality assessment of ADR	586 (96.38)	22 (3.61)
2	I have an idea on how to do causality assessment of ADRs	532 (87.5)	76 (12.5)
3	I am aware of different causality assessment scales	552 (90.78)	56 (9.21)
4	I depend on more than one scale for causality assessment of ADRs	448 (73.68)	160 (26.31)
5	I believe causality assessment of ADRs is mandatory	558 (91.77)	50 (8.22)
6	I am aware of the different categories of causality relationship present in the causality assessment scales	498 (81.9)	110 (18.09)
7	Through causality assessment, the suspected drug can be identified	480 (78.94)	128 (21.05)
8	I am aware that the results of the causality assessment of some ADRs vary from scale to scale	504 (82.89)	104 (17.1)
9	Any healthcare professional can perform the causality assessment of ADRs	438 (72.03)	170 (27.96)
10	The purpose of causality assessment is to find the relationship between the suspected drug and the reaction	570 (93.75)	38 (6.25)

Table 3. Perception of students on Causality Assessment of ADRs (N=608)

Sl. No	Question	Strongly Agree N (%)	Agree N (%)	Neutral N (%)	Disagree N (%)	Strongly Disagree N (%)
1	There is a need for a hands-on training on causality assessment of ADRs at college level	356 (58.55)	188 (30.92)	56 (9.21)	8 (1.31)	0 (0)
2	Clinical Pharmacist is necessary in the healthcare team for causality assessment of ADRs	482 (79.27)	112 (18.42)	14 (2.3)	0 (0)	0 (0)
3	Causality assessment of ADRs must be done only for serious ADRs	54 (8.88)	80 (13.15)	108 (17.76)	258 (42.43)	108 (17.76)
4	Reason for not performing causality assessment is because of its complexity	58 (9.53)	196 (32.23)	180 (29.6)	152 (25)	22 (3.61)
5	There should be only one standard causality assessment scale	100 (16.44)	166 (27.3)	136 (22.36)	170 (27.96)	36 (5.92)
6	The causality assessment team should involve physicians, clinical pharmacist and nurses for causality assessment of ADRs	344 (56.57)	202 (33.22)	46 (7.56)	12 (1.97)	4 (0.65)
7	The patient should be informed about the outcome of the causality assessment	178 (29.27)	248 (40.78)	112 (18.42)	68 (11.18)	2 (0.32)
8	The ADR reporting form should include the various causality assessment scales	194 (31.9)	256 (42.1)	82 (13.48)	66 (10.85)	10 (1.64)
9	Assessment of knowledge on performing causality assessment should be done periodically	262 (43.09)	282 (46.38)	52 (8.55)	12 (1.97)	0 (0)
10	ADRs can be reported to regulatory authorities without causality assessment	48 (7.89)	70 (11.51)	96(15.78)	264(43.42)	130 (21.38)
11	Reported ADRs should be audited by the causality assessment committee	264 (43.42)	258 (42.43)	72(11.84)	10(1.64)	4 (0.65)

Perception of Students on Causality Assessment of ADRs

The majority of students strongly agreed that there is a need for hands on training on causality assessment of ADRs at college level (58.55%). Around 80% of the participants strongly agreed that clinical pharmacist is necessary in the healthcare team for causality assessment of ADRs. Also, most of the participants (42%) disagree that causality assessment should be performed to serious ADRs only. Around 32% of the agreed that complexity of causality assessment scales was the reason for not performing it. 28% of the participants disagree to have only one causality assessment scale. The majority of participants agreed to inform the outcome of causality assessment to the patient. The perception of students on causality assessment of ADRs are presented in table 3.

4. Discussion

Through this study, we were able to understand the students' knowledge and perception towards causality assessment of ADRs. Overall, the knowledge and perception of students in causality assessment of ADRs was satisfactory. Most of our participants (87.5%) were

aware of performing causality assessment of ADRs. This result was in contrast with a study conducted in Malaysia by Rajiah K et al., [14] where only 12% of the participants were aware of performing causality assessment of ADRs. The reason for more knowledge among participants in our study was the implementation of ADR reporting culture by Pharmacovigilance Programme of India where Pharm D and M. Pharm Pharmacy Practice institutions were involved in reporting ADRs to the ADR monitoring centers (AMCs) and regulatory authorities [7]. The majority (32.33%) of participants agreed that complexity of scales was the reason for not performing causality assessment. This explains that there is a need for continuous training on causality assessment of ADRs which help students to adapt to the procedure. This was supported by 58% of the participants who expressed their interest in need of hands-on session on causality assessment of ADRs at college level. Agbabiaka T [5] found that there is no standard causality assessment scale designed till date. This could be attributed to differences in the judgement which is subjective. This can be supported by Belhekar M [15] which concluded that there is a poor disagreement between WHO UMC causality assessment scale and Naranjo algorithm. Therefore, we believe that the idea of creating a standardized scale which is acceptable worldwide is a challenging task.

We understood that around 90% of the participants agreed that the causality assessment team should include multiple healthcare professionals such as doctors, clinical pharmacists, and nurses. Particularly, 97.6% of the participants said that clinical pharmacist is necessary in the healthcare team for causality assessment of ADRs. This is attributed to the fact that clinical pharmacists work directly with doctors and other healthcare professionals in providing drug therapy. Also, they are specialized in providing drug information services and identifying, reporting, and preventing ADRs [16].

To our knowledge, this was the first study conducted in India and globally to understand the knowledge and perception of students on causality assessment of ADRs. Therefore, we were unable to compare out results with other studies. We hope this study will lay the foundation for creating new job opportunities for V & VI Pharm. D, M. Pharm Pharmacy Practice students in the field of pharmacovigilance in causality assessment of ADRs.

5. Strengths and Limitations

This is the first study conducted to assess knowledge and understand the perception of Pharmacy Practice students on causality assessment of ADRs. The rigorous methodology used in this study, in accordance with the reporting survey-based research submitted to academic medicine guidelines, strengthen the results of the study. Due to its novelty, we were unable to compare our results with other studies which might have affected the generalizability of the study.

6. Conclusions

It was found that the knowledge and perception of participants on causality assessment of ADRs was satisfactory. However, participant's opinion was that a regular workshop should be formed on causality assessment of ADRs through which students will be experts in performing causality assessment of ADRs. These skills may help in identifying suspected medications in ADRs which provides better patient care.

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