ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH

INNOVARE ACADEMIC SCIENCES
Knowledge to Innovation

Vol 7, Issue 3, 2014

ISSN - 0974-2441

Original Article

IMPACT OF SERIES OF INTERVENTIONS ON CLINICIANS' AWARENESS ABOUT PHARMACOVIGILANCE SYSTEM IN WESTERN INDIA

SANGHAVI DHARA R*, DHANDE PRITI P, KARANDIKAR YOGITA S, SAHASRABUDHE RANJANA A, PANDIT VIJAYA A

Department of Pharmacology, Bharati Vidyapeeth Deemed University Medical College, Pune, Maharashtra, India
E-mail address: dr_dharasanghavi@yahoo.com

Received: 3 March 2014, Revised and Accepted: 2 April 2014

ABSTRACT

Objective: In order to improve the participation of health professionals in spontaneous reporting, it is necessary to design strategies that modify their knowledge, attitude and practices (KAP) about pharmacovigilance.

Methods: Initially KAP about pharmacovigilance among consultants and residents was assessed using a pre-tested questionnaire and interventions carried out according to the need. Starting with an informative lecture with voluntary participation, we extended it to various interventions like targeting specific groups of participants, displaying posters, distributing brochures, one to group communication, sending reminders as emails and also educating patients by putting up charts. Post intervention KAP was measured by re-circulating the questionnaire. Influence of interventions on KAP of pharmacovigilance was analyzed using Chi-square test.

Results: Pre-Intervention knowledge regarding pharmacovigilance was very low; particularly in residents than consultants ($p<0.001$).Though majority (98%) of the participants knew they could report ADRs, none of them had ever reported because of unawareness of reporting system. 96.4% participants wished to be trained for ADR reporting. Interventions significantly improved knowledge about ADR reporting system among them ($p<0.0001$). 34% Participants reported ADRs to the cell after getting sensitized by interventions ($p<0.0001$).

Conclusion: Overall effect of all the interventions was positive and successful in building up an ADR reporting system at the study site. Constant reminders to the doctors are needed for pharmacovigilance culture to persist and flourish in clinical settings.

Keywords: Pharmacovigilance, Clinicians, Awareness, Interventions, Influence

INTRODUCTION

While medicines have led to major improvement in treatment & control of disease, they also produce adverse effects on human body time to time. When a new drug is licensed, drug safety information tends to be limited. Study populations often exclude patients with complicated medical conditions, those receiving concurrent drug therapy, young persons, elderly persons, pregnant and lactating females. Hence, after a drug is marketed, previously unidentified adverse drug reactions (ADRs) may occur. Post marketing surveillance is important for the identification of unseen ADRs and should be an inevitable part of clinical practice [1].

Numerous studies have demonstrated that the incidence of ADRs leading to patient hospitalization is 6.7%, the percentage of fatal side effects being 0.3% of all hospitalized patients [2]. Thus, adverse drug reactions represent a serious issue of the drug therapy, a major concern of the public health system and an economic burden. It is estimated that only 6–10% of all ADRs are reported. This high rate of under-reporting can delay signal detection and consequently impart negatively on the public health [3].

In order to identify the culprit drugs causing ADRs, several countries have initiated pharmacovigilance programs in the recent past. Because of the variation in drug response among individuals, prescribing habits, drug regulatory system, availability of drugs etc, it has been recommended for every country to set up their own pharmacovigilance programs [4]. In India ADR monitoring centers (AMCs) are being set up across the country under Pharmacovigilance Program of India (PvPI) re-initiated in 2010.This whole program is under the Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Government of India[5].

As per PVPI, a Pharmacovigilance center / cell is mandatory in every teaching hospital. In the study institute, there was no cell/center working for ADR reporting. There was no culture in clinicians to report any ADR which they come across in their practice. Before applying to the National Coordination Centre-PVPI [Pharmacovigilance program of India] for setting up a center in this institute, we thought of assessing the awareness about this important issue in consultants and residents of the clinical departments and to carry out interventions.

MATERIALS AND METHODS

The study was started after getting approval from Institutional Ethics Committee (BVDU/MC/37/2011). This was an interventional, prospective study conducted among 250 doctors including consultants and residents of a tertiary care teaching hospital in Pune, where there was no ADR reporting cell/centre. The study was carried out from September 2011 to August 2013 and was based on Knowledge, attitude and practice (KAP) questionnaire as a research tool.

Prior to this study, KAP survey questionnaire was pretested and evaluated for its content validity using a method developed by Lynn M [6]. To test the content validity experts selected were clinicians and pharmacologists who were aware of ADR reporting and monitoring system in India and the ADR monitoring culture at the institute. They were provided with a copy of the KAP survey questionnaire and the rationale and objectives of the study. Few changes in the order and phrasing of the questions were made after discussion. The final KAP questionnaire consisted of demographics of the doctors and 17 questions out of which– 6 about knowledge, 6 about attitude and 5 about practice were designed specifically to answer the awareness about pharmacovigilance. The questionnaire

was designed in such a way that the answers were not mutually exclusive. Participants were allowed to give more than one answer.

