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A comparative evaluation of different teaching aids among fourth term medical students to improve the knowledge, attitude and perceptions about pharmacovigilance: An experimental study

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Abstract

Objectives: The Study was designed to assess the awareness of Pharmacovigilance and Adverse Drug Reactions (ADR's) and to evaluate the effectiveness of different teaching aids.

Materials and Methods: This was a questionnaire-based pre- and post-test evaluation study on (KAP) Knowledge, Attitude, Perception about pharmacovigilance. Students were given handouts regarding pharmacovigilance and ADR reporting one week before the educational interventions. Fourth term medical students (n=72) participated in the study. They were randomly allocated into group A (n=24), group B (n=24) and group C (n=24). A pre-validated 20-point questionnaire on Pharmacovigilance and Adverse Drug Reactions (ADR's) reporting was distributed to each group of students before the educational intervention to know their awareness. The interactive educational interventions on Pharmacovigilance were given using Overhead projector (OHP) and transparencies to group A students, Black board (BB) method to group B students, Power point presentation (PPT) method to group C students respectively. Theoretical content was the same in all the educational interventions. The chi-square test and one way ANOVA was used for statistical calculation.

Results: The overall response rates were expressed as percentages, Mean±SD. The Mean Pre-KAP scores on knowledge was (7.7±0.48) but the total post- KAP scores after (OHP), (BB), and (PPT) were (12.1±0.39), (17.4±0.3), (19.4±0.21) respectively. The correct response rates were found to be statistically significant (P<0.001).The feedback from the students was encouraging; handouts before the class were greatly welcomed.

Conclusion: The study greatly imparted knowledge about pharmacovigilance, ADR's reporting and students preferred power point presentations the most.

Keywords: Medical education, Pharmacovigilance, ADR's reporting, KAP questionnaire

1. Introduction

Pharmacovigilance is a science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems[1]. Pharmacovigilance has constantly grown in its importance during the last 15 years, considering the number of adverse drug reactions (ADR's) reported and to the fact that several hospital admissions are due to ADR's[2-3]. ADR's affect both children and adults with varying magnitudes; causing both morbidity and mortality[4-7]. Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitudes that are associated with a high degree of under-reporting [8-13]. ADR's lead to number of medical and economic consequences like prolonged hospital stays; increase in the cost of treatment and risk of death. Because of variation in drug response, individual prescribing habits, drug regulatory systems and availability of drugs etc., it has been recommended for every country to set up their own pharmacovigilance programme[14].

The most expert teachers emerge from years of experience with a variety of teaching methods[15-17]. To date, the most common methods used for teaching pharmacology in the lecture classes include lectures using overhead projector (OHP) and transparencies, PowerPoint presentations, and traditional black board method[18].Various studies have been conducted to know the best method from these available teaching methods and some of these studies have even ended inconclusively. To mention, some studies like Gag *et al*[17] have observed that there should be an inclusion of audio-visual aids and group discussions in the teaching Seth *et al* have concluded that traditional black board and power point teaching was far better than OHP & transparencies in improving students' performance[19]. On other hand, other studies have recommended need of clinical orientation to the pharmacology teaching and case based learning at the undergraduate

level [20]. Assessment of awareness of pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions. Therefore, the aim and objective of this study was to evaluate knowledge, attitude and perceptions about pharmacovigilance and ADR's among medical students at a medical college in south India by interactive educational modules as an intervention.

2. Materials and Methods

The study was conducted at MVJ medical college and research hospital, Bangalore. Permission was duly taken from Institutional Ethics Committee to conduct the study. This was a prospective, Knowledge, Attitude and Practice (KAP) questionnaire based study. Fourth term (n=72) medical students, participated in the study. Before the educational intervention was conducted, students were given handouts containing information about pharmacovigilance and ADR reporting one week before the intervention. Questionnaire was used for data collection as a research tool. A semi-structured, pre-validated questionnaire was designed after minor modifications from the work of Reddy *et al*[21], Radhakrishnan *et al* [22] and Bagewadi HG *et al*[23].

