Evaluation and assessment of the knowledge, attitude and practice of pharmacy students with respect to pharmacovigilance in a Saudi pharmacy school: a cross-sectional study.

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Abstract

BACKGROUND: Pharmacovigilance is an important part of the health care system as it helps in the detection, assessment, reporting and prevention of Adverse Drug Reactions. Spontaneous reporting of adverse drug reaction plays a vital role in the success of Pharmacovigilance programs and pharmacy students are supposed to acquire sufficient knowledge and necessary skills required for practicing pharmacovigilance under different clinical settings. Hence, this study was carried out in the students of College of Pharmacy of a University in the Southern Province of Saudi Arabia to assess the Knowledge, Attitude and Practice (KAP) of undergraduate Pharmacy students towards Pharmacovigilance.

METHODS: A quantitative, prospective, cross-sectional online survey was carried out using a validated, self-administered questionnaire constituting 4 domains i.e. Demographics, Knowledge, Attitude and Practice of Pharmacovigilance among the pharmacy students of King Khalid University.

RESULTS: The questionnaire was administered to 360 students out of which 329 responded (response rate of 91.3 %). The mean score of Level 7,8,9,10 and intern students for Knowledge was (3.03,5.37, 6.38, 6.19,6.42), Attitude (5.28,4.16, 5.62, 5.01, 5.29), and Practice (2.99, 3.25, 3.04, 3.43, 3.13) respectively. In addition, the findings indicated a significant difference in the mean score among different level of students for knowledge and attitude with a p-value of <0.0001, and 0.0002 respectively. The practice mean score showed there was no much significance among different level of students (p-value = 0.4108)

CONCLUSION: Our research findings revealed that the pharmacy students of the focused university have adequate knowledge and positive attitude towards adverse drug reaction. However, there is a dire need to understand and address concerns regarding real time practice patterns prevalent among Health Care Providers about pharmacovigilance under different clinical settings.

Keywords: Pharmacovigilance, Knowledge, Attitude, Practice, Pharmacy students

Background

Pharmacovigilance is an important part of the health care system because it helps in the detection, assessment, understanding and prevention of adverse drug reactions [1]. It involves the evaluation over time of the safety of marketed medicines and primarily focuses on adverse drug reactions and patient care [2]. To fully realize its benefits, pharmacovigilance must also involve building healthy collaborations at national and international levels. At the international level, the Uppsala Monitoring Centre (UMC) was the first World Health Organization (WHO) collaborating center to be established for pharmacovigilance, which is the scientific and technical responsibility of the WHO Programme for International Drug Monitoring [1]. In Saudi Arabia, The National Pharmacovigilance and Drug Safety Center has been established under the Saudi Food and Drug Authority and is responsible for promoting pharmacovigilance [3]. Adverse event reporting is a responsibility of clinical researchers as well as health care professionals (such as physicians, pharmacists, and nurses) and consumers (such as patients, family members, and lawyers), even if the side effects are only suspected. Such reporting supports the

determination of which side effects are worth the risk to patients considering how effectively the reaction-causing drug treats a disease. Spontaneous reporting of adverse drug reactions plays a prominent role in the success of the pharmacovigilance program[4,5]. One initiative of the Saudi 2030 vision plan is to advance patient care through a more robust, safety/quality-centered culture together with a more collegial relationship between local and international drug manufacturers and Saudi regulatory authorities[6]. As pharmacovigilance is a subject of broad and current interest, significant studies have been carried out on this topic globally by Suyagh et al, Alsaleh et al, and Gupta et al, but limited studies have been carried out in this important domain in Saudi Arabia[7,8,9]. Therefore, our aim was to expand the research and conduct a survey among pharmacy students, who are future health care providers and are tasked with acquiring the knowledge and skills required for practicing pharmacovigilance in different clinical settings. This study may enhance adverse drug reaction reporting in the future, which might reduce the health care expenditures and costs associated with adverse drug reactions and their treatment, which may be extensive.

Methods

Aim of the study

This study was carried out in a sample of students attending the College of Pharmacy at a university in a southern province in Saudi Arabia to assess the knowledge, attitude and practice (KAP) of undergraduate pharmacy students with respect to pharmacovigilance.

Study design and setting: This prospective, cross-sectional descriptive online study was designed to assess the level of knowledge, attitudes and practices of pharmacovigilance among undergraduate students attending the College of Pharmacy, King Khalid University, Abha, Saudi Arabia.