Questionnaire was circulated to consultants and resident doctors of the tertiary care teaching hospital before and after all interventions. Before filling up the questionnaire, the objectives of the study and the contents of the questionnaire were personally briefed to each participant. They were given sufficient time of 20 minutes to fill in the questionnaire in the presence of the investigator.

The analysis of Pre-KAP survey questionnaire depicted an urgent need to sensitize the clinicians who shared the major responsibility in this pharmacovigilance system. Hence different forms of interventions were planned accordingly.

To start with, an educational intervention in the form of a lecture by an expert having work experience in the field of pharmacovigilance was planned for all participants. Head of the departments were informed to encourage doctors of their respective departments to attend the session and to adjust the clinical duties accordingly so that we have maximum participants. The lecture lasted for 45 minutes and consisted of the definition of pharmacovigilance, examples of drugs that have been banned due to fatal ADRs, classification of ADRs (i.e. in terms of causality assessment, seriousness and severity), ADR reporting systems from various countries, WHO online database for reporting adverse drug reactions, pharmacovigilance program (PVPI) by government of India, CDSCO, as well as how to report a suspected adverse drug reaction followed by an economic and epidemiological importance of reporting the ADRs and its effect on patient safety. During the lecture it was emphasized that only 5 minutes will be required to fill in the ADR reporting form. As the participation in this session was voluntary, only 80 participants consisting 50 residents and 30 consultants attended the lecture.

Looking at this poor response in the first intervention, we planned to divide the participants in groups for further interventions. The first group selected was of junior residents of clinical departments who had to mandatorily attend a Research Methodology workshop in their first year of residency. One session in this workshop was on Pharmacovigilance which covered the basic concepts of pharmacovigilance and need for the involvement of residents in this activity was stressed on.

Then the next target group was planned as the departmental heads, one senior staff member and 2 senior residents of all the clinical departments who were given hands on training on how to document ADRs apart from the basic concept revision of pharmacovigilance. An imminent personality working for the same cause of developing an efficient Pharmacovigilance system in our country, who was a pharmacologist by profession, was invited to cover this session. The practical part of this intervention included practical examples of ADR cases, training how to document these ADRs in the ADR reporting forms and causality assessment of ADRs.

The next step we considered was putting up simple posters in all the OPDs, wards, Intensive care unit and operation theatre complex which highlighted the message to report ADRs. To aid them in doing so with least investment of their time, we provided ADR forms and contact numbers of staff & residents from our department to get the form filled and collect the ADR report.

There could have been a chance of missing some participants during above interventions for whatsoever reason. So finally we planned one to group interaction in post graduate seminars/clinics in all the departments where all their residents and consultants were supposed to be present. It was a 10 minutes brush up talk regarding how pharmacovigilance is important, how to document ADRs in the ADR reporting form, what type of ADRs should be reported, what happens to their reported ADRs and again reminding them to just give a call whenever they face ADRs of prescribed drugs. Already reported ADRs from respective departments were communicated to all. This was followed by circulation of brochures to each and every participant for acknowledging them for whatever ADR reports they have sent until then and depicted a graph showing number of ADRs received from each department.

Lastly to make sure that not a single participant is missed from any intervention and to remind those who already have undergone different form of interventions, we emailed them a encouraging and informative message which included the basics of pharmacovigilance, type of ADRs to be reported, fate of their reported ADRs and a reminder to report ADRs along with an ADR form for the reference.

We also made a patient information chart in local language conveying a message to the patients that they should inform their treating doctor if they faced any side effect after taking medicines. We illustrated pictorial examples of side effects with common drugs for the better understanding of patients considering them an important population in the development of a pharmacovigilance environment. Such charts were displayed at the Hospital entrance and near the admission form counter to have maximum chances of being noticed by the patients or their relatives.

RESULTS

250 doctors from various medical and surgical branches, of which 100 were consultants and 150 were resident doctors, participated in the study.

Pre-intervention analysis

An attempt was made to quantify the knowledge of the respondents. It was calculated by assessing the responses to certain questions regarding knowledge of ADRs and its reporting. One point was given for each correct option and maximum score was 17. Using this scoring system, it was observed that the overall mean score of the knowledge of participants was 5.3(±2.6) of which consultants and post graduate students scored 6.9(±2.4) and 4.4(±2.3) respectively. Consultants had statistically significant more knowledge regarding ADRs and ADR reporting system than residents (t=8.5, p=0.001)

A total of 214 respondents out of 250 (85.6%) stated that they have encountered ADRs in their practice of consultants (94%) had experienced significantly more ADRs in their practice than residents (80%) (p=0.001). The common drug groups mentioned to cause ADRs were antimicrobials (45.7%), analgesics (25.7%), iron sucrose (7.1%), anti-tubercular drugs (5.7%) and antiepileptics (4.3%).The common ADRs observed were cutaneous (35.7%) (rashes, urticaria, SJ syndrome) followed by gastrointestinal adverse effects (27.7%) (nausea, vomiting, gastritis, diarrhea) and fever with chills (10%).