The KAP questionnaire consisted of 20 questions regarding pharmacovigilance and ADR reporting. Out of which, 11 questions were related to knowledge, 05 questions were related to attitude, 04 questions were related to perception. The correct responses were scored 1 point and wrong responses were given zero point for knowledge related and Perceptions related questions. The attitude related questions were scored based upon the participant's degree of agreement using Likert scale as: 0–strongly disagree, 1–disagree, 2-uncertain, 3-agree and 4-strongly agree. The pre-KAP questionnaire was administered and asked to submit the same. They were randomly allocated into group A (n=24), group B (n=24) and group C (n=24).

The interactive educational interventions on pharmacovigilance were given using Overhead projector (OHP)and transparencies to group A students, Black board (BB) method to group B students, Power Point presentation (PPT) method to group C students respectively. All the interactive educational interventions were taken by trained faculty for one hour each. The educational intervention consisted of a theoretical presentation on what is pharmacovigilance, its main objectives, adverse drug reactions reporting, its effect on patient safety and causality assessment of ADR's, vigiflow database, classification of ADR's, incidence of ADR's, role of health care professionals in ADR's monitoring. Theoretical content was the same in all the educational interventions. After the interactive educational interventions students were given Post-KAP questionnaire and correct responses were analyzed.

2.1 Statistical methods

The chi-square test and one way ANOVA was used for statistical calculation to compare the difference in correctness for each question. The p value ($p<0.05$) was considered to be statistically significant.

3. Results

All the correct responses are expressed in terms of numbers, percentages and Mean±SD, tabulated in table.1, 2, 3, 4 and figure 1.

Table1: Knowledge of Pharmacovigilance before & after educational interventions

Q. no	Knowledge questions	Pre–KAP Score n (%)	Post-KAP Score n (%)	p-value
1.	For reporting ADR's in the hospital following healthcare professional is/are responsible - **a)** Doctor **b)** Pharmacist **c)** Nurses **d)**All of the above**	09(37.5) 09(37.5) 10(41.6)	**PPT**-23(95.8) **OHP**-18(75) **BB**-15(62.5)	0.001* 0.02* 0.25
2.	Define Pharmacovigilance? **a)** The science of monitoring ADR's in the Hospital **b)** The process of improving the safety of Drugs **c)**The detection, assessment, understanding and prevention of adverse effects** **d)** The science of detecting rare ADR's only	07(29.2) 09(37.5) 10(41.6)	**BB**-22(91.6) **PPT**-19(79.2) **OHP**-7(29.2)	0.001* 0.001* 0.91
3.	The Primary objective of Pharmacovigilance is: **a)** To identify safety of drugs**b)** To calculate incidence of ADR's **c)** To identify predisposing factors to ADR's **d)** To identify ADR's occurring at high doses	08(33.3) 07(29.2) 09(27.5)	**OHP**-20(83.3) **BB**- 17(70.8) **PPT**-16(66.6)	0.001* 0.02* 0.08
4.	To assess the causality of an ADR Which of the following scales is commonly used: **a)**Hartwig scale **b)**Schumock& Thornton scale **c)**Naranjo algorithm** **d)**Karch&Lasagna scale	06(25) 08(33.3) 05(20.8)	**BB**-21(87.5) **PPT**-20(83.3) **OHP**-7(29.2)	0.001* 0.001* 0.02*
5.	The international center for ADR monitoring is based at: **a)** Unites States of America **b)**Australia**c)** Canada **d)** Sweden**	08(33.3) 07(29.2) 08(33.3)	**OHP**-21(87.5) **BB**-19(79.2) **PPT**-16(66.6)	0.001* 0.001* 0.043*
6.	Rare ADR's are identified in: **a)** phase-1 clinical trials **b)** phase-2 clinical trials**c)** phase-3 clinical trials**d)** phase-4 clinical trials**	06(25) 06(25) 07(29.2)	**BB**-19(79.2) **PPT**-16(66.6) **OHP**-9(37.5)	0.001* 0.01* 0.04*