Target population, Sampling Criteria and Sample size: The College of Pharmacy of King Khalid University has a large group of students, both male and female, distributed across ten levels, from Level–1 to Level–10. Each academic year comprises 2 levels, for a total of 5 years. Each level refers to a single semester of study. After completing the ten levels, students are subjected to a training period of one year in primary health care centers and pharmacies, which is known as an internship. The web-based survey was administered to a sample of study participants comprising both male and female fourth- and fifth-year students (Level–7, –8, –9, and –10) and those involved in their internship during the study period (October 2018–November 2018). We excluded students below Level–7 and students not enrolled in the College of Pharmacy. We used a simple random sampling technique, and our estimated sample size was 359, as calculated via Raosoft with a confidence interval of 99% [10]. The online questionnaire link was given to the class representative of each level, and the representatives forwarded the link to the students through their WhatsApp groups.

Survey instrument development and Data collection: A self-administered structured pre-validated questionnaire based on instruments used in previous similar studies was adapted [9]. Then, by conducting an extensive literature review and holding focus group discussions, a final questionnaire was

prepared that could fulfil the objective of this study. The questionnaire was then subjected to a face and content validation process involving experts from the research team to ensure that the survey was sufficiently comprehensive. A pilot study was carried out to determine the validity, reliability and clarity of the questionnaire. The results of the pilot study were not included in the final results. The feedback was analyzed, the double-barreled, confusing and leading questions were modified, and a finalized questionnaire was created accordingly. The internal consistency of the questionnaire was also evaluated, and a Cronbach's alpha value of 0.844 was obtained (by SPSS), which indicates that the questionnaire is reliable. The questionnaire comprised 4 domains. The first section included the independent variables of the study, i.e., information such as participants' sex and level of education. The second section consisted of 11 closed-ended questions presented in a multiple choice format that assessed the students' knowledge of pharmacovigilance. The third section consisted of 7 questions presented in a yes/no format that assessed students' attitude towards pharmacovigilance, whereas the last section, i.e., the fourth section, comprised 6 questions pertaining to the practice of pharmacovigilance presented in a yes/no format. The dependent variables in this study were knowledge, attitude, and practice. The questionnaire was converted into a web-based format and was then delivered to the study participants; the data were collected from October to November 2018. Eligible participants were approached.

Statistical Analysis: The results were downloaded and stored in Microsoft Excel spreadsheets. The data were analyzed using SPSS version 21.0 statistical software (IBM Inc., Chicago, USA). Descriptive statistics (mean and standard deviation) were used to describe the categorical study and outcome variables. Unpaired Student's t tests, one-way analysis of variance and Bonferroni multiple comparisons were used to compare the mean scores of the domains, i.e., knowledge, attitude and practice, between the sexes and across the academic levels. A p value of ≤ 0.05 and 95% confidence intervals were used to report the statistical significance and precision of the results in the tables.

Results

The online questionnaire measuring 3 dependent variables, knowledge, attitude, and practice, which had total possible scores of 11, 7, and 6, respectively, was self-administered to 359 participants. Three hundred twenty-nine responded, giving a response rate of 91.3 %. Seventy-seven percent (n = 254) of the students were based on the female campus, while the remaining 23% (n = 75) were based on the male campus.

Table 1: Sex-based comparison of the mean scores for the Knowledge, Attitude and Practice subscales:

Table-1: : Sex-based comparison of the mean scores for the Knowledge, Attitude and Practice subscales						
	Knowledge questions		Attitude questions		Practice questions	
	Females	Males	Females	Males	Females	Males
Mean	6.2	5.79	5.22	4.64	3.21	3.03
Std. Deviation	2.1	2.25	1.78	1.8	1.47	1.47
Std. Error	0.132	0.26	0.112	0.208	0.092	0.17
Lower 95% CI	5.95	5.27	5.04	4.29	3.06	2.74
Upper 95% CI	6.46	6.3	5.41	4.99	3.36	3.31
Std-standard, CI-confidence interval						

The mean knowledge scores were calculated and are shown in Table–1. An unpaired Student's t-test was carried out to compare the knowledge of male and female participants, and it was estimated that the mean score for female participants was 6.2 ± 2.1, whereas for males, it was 5.79 ± 2.25. The estimated two-tailed p value was 0.1374 (<0.05), indicating that the means were not significantly different. Furthermore, Table–1 shows the mean attitude scores of the male and female participants. An unpaired Student's t-test was carried out to compare the attitudes of the male and female students, and it was estimated that the mean score for female participants was 5.22 ± 1.78, whereas for males, it was 4.64 ± 1.8. The estimated two-tailed p value was 0.0131 (<0.05), indicating a significant difference. The students were also asked some basic questions that assessed their practice with respect to pharmacovigilance; the results are also summarized in Table–1. An unpaired t-test was carried out to compare the practice of the male and female participants, and it was estimated that the mean score for female participants was 3.21 ± 1.47, whereas for males, it was 3.03 ± 1.47. The estimated two-tailed p value was 0.3459 (<0.05), indicating no significant difference.