Majority (98%) of the participants were aware that doctors are qualified to report ADRs. Other professionals who could report ADRs were chosen as nurses (44 %), dentists (41.2 %), pharmacists (36.8%), health workers (20. 8%) and physiotherapists (8 %). Interestingly about 32.5 % of the respondents opined that patients should also be allowed to report ADRs.

Table 1: Participant's knowledge regarding drugs banned due to ADRs

Level of knowledge	Consultants	Residents	
	Frequency (%)	Frequency (%)	Chi^2 value (df) =18.7(2) p=0.0001
No knowledge	19(19)	45(30)	
Partial knowledge	38(38)	78(52)	
Correct knowledge	43(43)	27(18)	
Total	100	150	

No knowledge: *No drugs mentioned that has been banned*
Partial knowledge: *Drug has been mentioned but no ADR mentioned or incorrect ADR mentioned for its banning*
Correct knowledge: *Banned Drug with the correct ADR mentioned. for which it is banned*

Table 1: depicts that the correct knowledge regarding banned drugs was significantly higher in consultants as compared to residential doctors (p=0.0001). Residents either had incomplete or lack of knowledge of this aspect which was statistically significant.

52% participants have mentioned that their patients don't complain about any side effects caused by prescribed drugs. Among these, 56.7% were resident doctors and this result is statistically significant as consultants were more frequently informed about ADRs by their patients (p=0.048). Majority consultants (94%) enquired about ADRs to their prescribed drugs in their patients which is significantly higher than resident doctors (77%) (p=0.044).

Table 2: Participant's knowledge about ADR reporting authority

To whom ADRs should be reported	Consultants Frequency (%)	Residents Frequency (%)	Total Frequency (%)
Head of the department	27(27)	60(40)	87(34.8)
World Health Organization	3(3)	10(6.7)	13(5.2)
Government	27(27)	23(15.3)	50(20.0)
Drug manufacture	37(37)	32(21.3)	69(27.6)
FDA	41(41)	27(18)	68(27.2)
Don't know	37(37)	71(47.3)	108(43.2)

It is depicted from the Table 2 that a large number of participants (108) didn't know where ADRs should be reported. Most of the consultants considered FDA (41%) and drug manufacturers (37%) as reporting authorities while majority of the residents reported ADRs to their department heads only (40%). Very few participants knew about WHO as reporting authority (5.2%).Only 15% of participants including residents and doctors were aware of pharmacovigilance program by CDSCO, Government of India.

When enquired about the way of reporting, 53% consultants and 44.7% did not know how to report ADR while 45.4% residents considered reporting verbally to their departmental heads. Only 19% consultants and 10% residents knew about filling up a form for reporting ADRs in our country. Some of the participants (16% consultants and 18.7% residents) even mentioned about website for reporting ADRs. But majority of them (98% consultants and 100% residents) had never reported ADR to any regulatory authorities or ADR monitoring centre.

Table 3: Respondent's attitude towards type of ADRs to be reported

ADRs which participants were encouraged to report	Consultants Frequency (%)	Residents Frequency (%)	Total Frequency (%)
All ADRs	62(62)	17(11.3)	79(31.6)
Serious ADRs	33(33)	121(80.7)	154(61.6)
ADR to new drugs	21(21)	108(72)	129(51.6)
Unknown ADRs	17(17)	24(16)	41(16.4)
ADR to non-allopathic drugs	18(18)	21(14)	39(15.6)
ADR to vaccine	19(19)	35(23.3)	54(21.6)

Table 3 shows that the residents were encouraged to report if ADRs were serious (80.7%) and due to new drugs (72%). They (11.3%) were significantly resistant to report all types of ADRs in comparison to consultants (62%).[Chi^2(df)=71.2(1), p=0.0001)]

While 92% consultants felt that ADR reporting should be made mandatory, significant number of residents (72.7%) didn't believe in making it a compulsion (Chi^2 (df) =100.8(1), p=0.0001.

Table 4: Reasons for under-reporting of ADRs among participants

Factors that may discourage to report an ADR	Percentage (%)
ADR reporting is time consuming	37.6
No influence on treatment scheme	15.6
Busy schedule	*38.4*
Lack of incentives	24.4
Legal liability issues	34.4
Difficult to pin point suspected drug	*46.4*
Already known to prescriber	22.8
Don't know where to report	*58.8*
Insufficient clinical knowledge	28.8
One report doesn't make any difference	25.2

Table 4 reveals that 58.8% respondents accepted the fact of not knowing where to report as the major reason for their under-reporting of ADRs. Other reasons considered by respondents were difficult to pin-point suspected drug and lack of time because of their busy schedule. One of the surprising results was that participants (28.8%) themselves confessed about their insufficient clinical knowledge as a hurdle to recognize ADRs to report. The major reasons for underreporting of ADRs were similar in both the participant groups (Figure 1).