7.	The 'WHO online database' for reporting ADR's is: **a)** ADR advisory committee **b)** Med safe **c)**Vigibase** **d)** Med watch	04(16.6) 05(20.8) 07(29.2)	**PPT**-20(83.3) **BB**-16(66.6) **OHP**-10(41.6)	0.001* 0.003* 0.04*
8.	It is important to report ADRs leading to- **a)** Hospitalization **b)** congenital abnormality **c)** patient death **d)** All of the above**	10(41.6) 07(29.2) 07(29.2)	**PPT**-22(91.6) **BB**-15(62.5) **OHP**- (37.5)	0.001* 0.04* 0.02*
9.	Select the correct (ADR and its causative drug): **a)** Yellowish discoloration of teeth- Isotretinoin **b)**Ebstein's cardiac anomaly-Warfarin **c)** Neural tube defects-Valproic acid** **d)**depressed nose, hand defects- Lithium	11(45.8) 08(33.3) 09(37.5)	**PPT**-17(70.8) **BB**-14(58.3) **OHP**-10(41.6)	0.02* 0.41 0.77
10	Regarding classification of ADR, the correct optionis: **a)** Type A is predictable, dose related **b)** Type B is unpredictable, dose unrelated **c)** Both 1) and 2) are correct** **d)** None of the above	12(50) 07(29.2) 09(37.5)	**OHP**-20(83.3) **BB**- 18(75) **PPT**-14(58.3)	0.02* 0.01* 0.03*
11	Select the correct (ADR and its causative drug) option: **a)**Hemolyticanemia-Thalidomide **b)**Phocomelia-Streptomycin **c)**Cleft lip-Phenytoin** **d)** Limb defects-Ofloxacin	07(29.2) 09(37.5) 06(25)	**BB**-23(95.8) **PPT**-19(79.2) **OHP**-8(33.3)	0.001* 0.09 0.44

Correct Response**, P<0.05*(comparison between the pre- KAP and Post- KAP responses).

OHP-Overhead projector (OHP) and transparencies, **BB**-Black board, **PPT**-Power point

Table 2: Attitude of Pharmacovigilance before &after educational interventions

Q. no	Attitude questions	Pre–KAP Scoren (%)	Post–KAP Scoren (%)	p-value
12.	When the drug is administered in normal dose would you suspect ADR's? -Strongly agree**	08(33.3) 08(33.3) 07(29.2)	**OHP**-23(95.8) **PPT**-21(87.5) **BB**- 20(83.3)	0.001* 0.04* 0.001*
13.	Do you agree that ADR reporting system would benefit patient care? -Strongly agree**	07(29.2) 06(25) 05 (20.8)	**OHP**-22(91.6) **BB**-19(79.2) **PPT**-19(79.2)	0.001* 0.01* 0.02*
14.	Do you agree reporting of adverse drug reactionis necessary? -Strongly agree**	09(37.5) 09(37.5) 11(45.8)	**PPT**-20 (83.3) **OHP**-11 (45.8) **BB**- 16 (66.6)	0.001* 0.04* 0.56
15.	Do agree all healthcare professionals should be taught in detail about Pharmacovigilance? -Strongly agree**	07(29.2) 07(29.2) 05(20.8)	**BB**-16(66.7) **PPT**-23(95.8) **OHP**-7(29.2)	0.001* 0.001* 0.009*
16.	Do you agree that for a new drug reporting of all ADR's is essential? -Strongly agree**	11(45.8) 06(25) 06(25)	**OHP**-22(91.6) **BB**-19(79.2) **PPT**-21(87.5)	0.001* 0.001* 0.02*

