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ORIGINAL ARTICLE

Pharmacovigilance and Adverse Drug Reactions (Adrs) Practice of Healthcare Professionals

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ABSTRACT

Aim: To assess pharmacovigilance and adverse drug reactions practice of healthcare professionals in Ribat University Hospital, Khartoum, Sudan.

Methods: This was a cross-sectional study to evaluate pharmacovigilance and ADRs practice among physicians, pharmacist and nurses working in the National Ribat University, Khartoum, Sudan. The sample size was calculated as 100. Data were collected by a pre-tested questionnaire after obtaining ethics approval. Data analysis was performed by SPSS software.

Results: The HCPs who acquired good and poor pharmacovigilance practice were 16 (16%) and 84 (84%) respectively. Ninety-eight (98%) of the healthcare professionals have ever experienced ADR in their patients during professional practice. Ninety-four (94%) have ever seen ADR reporting form. Forty (40%) have ever reported ADR to the pharmacovigilance center. Pharmacists, Physicians and nurses with good practice were30.8%, 18.4% and 7.9% respectively.

Conclusion: Most healthcare professionals acquire good pharmacovigilance practice. The pharmacist acquires higher level of pharmacovigilance practice followed by physicians and nurses. Healthcare professionals with shorter years of experience have significantly higher pharmacovigilance practice.

Keywords: Pharmacovigilance, Adverse Drug Reactions, Healthcare Professionals

INTRODUCTION

Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems [1]. An adverse drug reaction (ADR) is defined as "an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product; adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen, or withdrawal of the product" [2]. ADRs are leading reasons behind morbidity and mortality worldwide most of which passes unreported. Hence, proper monitoring of ADRs is a top priority for healthcare systems [3]. ADR reporting which is the foundation of pharmacovigilance and patient safety involves voluntary submission of patient-specific data on a suspected ADR, to a drug regulatory agency, following administration of at least one medicinal product [4,5].

The recent epidemiological studies have estimated that adverse drug reactions are the fourth to sixth leading causes of death.[3] Moreover, detection of ADRs has become increasingly significant because of introduction of a large number of potent toxic chemicals as drugs in the last decades. Thus, it became very crucial to monitor both known and unknown adverse effects of medicines.

It is estimated that ADRs are the sixth leading cause of death worldwide and represent the fourth leading cause of death in the United States and Canada [6]. In the developing countries ADRs incidence was found to be around 15.1% [7]. It has been reported that ADRs account for 5% of hospital admissions, and 10–20% of hospitalized patients experience the condition [8]. The incidence of serious ADRs among hospitalized patients is estimated as 6.7%, 33% of them occur in patients over 65 years of age [9]. The incidence of fatal ADRs is estimated as 0.32%[8]. In some occasions, ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications[10].

The growing evidence on the increased frequency and severity of ADRs, associated with a negative impact on patient's health status, also reveals that ADRs entail a significant burden on healthcare facilities, increasing the length of hospital stay, and requiring additional investigations and medicines [11,12]

It is well known that most healthcare professionals lack knowledge of pharmacovigilance and ADR reporting [13]. Low awareness and practice among health care professionals towards ADRs was reported in Sudan, may reflect lack of basic knowledge and lack of vigilance [14,15]. These findings reflect the urgent need to improve and innovate the current pharmacovigilance education and helps current healthcare professionals to meet pharmacovigilance responsibilities [16].

The objectives of the currents study were to assess pharmacovigilance and adverse drug reactions practice of healthcare professionals in Ribat University Hospital, Khartoum, Sudan.

MATERIAL AND METHODS

This was a cross-sectional and hospital-based study to evaluate Pharmacovigilance and ADRs practice and reporting. The study population were physicians, pharmacist and nurses working in the National Ribat University, Khartoum, Sudan. The sample size was calculated using the formula: $n=Z^2*p\ q/d^2$ (estimated proportion= 0.10, accepted error= 0.05, CI =9.90, Z=1.64). Sample size was 98, taken as 100.

Data were collected by a pre-tested questionnaire after obtaining ethics approvals from Sudan Federal Ministry of Health IRB. An informed consents was obtained from all participants. The content validity of the questionnaire was assessed based on relevance and representativeness. Content Validity Indices (CVIs) were calculated for each question, items with CVIs less than 0.8 were reframed and corrected. The questionnaire comprised of two sections. Section A composed of questions related to sociodemographic, classification and year of experience of the respondents. Section B composed of eight questions related to Pharmacovigilance and ADRs practice, Monitoring and Reporting. If the respondent scored four to eight correct answers were considered as having good practice and if scored below four correct answers were considered as having poor practice.

The analysis of data was performed by Statistical Package of Social Sciences (SPSS) software, version 24. Descriptive as well as inferential statistics were used. Comparison between qualitative variables was done by the person's Chi-square to test significance; p of less than 0.05 was considered as significant.

RESULTS

One hundred questionnaires were distributed to the healthcare and all of them responded. Females were 84 (84%). Physicians, nurses, and pharmacists were 49 (49%), 38 (38%) and 13 (13%) respectively. Forty-six (46%) respondents had less than two years of experience in their field, whereas 18 (18%) and 36 (36%) had 2-5 years and more than five years of experience respectively.