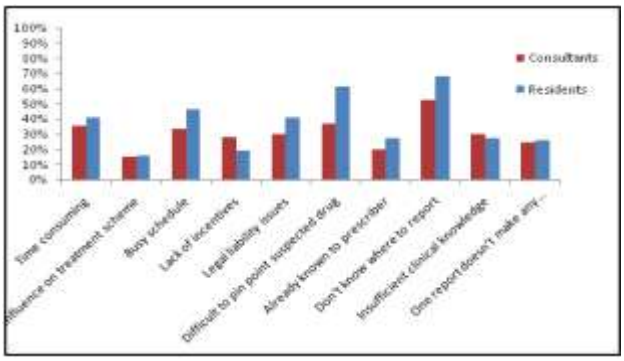

Fig 1: Reasons for under-reporting among consultants and residents

Post intervention analysis*:*

Using the scoring system to quantify knowledge of the participants, it was observed that the overall mean score of their knowledge increased significantly to score 13.8(±1.5) from 5.4(±2.6) after the interventions (t=42.9, p=0.000).Post intervention consultants and post graduate students scored 14.2(± 1.2)and 13.5(± 1.6) respectively for knowledge questions.

After undergoing various interventions, > 90% participants were now aware that all the healthcare professionals (doctors, nurses, pharmacists, dentists, physiotherapists and health workers) are eligible to report ADRs to the Pharmacovigilance centre. Respondents still expect that even the patients should be allowed to report ADRs.

Now 179 (71.6%) participants could write about banned drugs with the correct reason showing significant increase in knowledge of banned drugs causing fatal ADRs (p=0.000). 88.8% of the participants now knew to report ADRs at the ADR reporting cell of the institute using ADR reporting form. But 77% of residents still opted for head of the department for reporting ADRs.

78.8% participants agreed to report all types of ADRs which is statistically significant after intervention (Chi^2(df)=20.4(1);p=0.0001). 86 participants have even reported ADRs to the cell, which is also statistically significant (Chi^2(df)=95.3

(1);p=0.0001). 35(35%) consultant doctors and 51(34%) residents have equally contributed in this reporting.

Table 5: Effect of intervention on knowledge about Pharmacovigilance system in participant doctors

	Consultants			Residents		
	Pre (%)	Post (%)	Chi²(df)	Pre (%)	Post (%)	Chi²(df)
Familiar with ADR reporting form	19	99	132.2(1) P<0.001	10	97.33	226.3(1) P<0.001
Knowing any ADR reporting centre	22	98	120.3(1) P<0.001	3.33	98	268.9(1) P<0.001
Aware of PVPI of CDSCO	18	98	131.3(1) P<0.001	2.66	85.33	208.0(1) P<0.001

*PVPI- Pharmacovigilance Program of IndiaCDSCO-Central Drug Standard Control Organization *p<0.001 on comparison with pre-interventional values*

Above table 5 and figure 2 show that the interventions significantly increased participants' knowledge about the ADR reporting form, other ADR reporting systems and specifically the pharmacovigilance program of India (PVPI of CDSCO) (p<0.001).

Significant effect of interventions was also seen on the number of patients complaining about ADRs of drugs (prescribed to them) to their treating doctors. Before interventions, >50% of the consultants had mentioned that their patients were not complaining about any ADRs to drugs prescribed, but post-intervention upto 60% of them agree that patients have started complaining about ADRs. This observation is statistical significant [Chi²(df)=14.5(4); p=0.046]. This scenario was different with the residents where > 50% still mentioned that patients did not complain about any ADR to them.

As an effect of various interventions, >80% of the participating doctors have now themselves also started enquiring about ADRs to prescribed drugs with their patients which is statistically significant. [Chi²(df)=86.4(9); p=0.0001]

Table 6: Plan of various interventions in the study and ADR reports in response to them

Sr No	Intervention	Duration in which ADRs were collected	ADRs collected during this period
1	Lecture	6 months	10
2	Hands on training	3 months	20
3	Charts in OPDs as reminder and circulating brochures	3 months	20
4	***Interactive sessions in post graduate teaching programs***	***15 days***	***10***
5	Sending Emails	2 months	5
TOTAL		**14.5 months**	**65**

Table 6 shows that a total of 65 ADR reports were submitted during the period from first intervention to getting post-questionnaire filled up (14 months). The most effective of all the interventions, according to number of ADR reports submitted, came out to be the interactive sessions with residents and consultants in departmental seminars. 10 ADRs were reported only within a span of 15 days which was a great achievement in itself. In the initial study days after the first intervention, it had taken duration of 6 months to gather 10 ADR reports from the same study population.

DISCUSSION

Pharmacovigilance program of India (PVPI) was launched in 2004 and re-initiated in 2010 under government of India, CSDSCO in which now any medical college can be an peripheral ADR monitoring centre and directly can send ADR reports to National Co-ordinating Centre (NCC), Ghaziabad working under CDSCO, Government of India. To make the institute a peripheral ADR monitoring centre; awareness about pharmacovigilance was to be checked and further work up needed to be done with the prescribing doctors working in the institute. So this questionnaire based knowledge, attitude and practice (KAP) interventional study was planned in a tertiary care teaching institute where ADR monitoring centre was yet to be established.