Correct Response**, P<0.05*(comparison between the pre- KAP and Post- KAP responses).**OHP**-Overhead projector (OHP) and transparencies, **BB**-Black board, **PPT**-Power point presentation

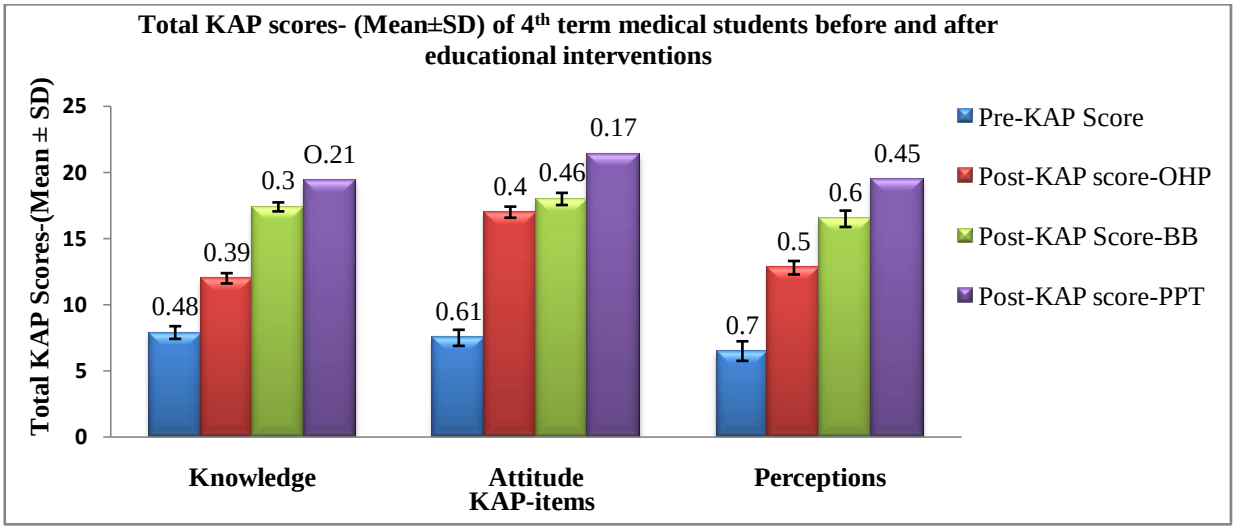
Table3: Perception of Pharmacovigilance before &after educational interventions

Q. no	Perception questions	Pre–KAP Scoresn (%)	Pre–KAP Scoresn (%)	p-value
17.	Communication of safety information between all health care professionals can minimize the risk of marketed medicines? -Yes**	07(29.2) 06(25) 05(20.8)	**PPT**-21(87.5) **BB**-16(66.6) **OHP**-12(50)	0.001* 0.01* 0.03*
18.	Is it important to know national, international centers for ADR monitoring? -Yes**	06(25) 05(20.8) 05(20.8)	**PPT**-23(95.8) **BB**-17(70.8) **OHP**-12(50)	0.001* 0.001* 0.01*
19.	Can ADR monitoring help to promote rational use of medicines? -Yes**	11(45.8) 06(25) 06(25)	**BB**-17(70.8) **OHP**-14(58.3) **PPT**-14(58.3)	0.01* 0.04* 0.04*
20.	Did educational sessions stimulate you to read an article (online /newspaper/Magazine) about ADR's in future? -Yes**	09(37.5) 07(29.2) 05(20.8)	**PPT**-20(83.3) **BB**-16(66.6) **OHP**-13(54.2)	0.001* 0.031* 0.016*

Correct Response**, P<0.05*(comparison between the pre- KAP and Post- KAP responses).

