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Does an educational intervention really help to create a positive impact on knowledge and awareness levels of pharmacovigilance – A Survey-Based Study

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ABSTRACT

Drugs though are beneficial, also tend to produce adverse drug reactions. Adverse drug reaction (ADR) is considered to be one of the major causes of hospitalization and patient incompliance. It also leads to significant morbidity and mortality. The main solution for this could be the timely and proper reporting of ADR, which is lagging (under reporting) in the current scenario. It can be improved by increasing the awareness and knowledge among the different stake holders by various methods including educational intervention. A survey-based study survey was conducted among public from non-pharmaceutical background, in which 269 persons participated. Pre-intervention questionnaire (PIQ) was given to the participants to fill after appropriate instructions. After completion of PIQ, an educational programme was conducted for duration of around 45 minutes. Then the participants were given a post-interventional questionnaire (PoIQ) and were asked to complete the same. The results of the study showed that there was an improvement in the awareness and knowledge of the participants regarding the pharmacovigilance. Also, the results of the study helped to find the preferable modes of reporting ADR and suggestions regarding the methods to create the awareness of reporting ADR from the participants who are future healthcare professionals. The results of the study concluded that the educational intervention definitely increased the awareness and knowledge of participants regarding pharmacovigilance.

Keywords: ADR reporting, Questionnaire.

1. INTRODUCTION

Medicines are known to have an appreciable improvement in control and treatment of disease. However, they are also known to cause adverse effects or adverse drug reactions (ADRs) [1,2]. One of the major problems associated with medicines are ADRs and they are the recognized hazards of drug therapy [3,4]. At the time when a new drug is marketed, the safety information pertaining to the product is usually limited. As clinical trials have a controlled inclusion and exclusion criteria, special population including patients with complicated medical conditions, receiving concomitant medications, paediatric and geriatric patients, pregnant and lactating females are excluded. Obviously, as and when only the drug is available in the market, it would be possible to capture the previously non-documented ADR and increase in the frequency of documented ADR [1,2]. These adverse drug reactions are associated with significant morbidity and mortality. Adverse drug reactions was reported to be the fourth major cause of death in USA [5-7]. Apart from this, ADRs, by imposing a considerable economic burden on the society and the already-stretched healthcare systems it creates a major impact on public health [8,9]. It has been demonstrated by the studies that the ADRs leads to 6.7% of patient hospitalization and the percentage of fatal side effects being 0.3% of all hospitalized patients. It is estimated that only 6 - 10% of all ADRs are reported. Underreporting is of great concern not only in India, but also globally [9,10]. India has a diversified patient population and hence has a huge potential of creating a viable database. But due to the lack of lack of awareness among healthcare professionals and students, underreporting of ADRs prevail in India. Also, the common man who actually experiences ADR also lack awareness about ADR and its reporting. In

order to assess the current situation and to find whether educational intervention can really help in creating awareness about pharmacovigilance in common man, this survey-based study was planned.

2. MATERIALS AND METHODS

This was a survey based study conducted among common public. The study group included public from non-pharmaceutical background. The objective and the need of the study was explained and necessary consent was obtained. The questionnaires were self-developed, semi-structured consisting of both open- and close-ended items. The following information was obtained: awareness and knowledge of ADR and suggestions on desirable mode and possible ways to improve ADR reporting. Appropriate instructions to fill the questionnaires were given at respective time. Identity of the participants was not revealed. In total, there were 269 participants in the study. The PIQ consisted of 10 questions. Initially PIQ was briefed to all participants. The PIQ survey questionnaire was analyzed, question wise and their percentage value was calculated. An interactive educational intervention for about 45 minutes was designed separately for all participants of PIQ survey in order to educate them about medicines, adverse drug reactions and its impacts. The educational intervention programme covered the basics of drugs, its benefits, side effects and the significance of reporting side effects. During this session the participants were also encouraged to report all suspected ADRs, including those that were mild or anticipated. After the educational intervention, all the participants of PIQ were provided a PoIQ consisting of 12 questions. Two additional questions were related to the desirable mode to report ADR and suggestions to improve ADR reporting. The PoIQ was analyzed, question wise and their percentage value was calculated. Data were expressed as counts and percentages.