Table 2: Comparison of mean knowledge scores across different levels of students:

The mean knowledge score of the participants was estimated and compared across the academic levels for both sexes. The mean scores for the Level–7, –8, –9, and –10 students and the intern students were found to be 3.03±1.47, 5.37±2.14, 6.38±2.21, 6.19±2.03, and 6.42±2.31, respectively. A one-way analysis of variance was carried out, and the estimated p value was <0.0001 (<0.05), indicating a significant difference. Bartlett's test for homogeneity of variances was also carried out and yielded a p value of 0.0026 (<0.05), indicating a significant difference between the groups. Bonferroni's multiple comparisons test was also carried out to compare the academic levels and determine significant differences among the groups, and the results are clearly displayed in Table–2. [Table–2]

Table 3: Comparison of mean attitude scores across different levels of students

The mean attitude scores of the participants were estimated and compared across the academic levels for both sexes. The mean scores for Level–7, –8, –9, and –10 students and the intern students were 5.28±1.82, 4.16±1.93, 5.62±1.56, 5.01±1.62, and 5.29±1.76, respectively. A one-way analysis of variance was carried out, and the estimated p value was 0.0002 (<0.05), indicating a significant difference. Bartlett's test for homogeneity of variances was also carried out, yielding a p value of 0.4716 (<0.05), suggesting no significant differences between the groups. Bonferroni's multiple comparisons test was also carried out to compare the groups, and the details are summarized in Table 3. [Table–3]

Table 4: Comparison of mean practice scores across different levels of students

The mean practice score of the participants was estimated and compared across the academic levels for both sexes. The mean scores for Level–7, –8, –9, and –10 students and the intern students were 2.99±1.53, 3.25±1.54, 3.04±1.56, 3.43±1.29, and 3.13±1.42, respectively. A one-way analysis of variance was carried out, and the estimated p value was 0.4108 (<0.05), indicating no significant difference. Bartlett's test for homogeneity of variances was also carried out, yielding a p value of 0.5233 (<0.05), suggesting no significant difference between the groups. Bonferroni's multiple comparisons test was also carried out to compare the groups, and the details are summarized in Table–4. [Table–4]

Discussion

The findings of this study clearly indicated that the students attending King Khalid University have adequate knowledge and positive attitudes towards pharmacovigilance (p value < 0.05), which corroborates the findings of Abdel-Latif. In the study of Abdel-Latif, the respondents were unable to correctly define the term pharmacovigilance, but they were aware of adverse drug reactions, whereas in our study, many students were able to define the term pharmacovigilance correctly, and they were very much aware of adverse drug reactions and the systems for reporting them. However, most of them were not aware of the system used in Saudi Arabia for reporting adverse drug reactions, and most of them had not seen the form used in Saudi Arabia [11]. In a previous study conducted by Othman and colleagues among pharmacy students, most of the respondents had poor knowledge of this concept, which differs from the results at our university [12]. In another study conducted in Dammam, Saudi Arabia, by Ali and his colleagues, respondents also had inadequate knowledge and poor attitudes, in contrast to our results [13]. This difference in the findings regarding knowledge and attitude across studies may be due to differences in the teaching curriculum as well as the level of training received. Regarding the practice of pharmacovigilance, our findings showed that students required adequate training to improve their skills. Many studies conducted previously on student samples or samples of health care professionals, such as those of Suyagh Alsaleh *et al.* and Gupta *et al.,* found that participants also had poor practice, which is in accordance with our findings [7,9]. Vora et al. (2012) suggested that the initiation of organized training programs for pharmacovigilance in undergraduate medical curricula is mandatory if we wish to see better results in the future, as pharmacy students are society's future prescribers. They also suggested providing