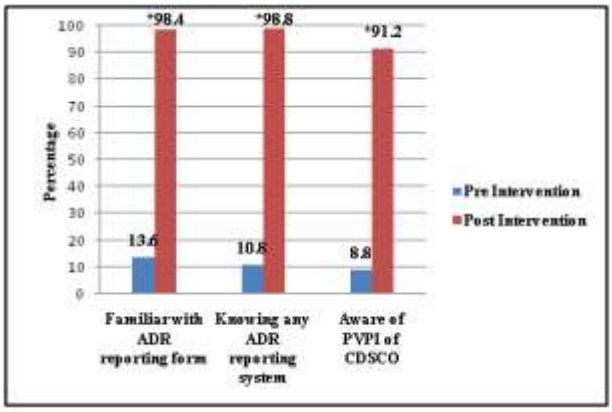

Fig.2: Effect of intervention on knowledge about pharmacovigilance system of our country in participant doctors

Pre Intervention

This study showed that inspite of having the right attitude for ADR reporting, our participants were lacking in adequate knowledge and the actual practice of ADR reporting before intervention. These results were similar to studies done by Bhatia A et al (Delhi)[7],Gupta P et al(Mumbai)[8] and Ghosh S et al (Muzzafarnagar)[9] in India. In contrast to this an Indian study by Ramesh M (Mysore)[10] has shown high knowledge, but poor practice of pharmacovigilance among their participants.

The average knowledge score of the respondents was 31% indicating that there was still much to be done to educate prescribers regarding ADR reporting.[Consultants 40.9% and Residents 25%,p<0.001].Majority respondents(98%) knew that as doctors they were eligible to report ADRs. Spontaneous ADR reporting by other professionals is also being recommended by national pharmacovigilance program [11] and spontaneous reporting by patients and other health care personnel, other than doctors, is practiced in many parts of world [12-14]. This awareness that even a nurse, pharmacist, physiotherapist, healthcare worker can report was very low among our study participants [Figure 1]. Similar results were obtained in other studies done in India at Mumbai [7], Indore[15] and Ahmedabad[16]. Active involvement of the paramedical staff in spontaneous reporting of ADR will go a long way in improving the reporting rates, since they are in closer contact with the patients for a longer duration than the doctors.

Major participants confessed that they have encountered ADRs in their practice which was a positive reflection on the skills and awareness about ADRs among practitioners. Consultants had encountered significantly more ADRs than residents (p<0.001) which might be due to their long tenure of clinical practice and experience with large number of patients. A parallel result which reflected the influence of this aspect in their practice was that majority consultants bothered to ask about ADRs in more than 30% of their patients. But resident's proportion was less in this aspect, possibly due to unnoticed ADRs. These results were found similar in the studies done by Ramesh M et al (Mysore)[10] and Kamtane R et al (Hyderabad)[17]. Unless the clinicians are trained to have a high index of suspicion, it is difficult to consider ADR as a part of differential diagnosis.

More alarming, however, was the result that inspite of knowing they should report ADRs encountered in their practice, they had not

reported ADRs to any authority or national ADR monitoring centre till date. This was similar to the result obtained in studies done at China[18] and Nigeria[19]. In studies done at Mysore[10] and Netherlands[20] more than 50% participants had reported an ADR at least once.

The lack of practice of pharmacovigilance among these participants was because many of them didn't know where and how the ADRs should be reported. This result was found to be similar to a study done at Ahmedabad [16].We were surprised to find that only 5% participants knew about World Health Organization (WHO) as authority to report ADRs. Very few participants were aware of pharmacovigilance program by CDSCO, Government of India and any national ADR reporting system. This was comparable in Indian studies done by Kamtane R et al [17] and Bharatan B et al [21]. Only in studies conducted at Mysore [10] and Nepal [22], their participants had adequate knowledge about ADR reporting centre.

Many participants (52%), of which most of them were residents, said that their patients do not communicate about ADRs in follow-up visits. This reflects the reluctance of the patients in having a good communication with trainee doctors. Atleast a ray of hope was given by the consultants when they said that upto 30% of their patients complained about ADRs to them. This result was better than that of the study conducted at Hyderabad where only 10-20% of the patients complained about ADRs to their treating doctors. Another interesting fact was that participants opined that patients should be allowed to officially report ADRs to the reporting authorities and participate in the pharmacovigilance program actively. This would be similar to the yellow card system which is already present in many countries like UK [23], Nigeria [19] and Europe[24]. It can be another way to increase the reporting of ADRs through the promotion of patient self-reporting. The benefits of this idea have been confirmed in different studies [25,26].