3. RESULTS AND DISCUSSION:

As per our knowledge attained from the literature search through Pubmed, this is the first study to be conducted in public who are from non-pharmaceutical background to discuss how the educational intervention helps to increase the awareness and knowledge of pharmacovigilance as well as to obtain the desirable modes of reporting ADR and suggestions to increase the awareness of reporting ADR. Two hundred and sixty nine PIQ and PoIQ were circulated to the participants and the response was received.

A total of 269 participants were enrolled and analysed in the study out of which 183 (68.03%) respondents were male and 86 (31.69%) were female (Table 1).

Table - 1 : Gender distribution of participants (N = 269)

Gender	Male	Female
Frequency (%)	183 (68.03%)	86 (31.97%)

Question 1 was about what is a side effect. Response rates for Question 1 differ between PIQ and PoIQ i.e. after educational intervention (Table 2), 30.48% and 69.14% respectively. Question 2 sought the information regarding do drugs cause side effect. Response rate improved from 31.60% in PIQ to 65.43% in PoIQ (Table 2). Question 3

Table - 2: Response to both pre-intervejntion questionnaire (PIQ) and post-intervention questionnaire (PoIQ) (N = 269)

Q. No.	PIQ		PoIQ	
	Correct response	False response	Correct response	False response
	Number of respondents (%)	Number of respondents (%)	Number of respondents (%)	Number of respondents (%)
01	82 (30.48%)	187 (69.52%)	186 (69.14%)	83 (30.86%)
02	85 (31.60%)	184 (68.40%)	176 (65.43%)	93 (34.57%)
03	82 (30.48%)	187 (69.52%)	181 (67.29%)	88 (32.71%)
04	93 (34.57%)	176 (65.43%)	174 (64.68%)	95 (35.32%)
05	4 (1.49%)	265 (98.51%)	4 (1.49%)	265 (98.51%)
06	76 (28.25%)	193 (71.75%)	171 (63.57%)	98 (36.43%)
07	74 (27.51%)	195 (72.49%)	163 (60.59%)	106 (39.41%)
08	86 (31.97%)	183 (68.03%)	167 (62.08%)	102 (37.92%)
09	87 (32.34%)	182 (67.66%)	171 (63.57%)	98 (36.43%)
10	90 (33.46%)	179 (66.54%)	172 (63.94%)	97 (36.06%)

dealt with the basic awareness of what will you do if you get a side effect. The response rate in PIQ was 30.48% whereas in PoIQ, it was 67.29% (Table 2). Question 4 was to test the opinion about side effects among the participants. In the PIQ, 34.57% of participants chose the right option and in PoIQ, 64.68% of participants chose the right option. Question 5 investigated have you ever reported any side effect. The correct response was given by 1.49% of participants in both PIQ and POIQ (Table 2). Question 6 sought information about do we have any centre for reporting side effects. Significant rise in the correct response was found i.e., the percentage of correct response of the participants rose significantly from 28.25% to 63.57% (Table 2). In case of Question 7, which sought information that has anyone insisted you about the importance of reporting side effects, the correct response significantly rose from 27.51% in PIQ to 60.59% in PoIQ (Table 2). Question 8 tested the knowledge of the participants whether do you really think it is important to report side effects. 31.97% provided correct response in PIQ, whereas in PoIQ 62.08% 0f participants provided the correct response (Table 2). Question 9 investigated the participant's knowledge on does reporting side effects have any positive impact. Response in PIQ was 32.34% whereas in PoIQ it was 63.57% (Table 2). Question 10 investigated the awareness of what response would you expect from the Government with these reports. The participant's response was 33.46% in PIQ and 63.94% in PoIQ (Table 2).