online and telephone line access to facilitate adverse drug reaction reporting [14]. In another study carried out by Khan S, the participants were deficient in knowledge and attitude, and the author suggested that urgent attention was required not only to improve the rate of spontaneous reporting but also to improve safety for patients and society at large[15]. Shanko H also recommended the development of specific strategies to improve awareness, knowledge and practice in his study population, because he found gaps in the knowledge, awareness and practice of healthcare professionals with respect to adverse drug reaction (ADR) reporting [16]. There was even a study carried out by Aljadhey H in Saudi Arabia to explore the challenges of pharmacovigilance from the perspective of healthcare professionals in Saudi Arabia. The author recommended that healthcare professionals be trained continuously on the importance of pharmacovigilance and that the regulatory authority should make serious efforts to increase the awareness of patients and the public regarding ADR reporting. Health sciences colleges were also recommended to incorporate pharmacovigilance courses into their curriculum to increase future healthcare providers' awareness at an early stage of their career [17]. Some studies also recommended that educational interventions in pharmacovigilance and strategies for promoting ADR reporting by healthcare professionals that have proven effective in other countries should also be adopted in Saudi Arabia [17–19]. Such recommendations are applicable to the students in our study because pharmacy students are also future health care providers. Thus, conducting workshops in the future to create awareness among them could be beneficial. However, this study has several limitations. Data collection was limited to a single point of time, so changes over time were not assessed. The participants might have easily answered the questions with help from their classmates or by searching online because we used a self-administered web-based questionnaire. This could have affected the accuracy of our findings, particularly for the knowledge section, because this method does not allow us to examine the behavior of the participant while completing the survey. The survey was carried out in a single pharmacy school; therefore, these findings could not be generalized to other schools in Saudi Arabia. Thus, a future study in other schools in Saudi Arabia might help in creating a clear picture.

Conclusion

Our research findings revealed that the pharmacy students at King Khalid University have adequate knowledge and positive attitudes towards adverse drug reaction reporting; however, there is a dire need to understand and address concerns regarding real-time pharmacovigilance practice patterns among health care providers in different clinical settings. Educational interventions, such as the incorporation of this concept in undergraduate practical training, continuous medical education (CME), and workshops on pharmacovigilance, may help improve adverse drug reaction monitoring and reporting skills.

List Of Abbreviations

World Health Organization (WHO)

Knowledge, attitude and practice (KAP)

Continuous medical education (CME)

Adverse drug reaction (ADR)

Declarations

ETHICS APPROVAL AND CONSENT TO PARTICIPATE:

The study was approved by the Ethics Committee of College of Pharmacy, King Khalid University and all the respondents were asked for their verbal consent before participation in the study. Assessment of the responses was done blindly.

CONSENT FOR PUBLICATION:

Not applicable

AVAILABILITY OF DATA AND MATERIALS:

The data used to support the findings of this study are available from the corresponding author upon request.

COMPETING INTERESTS:

The authors declare that there are no competing interests regarding the publication of this paper.

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AUTHOR'S CONTRIBUTION:

AS, NA, MJ, were major contributors in writing the manuscript and they were involved in the analysis and interpretation of the data. AM, RA, SA, AA, WA performed the data collection and were involved in writing the manuscript as well. ME,JG, MK were major contributors in writing the manuscript. All authors read and approved the final manuscript.

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Tables

Table-2- Comparison of mean knowledge scores across different levels of students					
One-way analysis of variance					
P value	< 0.0001				
P value summary	***				
Are means signif. different? (P < 0.05)	Yes				
Number of groups	5				
F	36				
R squared	0.305				
Bartlett's test for equal variances					
Bartlett's statistic (corrected)	16.3				
P value	0.0026				
P value summary	**				
Do the variances differ signif. (P < 0.05)	Yes				
ANOVA Table	SS	df	MS		
Treatment (between columns)	598	4	149		
Residual (within columns)	1360	328	4.16		
Total	1960	332			
Bonferroni's Multiple Comparison Test	Mean Diff.	t	Significant? P < 0.05?	Summary	95% CI of diff
Level 7 vs Level 8	-2.34	6.54	Yes	***	-3.35 to -1.33
Level 7 vs Level 9	-3.36	9.27	Yes	***	-4.38 to -2.33
Level 7 vs Level 10	-3.16	9.32	Yes	***	-4.12 to -2.20
Level 7 vs In Training	-3.39	10.2	Yes	***	-4.33 to -2.46
Level 8 vs Level 9	-1.01	2.63	No	ns	-2.10 to 0.0756
Level 8 vs Level 10	-0.817	2.25	No	ns	-1.85 to 0.211
Level 8 vs In Training	-1.05	2.95	Yes	*	-2.06 to -0.0431
Level 9 vs Level 10	0.196	0.534	No	ns	-0.842 to 1.23
Level 9 vs In Training	-0.0392	0.109	No	ns	-1.06 to 0.981
Level 10 vs In Training	-0.235	0.697	No	ns	-1.19 to 0.719
ANOVA-Analysis of Variance, ns-not significant, vs-versus, df-degrees of freedom, ss-sum of squares, MS- Mean square, Mean diff-Mean difference					