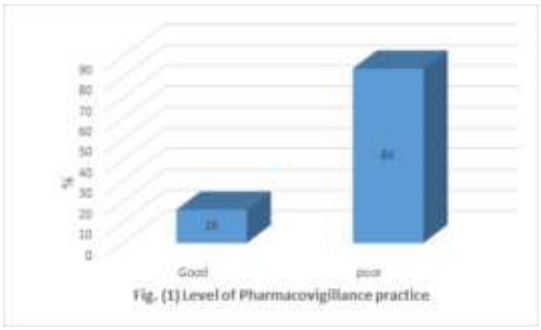

Fig. (1) Level of Pharmacovigilance practice

Fig (1) shows the average PV practice of HCPs. The respondents who acquired good practice were 16 (16%). Respondents who acquired poor practice were 84 (84%).

Table (1) shows Pharmacovigilance practice of the respondents. Ninety-eight (98%) of the healthcare professionals have ever experienced ADR in their patients during professional practice. Ninety-four (94%) have ever seen ADR reporting form. Forty (40%) have ever reported ADR to the pharmacovigilance center. Thirty-seven (37%) and 21 (21%) of the respondents read an article on ADR and ever been trained on how to report ADR respectively

Table 1: Pharmacovigilance practice of health care professionals

Practice	N (%)
Ever experienced ADR in your patients during professional practice	98 (98)
Ever seen ADR reporting form	94 (94)
Ever reported ADR to the pharmacovigilance center during professional practice	40 (40)
Read article on ADR	37 (37)
Ever been trained on how to report ADR	21 (21)

Table (2) shows the relation between PV practice and qualification/ years of experience. Nurses with good practice were 3 (07.9%) compared to 35 (92.1%) with poor practice. Physicians who had good practice were 09 (18.4%) compared to 40 (81.6%) with poor practice. Pharmacists with good practice were 04 (30.8%) compared to nine (69.2%) with poor practice. The relation between practice and qualification is significant (p = 0.0002).

Table (2) Relation between pharmacovigilance practice and qualification/years of experience

Qualification and experience	Q		Total No. (%)	p
	Good No. (%)	Poor No. (%)		
Qualification:				
Nurse	03 (07.9%)	35 (92.1%)	36 (100%)	
Physician	09 (18.4%)	40 (81.6%)	49 (100%)	0.0002
Pharmacist	04 (30.8%)	09 (69.2%)	13 (100%)	
Years of experience				
Less than 2	14 (30.4%)	32 (69.6%)	46 (100%)	
2-5	05 (27.8%)	13 (72.2%)	18 (100%)	0.02
More than 5	02 (05.6%)	34 (94.4%)	36 (100%)	

Healthcare professionals with less than 2 years of experience and had good practice were 14 (30.4%). Healthcare professionals with 2-5 years of experience and had good practice were five (27.8%) and those with more than 5 years of experience and had good practice were two (05.6 %). The relation between PV practice and years of experience is significant (p < 0.02)

DISCUSSION

The need for an adequate PV system that can be followed is recently recognized more, to assure the safe Patients medication use. The results showed that only 16% of the sample showed a good (satisfactory) pharmacovigilance practice compared to 84% who showed poor (unsatisfactory) level of practice. These results are consistent with other studies [17-19]. However, a study in Jordan found that the health care professionals' practice towards ADR reporting was good and showed positive trend towards ADR improving reporting and patients' safety [20].

Among the participants, 98% have ever experienced ADR in patients during professional practice. This is higher than the rate of 59.5% and 64.45 reported by other researchers elsewhere [21, 22]. Our results showed that only 40% of the HCPs reported ADR to the pharmacovigilance center during professional practice. This finding is less compared with other studies[18, 21]; however: Gupta SK et al reported that among HCPs in India only 22.8% have ever reported ADR to the health authorities. He stated that only 13.9% healthcare professional were aware that a serious adverse event should be reported to the regulatory authority within 14 calendar days[22].

According to our findings, 94% of the subjects have ever seen ADR reporting form. This is inconsistent with a study conducted by Gupta SK et al who found that only 58.4% of the participants have seen the ADR reporting form [22]. A study conducted in Saudi Arabia found that only 38.5 % of the respondents know about electronic reporting of ADR [18].

Our results showed that only 21% have ever been trained on how to report ADR. This finding is less than other study [18,22]. Lack of training may be one factor behind low reporting. In our study most healthcare professionals prefers lectures as a method of learning pharmacovigilance.

V. SRINIVASAN et al reported that the factors discouraging health care professionals from ADR were reporting non remuneration for reporting (13.9%), lack of time to report ADR (33.4%), a single unreported case may not affect ADR database (17.3%), difficult to decide whether ADR has occurred or not (35.2%) [17].

Our results showed that Pharmacist have a significant higher level of pharmacovigilance practice compared to physicians and nurses (30.8% vs 18.4% and 7.9%; p=0.0002). This is finding is consistent with a study conducted in India [15] A study conducted in Kuwait showed that physician have a higher level of PV practice compared to pharmacists (80.8 vs. 69.7%; p = 0.006) [17]. The current study showed that healthcare professionals with short years of experience (Less than 2) had the highest level of PV practice. Participants with experience of 2-5 years and more than five years had PV practice of 27.8% and 5.6% respectively.

CONCLUSION

Most healthcare professionals acquire good pharmacovigilance practice. The pharmacist acquires higher level of pharmacovigilance practice followed by physicians and nurses. Healthcare professionals with shorter years of experience have significantly higher pharmacovigilance practice.

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