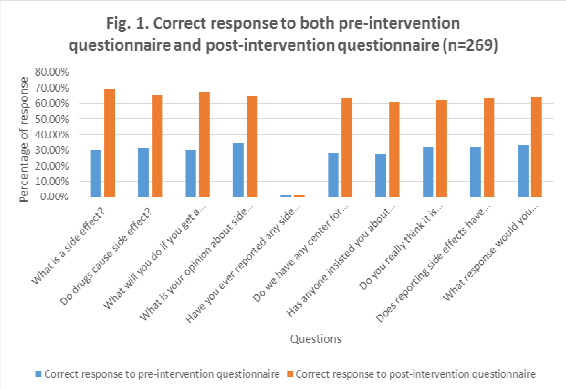


Table - 3: Response to preferred modes of reporting adverse drug reaction (N = 269)

Preferred modes of reporting adverse reaction	Number (%)
In person to doctor/pharmacist	153 (56.88%)
Dialling a toll free number	79 (29.37%)
SMS or E-mail	37 (13.75%)

Question 17 and Question 18 were given only in PoIQ. Question 17 was designed to capture the preferred mode by participants for reporting ADRs. 56.88% of participants preferred to report in person to doctor/pharmacist, 29.37% preferred to report by dialling a toll free number and 13.75% preferred to report by SMS or e-mail (Table 3 and Fig. 2).

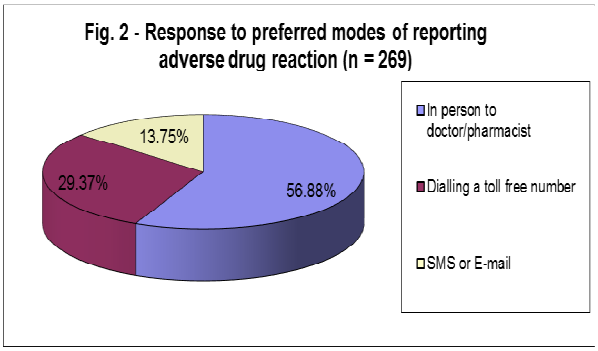
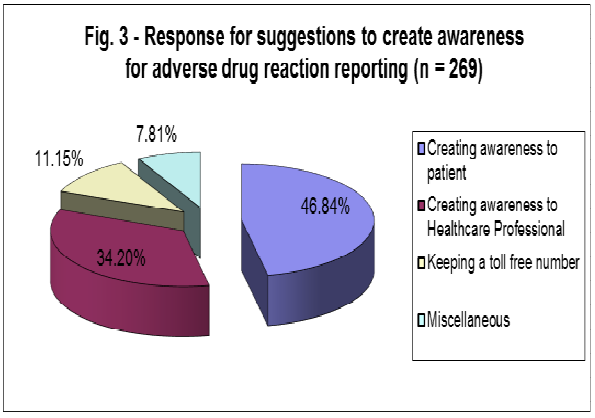


Table - 4: Response for suggestions to create awareness for adverse drug reaction reporting (n = 269)

Suggestions to create awareness for ADR reporting	Number (%)
Creating awareness to patient	126 (46.84%)
Creating awareness to Healthcare Professional	92 (34.20%)
Keeping a toll free number	30 (11.15%)
Miscellaneous	21 (7.81%)



Question 18 was designed to get suggestions from the participants regarding the methods to create the awareness of reporting adverse drug reaction. 46.84% of participants suggested that creating awareness among patients, 34.20% suggested creating awareness among healthcare professionals, 11.15% suggested keeping a toll free number for reporting ADR and 7.81% had other miscellaneous suggestions including discussing the side effect of the drug with medical professionals, not using medicine without prescription, getting feed back from patients, by conducting debates (Table 4 and Fig 3).

4. CONCLUSION

In conclusion, the survey results proved that an educational intervention had created a positive impact on awareness and knowledge of pharmacovigilance among the participants (common people). This study also demonstrated that creating awareness through educational intervention would help the common man to understand about the drugs, side effects and importance of reporting side effects. The preferable modes of reporting the ADR and the suggestions provided to increase the awareness for reporting ADR by the participants themselves is a value addition for the study. The study may be extended with more number of samples from different regions and different stake holders. Further study can be conducted in other population in different states.

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