Table-3- Comparison of mean attitude scores across different levels of students					
One-way analysis of variance					
P value	0.0002				
P value summary	***				
Are means signif. different? (P < 0.05)	Yes				
Number of groups	5				
F	5.82				
R squared	0.0668				
Bartlett's test for equal variances					
Bartlett's statistic (corrected)	3.54				
P value	0.4716				
P value summary	ns				
Do the variances differ signif. (P < 0.05)	No				
ANOVA Table	SS	df	MS		
Treatment (between columns)	70.8	4	17.7		
Residual (within columns)	990	325	3.04		
Total	1060	329			
Bonferroni's Multiple Comparison Test	Mean Diff.	t	Significant? P < 0.05?	Summary	95% CI of diff
Level 7 vs Level 8	1.12	3.62	Yes	**	0.245 to 1.99
Level 7 vs Level 9	-0.34	1.09	No	ns	-1.22 to 0.543
Level 7 vs Level 10	0.263	0.9	No	ns	-0.564 to 1.09
Level 7 vs In Training	-0.0117	0.0408	No	ns	-0.823 to 0.799
Level 8 vs Level 9	-1.46	4.43	Yes	***	-2.39 to -0.528
Level 8 vs Level 10	-0.856	2.75	No	ns	-1.74 to 0.0235
Level 8 vs In Training	-1.13	3.7	Yes	**	-2.00 to -0.267
Level 9 vs Level 10	0.604	1.92	No	ns	-0.285 to 1.49
Level 9 vs In Training	0.329	1.06	No	ns	-0.544 to 1.20
Level 10 vs In Training	-0.275	0.952	No	ns	-1.09 to 0.542
ANOVA-Analysis of Variance, ns-not significant, vs-versus, df-degrees of freedom, ss-sum of squares, MS- Mean square, Mean diff-Mean difference					

Table-4- Comparison of mean practice scores across different levels of students					
One-way analysis of variance					
P value	0.4108				
P value summary	ns				
Are means signif. different? (P < 0.05)	No				
Number of groups	5				
F	0.994				
R squared	0.0121				
Bartlett's test for equal variances					
Bartlett's statistic (corrected)	3.21				
P value	0.5233				
P value summary	ns				
Do the variances differ signif. (P < 0.05)	No				
ANOVA Table	SS	df	MS		
Treatment (between columns)	8.53	4	2.13		
Residual (within columns)	697	325	2.15		
Total	706	329			
Bonferroni's Multiple Comparison Test	Mean Diff.	t	Significant? P < 0.05?	Summary	95% CI of diff
Level 7 vs Level 8	-0.26	0.999	No	ns	-0.993 to 0.474
Level 7 vs Level 9	-0.0503	0.192	No	ns	-0.792 to 0.691
Level 7 vs Level 10	-0.442	1.8	No	ns	-1.14 to 0.252
Level 7 vs In Training	-0.145	0.604	No	ns	-0.826 to 0.535
Level 8 vs Level 9	0.209	0.756	No	ns	-0.573 to 0.992
Level 8 vs Level 10	-0.183	0.7	No	ns	-0.922 to 0.556
Level 8 vs In Training	0.114	0.444	No	ns	-0.611 to 0.839
Level 9 vs Level 10	-0.392	1.49	No	ns	-1.14 to 0.354
Level 9 vs In Training	-0.0952	0.367	No	ns	-0.828 to 0.638
Level 10 vs In Training	0.297	1.22	No	ns	-0.389 to 0.983
ANOVA-Analysis of Variance, ns-not significant, vs-versus, df-degrees of freedom, ss-sum of squares, MS- Mean square, Mean diff-Mean difference					

Supplementary Files

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- SupplementaryfileAppendixAyeshaIJCP.docx