OHP-Overhead projector (OHP) & transparencies, **BB**-Black board, **PPT**-Power point presentation

Figure 1: Mean KAP scores of knowledge, attitude and perceptions among the participants. (n=72)



In Figure 01, the Mean Pre-KAP scores on knowledge was (7.7±0.48) but the total post- KAP scores after (OHP), (BB), and (PPT) were (12.1±0.39), (17.4±0.3)and (19.4±0.21), respectively. The Mean Pre-KAP scores on attitude was (7.5±0.61), but the total post- KAP scores after (OHP), (BB), and (PPT) were (17.1±0.4), (18±0.46) and (21.4±0.17) respectively. The Mean Pre-KAP scores on Perceptions were (6.54±0.7), but the total post- KAP scores after (OHP), (BB), and (PPT) were (12.8±0.5), (16.5±0.6) and (19.5±0.45) respectively. There was an overall increase in correct response rate observed with statistical significance ($p<0.001$) after educational interventions.

Table 4: Student Feedback regarding Educational interventions on Pharmacovigilance and Adverse drug reactions reporting:

Students opinions:	Response	n (%)
1. Did the educational session gave information about Objectives of Pharmacovigilance-	Yes	**PPT**-22(91.6) **BB**- 20(83.3) **OHP-17**(70.8)
2. Did the educational session gave information about Vigiflow database for adverse drug reactions monitoring-	Yes	**PPT**- 20(83.3) **BB**- 19(79.2) **OHP-15**(62.5)
3. Did the educational session gave information required while filling an suspected ADR reporting form-	Yes	**PPT**-21(87.5) **BB**-17(70.8) **OHP**-14(58.3)
4. Did the educational session gave information about different types of ADR-	Yes	**PPT**- 19(79.2) **BB**- 20(83.3) **OHP**-17(70.8)
5. The hand-outs before the educational session helped us to grasp and inculcate concepts of the ADR monitoring and pharmacovigilance better during lecture better-	Yes	**PPT**-21(87.5) **BB**-19(79.2) **OHP-17**(70.8)
6. Do you think Handouts before every Pharmacology lecture class helps to imbibe the concepts better-	Yes	**BB**-20(83.3) **PPT**-19(79.2) **OHP**-20(83.3)

(%) -percentage of responses. **OHP**-Overhead projector (OHP) and transparencies, **BB**-Black board, **PPT**-Power point presentation

4. Discussion

Pharmacovigilance is an integral and essential part of patient care. Even in countries like UK where pharmacovigilance programmes are well established, a high level of underreporting is documented [24]. In our study, question 01 of table 01emphasized the knowledge about all the participating stakeholders responsible for reporting ADR's in the hospital. After the educational session by PPT teaching aid, the post-KAP scores were drastically improved with statistically significance ($p<0.001$) when compared to pre-KAP scores. Regarding the knowledge about objectives of pharmacovigilance in question 03 of table 01, the students who underwent educational session by (OHP) teaching aid, scored greater increase in post KAP scores when compared to pre-KAP scores with statistical significance ($p<0.001$). Based on our study results and the findings of Cosentino *et al* [25], Figueras *et al* [26] it is a positive approach to include pharmacovigilance in continuing education programmes to all health care professionals.

The post-KAP scores when compared to pre- KAP scores in questions 2,4, 6 from table 01, there was statistically significant increase in correct responses ($p<0.001$)after the educational session by (BB) teaching aid and our results are in accordance with earlier study by Suveges *et al* [27]. Questions 08,09,10,11 from table 01 were designed to obtain the

knowledge about ADR's and its causative drugs which medical students, the budding doctors must know to promote safe and rational use of medicines in future clinical practice. The correct response scores were increased in the above mentioned questions with statistically significance ($p<0.001$) after educational session by (PPT) teaching aid.

Questions 12, 13, 16 from table 02, showed that post-KAP scores increased with statistical significance ($p<0.001$)when compared to pre-KAP scores after educational session by (OHP) teaching aid, which strongly suggests the need to create awareness of ADR's reporting aspect on knowledge and attitude of medical students. The students who underwent educational session by (PPT) and (BB) teaching aids, showed greater increase in correct response scores when pre-KAP scores were compared to post-KAP in questions 14 and 15 respectively(Table no.2). Our results are in accordance with previous studies by Bagewadi HG *et al* [23] and Scolt *et al* [28].