The reasons for under-reporting of ADRs have been summarized by Inman as the "seven deadly sins"[27]. In our study the major reason observed was ignorance about the reporting system, which was also seen in the studies conducted at Mumbai [10] and Ahmedabad [16]. Ignorance was more evident in the residents as compared to the consultants. This suggests that an intervention to generate awareness on how to report ADRs was necessary for this group of respondents. The lack of incentives and legal liability after ADR reporting were not major hurdles in our study set-up, unlike the study conducted by Praveen S et al[28]. An interesting observation was that 28% of the respondents confessed that their insufficient clinical knowledge makes it hard to decide whether ADR has occurred or not. These observations were similar to a study done in a teaching hospital in Spain, where the potential obstacles to spontaneous reporting of ADRs were identified to be difficulty in diagnosis of ADRs, lack of knowledge regarding the ADR reporting system, clinical workload on the doctors, a concern for patient confidentiality, and possible legal implications of reporting [29]

Majority of the consultants (92%) agreed in making ADR reporting compulsory which was found similar to studies done by Bhatia A et al [7], Kamtane R et al [17] and Rehan HS et al [30]. But resident doctors opined negatively on this aspect which was found analogous to studies done by Gupta P et al [10] and Bateman et al [31]. To inculcate pharmacovigilance in their practice almost all the participants suggested that they should be trained for documenting ADRs. Parallel results were found in studies done at Udaipur [32] and Nagpur [33] showing attitude of participants was quite positive and their attitude towards the good clinical practice was very much appreciable.

An Indian study done by Rehan et al in 2002[30] reported that KAP about ADRs of the medical students and prescribers at LHMC, New Delhi, India was inadequate and needed further improvement. Subsequently in a span of 8 years, their next study [34] showed some improvement in their KAP by executing several forms of intervention on pharmacovigilance. Successful effect of intervention(s) has been addressed in other studies as well [35-40].

Immediately after the first interventional lecture, we started receiving ADR reports from various departments. This was a good start of building up an environment of pharmacovigilance in the institute. However, number of reports received was not satisfactory. As time constraint was a limiting factor for ADR reporting opted by the participants in pre intervention analysis, we supplied a stock of ADR reporting forms to every ward and outpatient departments. Contact numbers for assistance in the procedure were also provided along with the forms. This increased convenience of ADR reporting. Several studies have shown that not only improving knowledge and awareness of ADR reporting but also the convenient ADR reporting system increases reporting rates [41-43]

Along with providing knowledge, we also worked on to publicize the ADR reporting cell, working at the institute and give constant reminders to the participants for reporting ADRs. This was done by circulating brochures, putting up posters and sending e-mails, these acted as both facilitators and reminders. Several Indian studies [3,24] have suggested these methods of interventions from the feedback they received. We also acknowledged the participants for the ADRs already reported from their individual departments which were considered a better mean to encourage them for further reporting.

The intervention of interactive session in postgraduate seminars of clinical departments received best response from the participants in the form of maximum number of ADR reports in the shortest time interval. This is depicted in the table 6 which shows continuity in ADR reports submitted to the ADR cell of the institution after each intervention. In this study, personal communication with the residents and consultants of individual departments proved to be the most effective means of intervention amongst all.

Post Intervention

This is the first Indian study assessing the effect of interventions on KAP of pharmacovigilance among doctors through ADR reports and post interventional questionnaire analysis; at a hospital with no existing ADR reporting system. Lack of evaluation of the effect of intervention through questionnaire was one of the limitations in the study done by Tabali et al [44].

This study demonstrated that an educational intervention could increase the physicians' awareness on ADRs. The awareness of pharmacovigilance must have lead them to better patient communication as patients were encouraged to report any adverse reaction(s) to prescribed drug(s). This change was found statistically significant when doctors started enquiring about ADRs in more number of patients. Also patients were found to be responsive in informing about ADRs in follow-up ($p<0.001$).

Majority participants became aware of pharmacovigilance program run by government of India and knew that by reporting an ADR to a reporting centre they could be a part of it. Participants also got acquainted with information on various systems of ADR reporting other than that in India. The knowledge regarding banned drugs was significantly increased ($p<0.001$) among the participants. Our intervention might have sensitized the participants to a level, where they are proactively updating their knowledge about ADRs of drugs on regular basis.

The results of the present study show that the degree to which physicians were able to put the knowledge they had gained from training into practice was remarkably high. This is demonstrated by the observation that many participants (34.6%) had started reporting ADRs during the study period. The persistent effect of interventions throughout the study period was indicated by constant reports received during 14 months. But study done by Figueiras et al [1], Brachi et al [45] and Tabali et al [44] showed the fading up of the effectiveness of intervention, as the rate of ADR reporting had decreased. Cosentino et al recommended to include pharmacovigilance as a topic in continuing education programs of doctors [46].

Our data suggests that continuing education is an important tool for increasing physicians' awareness of ADRs. Based on our results and results of the other studies [1,34,44,45], we recommend a frequent repetition of such educational interventions. Study done by Manuela Tabali et al [44] focused on causality assessment in the educational

intervention, where the shift occurred from a predominance of reports indicating certain causality to reports in which causality was judged to be probable or possible following the intervention. This type of study and appropriate interventions could be planned further, as majority of the ADR reports we received were judged possible or probable.

CONCLUSIONS

- Baseline KAP assessment of pharmacovigilance showed a positive attitude of participants; but the inadequate knowledge about ADR reporting reflected in the lack of its practice.
- Voluntary participation of respondents in the interventions did not get good response. Mandatory sessions of imparting knowledge and hands on training for ADR reporting proved to be useful and personal communication with the clinicians was the most successful of all interventions.
- Overall effect of all the interventions was positive and successful in building up an ADR reporting system at the study site. This was depicted by the post-intervention assessment and number of ADR reports submitted to the Pharmacovigilance cell throughout the study period.
- Constant reminders to the doctors are needed for pharmacovigilance culture to persist and flourish in clinical settings

LIMITATIONS OF THE STUDY

This study has few limitations. Firstly, the study period was too short to evaluate long-term effects of interventions. Secondly, the study did not evaluate the total number of prescriptions in relation to the total number of ADR reports. We did not assess the effect of individual intervention on KAP of pharmacovigilance in our study.

ACKNOWLEDGEMENTS

The authors acknowledge all the study participants for their active involvement in the study. We are also thankful to the guest speakers and Abbott Healthcare Pvt. Ltd. for sponsoring these guest lectures. We show our gratitude towards the hospital management of the study site for allowing us to carry out various forms of interventions.

REFERENCES

1. Figueiras A, Herdeiro MT, Polónia J, Gestal-Otero JJ. An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. JAMA. 2006 Sep 6; 296(9):1086-93.
2. Rodríguez-Monguió R, Otero MJ, Rovira J. Assessing the Economic Impact of Adverse Drug Effects. Pharmacoeconomics 2003, 21 (9): 623-650.
3. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse reactions in hospitalized patients: A meta-analysis of prospective studies. JAMA1998 Apr 15;279(15): 1200-5
4. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. BMC ClinPharmacol2009,Aug 11;9:14.
5. Pharmacovigilance programme of India 2010. CDSCO, Ministry of Health and Family Welfare, Government of India. 2010
6. Lynn MR: Determination and quantification of content validity. Nurs Res.1986 Nov-Dec; 35(6):382 -85.
7. Bhatia A, Kapoor U, Tayal G. A survey of issues regarding ADR and ADR reporting amongst doctors in Delhi. Int J Risk Saf Med. 2005; 17: 30–46.
8. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions amongst resident doctors. J Pharm Sci Res 2011; 3: 1064-9.
9. Ghosh S, Ali S, Chhabra L, Prasad C, Gupta A. Investigation of attitudes and perception of medical practitioners on adverse drug reaction reporting – a pilot study. T Ph Res. 2010; 3: 1–9.
10. Ramesh M, Parthasarathi G. Adverse drug reactions reporting: attitudes and perceptions of medical practitioners. Asian J Pharm Clin Res. 2009; 2: 10–4.
11. Pharmacovigilance programme of India 2010. CDSCO, Ministry of Health and Family Welfare, Government of India. 2010. Available from: http://cdsco.nic.in/ pharmacovigilance.htm.
12. Van Grootheest AC, van Puijenbroek EP, de Jong-van den Berg LT. Contribution of pharmacists to the reporting of adverse drug reactions. Pharmacoepidemiol Drug Saf. 2002 Apr- May; 11(3):205–10.
13. de Langen J, van Hunsel F, Passier A, de Jong-van den Berg LT, van Grootheest K. Adverse drug reaction reporting by patients in the Netherlands. Three years of experience. Drug Saf. 2008; 31(6):515–24.
14. Morrison-Griffiths S, Walley TJ, Park BK, Breckenridge AM, Pirmohamed M. Reporting of adverse drug reactions by nurses. Lancet. 2003 Apr; 361(9366):1347–8.
15. Khan SA, Goyal C, Chandel N, Rafi M. Knowledge, attitudes, and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study. J Nat Sc Biol Med 2013 Jan;4(1):191-6.
16. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res 2011 Oct;2(4): 129-136.
17. Kamtane R, Jayawardhani V: Knowledge, attitude and perception of physicians towards adverse drug reaction (ADR) reporting: a pharmacoepidemiological study. Asian J Pharm Clin Res 2012;Vol 5(3):210-4
18. Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, Shi LY, Zeng FD: Awareness and attitudes of healthcare professional in Wuhan, China to the reporting of adverse drug reactions. Chin Med J (Engl). 2004 Jun; 117(6):856-61.
19. Okezie E O, Olufunmilayo F. Adverse drug reactions reporting by physicians in Ibadan, Nigeria. Pharmacoepidemiol Drug Saf. 2008 May; 17(5):517-522.
20. Eland IA, Belton KJ, Van Grootheest AC, Meiners AP, Rawlins MD and Ch. Stricker BH. Attitudinal survey of voluntary reporting of adverse drug reactions. Br J Clin Pharmacol 1999; 48: 623-27.
21. Bharathan B, Raju, N. A survey about the knowledge, attitude and practice of adverse drug reaction reporting among doctors in Bangalore city. Sixth annual conference of the Society of Pharmacovigilance (India), Kurupanidhi College of Pharmacy, Bangalore, India, 2006.
22. Aziz Z, Siang TC, Badarudin NS. Reporting of adverse drug reactions: predictors of under-reporting in Malaysia. Pharmacoepidemiol Drug Saf. 2007 Feb;16(2):223-228
23. Belton K J, Lewis SC, Payne S, Rawlins MD, Wood SM. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. Br J Clin Pharmacol. 1995; 39(3):223-326.
24. Belton K J. Attitude survey of adverse drug-reaction reporting by health care professionals across the European Union. The European Pharmacovigilance Research Group. Eur J Clin Pharmacol. 1997;52(6):423-427
25. Van Hunsel F, Passier A, van Grootheest K. Comparing patients' and healthcare professionals' ADR reports after media attention: the broadcast of a Dutch television programme about the benefits and risks of statins as an example. Br J Clin Pharmacol. 2009; 67: 558-564.
26. Blenkinsopp A, Wilkie P, Wang M, Routledge PA. Patient reporting of suspected adverse drug reactions: a review of published literature and international experience. Br J Clin Pharmacol. 2007; 63: 148-456.
27. Inman WH. Attitudes to adverse drug reaction reporting.Br J Clin Pharmacol 1996;41:433-5
28. Praveen S, Jai Prakash R, Manjunath GN, Gautham MS. Adverse Drug Reaction reporting among medical and dental practitioners: a KAP study. The journal of medical specialities 2013; 4(1):10-15.
29. Vallano A, Cereza G, Pedròs C, Agustí A, Danés I, Aguilera C, et al. Obstacles and solutions for spontaneous reporting of adverse drug reactions in a hospital. Br J Clin Pharmacol. 2005; 60: 653–8.
30. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: Knowledge, attitude and practices of medical students and prescribers. Natl Med J India 2002 Jan-Feb; 15(1): 24-6.