The questions17,18,19,20 from table 03 which highlights on the perceptions of the students, the correct response scores were increased from their pre-KAP scores to post-KAP scores with statistical significance ($p<0.001$)after educational session by (PPT) teaching aid. These observations are in accordance with earlier study done by Scolt *et al* [28]. The enthusiasm, motivation gained among students after educational interventions are good positive responses.
Table 4 shows the feedback from the students was encouraging and positive. The hand outs before the lecture classes helped them to understand the concepts better and potentiated easy grasping habits during lecture hours said by 87.5% students who underwent (PPT) educational intervention. The (PPT) educational session gave information about objectives of pharmacovigilance in 91.6% of students.

In our study, the mean score for correct answers regarding knowledge of pharmacovigilance before the educational session was 32.9%, but after educational session by(PPT) teaching aid, it was drastically improved to 80.8%, that means an alarming situation needs immediate attention of pharmacovigilance. Similar results were noted by Palaian *et al* [24] and suggested educational and awareness interventions for professionals. From our study it became evident that all the participants had very less information about pharmacovigilance and approaches of ADR's reporting before Pre-KAP but their Post-KAP score was definitely high after educational session by (PPT), (OHP) and (BB) teaching aids. As prevention is better than cure, knowledge of medical students in a tertiary care teaching hospital can be increased by including pharmacovigilance topic in undergraduate curriculum and again adding training programmes during internship and residency. As ADR's monitoring can definitely benefit patient care, the Pre-KAP score on their attitude aspect was 25% but after educational session by (OHP)as a teaching aid, the Post-KAP correct response score increased to 91.6% which highlights the role of continuous educational programmes to change the attitude among medical students.

With regards to the perceptions of communication of safety information among different health care professionals decreasing the risk of marketed medicines, the Pre-KAP score was 25% but educational session by (PPT) as a teaching aid, the correct response score increased to 87.5% as Post-KAP score. One of the better means of overcoming under-reporting is to increase the (KAP) of healthcare professionals regarding ADR's monitoring and pharmacovigilance programmes [24]. Earlier studies by Suveges *et al* and Scolt *et al*[27,28] have also revealed that enhancing knowledge, attitude, and perception of awareness of pharmacovigilance can increase the number of ADR reports. In one of the previous study by Kulkarni *et al* [29], it showed 91.78% doctors are of the opinion that pharmacovigilance programme should be included in undergraduate curriculum. Similar study on educational interventional program on pharmacovigilance by Li Q *et al* [30] showed that educational intervention improved awareness of pharmacovigilance on knowledge, attitudes, practice of healthcare professionals. Out of 20 questions, 08 questions correct response scores were highest among medical students who received educational session by (PPT) teaching aid. Whereas, 06 questions correct response scores were highest among medical students who received educational session in each of the (OHP) and (BB) teaching aids. The students were of the opinion that the handouts when given before every Pharmacology lecture would help them to absorb concepts better during lecture classes.

This study has two important limitations. Firstly, the study period was too short. Secondly, the study findings could not be applied to the wider community of medical students and other health care professionals as the study was restricted to 4^{th} term medical students in department of Pharmacology. Therefore we recommend that several such studies should be conducted among wider community medical students and other health care professionals to improve the knowledge, attitude and perceptions of pharmacovigilance in India and globally.

5. Conclusion

The results of the present study demonstrate that black board teaching along with (PPT) illustrations, diagrams can increase awareness of pharmacovigilance; ADR's reporting among the medical students and inculcate their acquired knowledge into their future clinical practice. The medical students would be made aware about benefit- risk ratio of safety of marketed medicines to promote better health for all in future.

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