31. Bateman DN, Sanders GLS, Rawlins MD. The attitudes to the adverse drug reaction reporting in the northern region. Br. J. Clin. Pharmacol. 1992; 34(5): 421–26
32. Agrawal A, Chaturvedi P. Awareness, attitude and practice of Pharmacovigilance among healthcare professionals and students in a tertiary care teaching hospital. Int J Cur Res Rev, Sept 2012; 4(17).
33. Pimpalkhute SA, Jaiswal KM, Sontakke SD, Bajait CS, Gaikwad A. Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. Indian J Med Sci 2012;66:55-61
34. Rehan HS, Sah RK, Chopra D. Comparison of knowledge, attitude and practices of resident doctors and nurses on adverse drug reaction monitoring and reporting in a tertiary care hospital. Indian J Pharmacol 2012; 44: 699-703.
35. Nagpure S, Kale R, Varma S, Bahekar S. Impact Of Educational intervention on knowledge, attitude and practice of pharmacovigilance among medical graduates of rural tertiary care, teaching hospital of central India. Mintage journal of Pharmaceutical & Medical Sciences2013; 2(2):51-54.
36. Radhakrishnan R, Vidyasagar S. An Educational Intervention to assess Knowledge, Attitude and Practice of pharmacovigilance among Health care professionals in an Indian tertiary care teaching hospital. Int.J. PharmTech Res.2011; 3(2):678-92.
37. Nazario M, Feliu JF, Rivera GC. Adverse drug reactions: the San Juan Department of Veterans Affairs Medical Center experience. Hosp Pharm. 1994; 244-6:249-250.
38. Scott HD, Thacher-Renshaw A, Rosenbaum SE et al. Physician reporting of adverse drug reactions. Results of the Rhode Island Adverse Drug Reaction Reporting Project. JAMA. 1990; 263: 1785-1788.
39. Fincham J. A statewide program to stimulate reporting of adverse drug reactions. J Pharm Pract. 1989; 239-244.
40. McGettigan P, Golden J, Conroy RM, Arthur N, Feely J. Reporting of adverse drug reactions by hospital doctors and the response to intervention.Br J Clin Pharmacol. 1997; 44: 98-100.
41. Wallace SM, Suveges LG, Gesy KF. Adverse drug reaction reporting part I: a survey of pharmacists and physicians in Saskatchewan. Drug Information Journal 1995; 29: 571-79.
42. Suveges LG, Gesy KF, Wallace SM, Blackburn JL, Appel WC. Adverse drug reaction reporting part II: evaluation of the Saskatchewan pilot project for a regional reporting program in Canada. Drug Information Journal 1995; 29:581-589.
43. Scolt HD, Thacher – Renshaw A, Rosenbaum SE, Waters WJ, Green M, Andrews LG et al. Physician reporting of adverse drug reactions: results of the Rhode Island adverse drug reaction reporting project. JAMA 1990; 263: 1785-88.
44. Tabali, M., Jeschke, E., Bockelbrink, A., Witt, C.M., Willich, S.N., Ostermann, T., Matthes, H., 2009. Educational intervention to improve physician reporting of adverse drug reactions (ADRs) in a primary care setting in complementary and alternative medicine. BMC Public Health, 9:274.
45. Bracchi RC, Houghton J, Woods FJ, Thomas S, Smail SA, Routledge PA: A distance-learning programme in pharmacovigilance linked to educational credits is associated with improved reporting of suspected adverse drug reactions via the UK yellow card scheme. Br J Clin Pharmacol 2005, 60:221-223.
46. Cosentino M, Leoni O, Banfi F, Lecchini S, Frigo G: Attitudes to adverse drug reaction reporting by medical practitioners in a Northern Italian district. Pharmacol Res 1997, 35:85-8.