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*Short Communication*

# Pharmacovigilance: Workshop for Undergraduate Medical Students

VeenaNayak[1*], Lalit Mohan[2], BhartiChogtu[1], K.L.Bairy[1]

[1]Dept. of Pharmacology, Kasturba Medical College, Manipal, India-576104
[2]Dept. of Pharmacology, Narayan Medical College and Hospital, Jamuhar - 821305 (Bihar)

[*]Correspondence Email: drveenayak@gmail.com

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## ABSTRACT

The Pharmacovigilance programme of India plans to include all MCI recognized medical colleges under this programme. To make this programme a success it is essential to train the undergraduate students effectively in this field as they are the future prescribers. In view of this we planned a workshop to educate the undergraduates in this regard by organizing a workshop wherein they were taught to fill the ADR forms , assess the severity and causality .

## INTRODUCTION

Safety of the patient has always been the main concern in the field of therapeutics and hence pharmacovigilance has gained great importance and momentum. The national pharmacovigilance programme in India has been restarted as Pharmacovigilance programmefor India (PvPI) jointly by CDSCO and Indian Pharmacopeia commission, Ghaziabad. The previous programmes were stopped because of varied reasons, under reporting being one of them. India is a country with a large population, despite which the reporting rate is only 1% .Hence this programme plans to include all the MCI, recognized medical colleges. Under this programme, a department for pharmacovigilancewill be started to implement pharmacovigilance activities and to improve the rate of reporting the adverse drug reaction (ADRs). [1] Moreover by implementing this programme into medical colleges,the medical students who are the future practioners will be aware of the methodology to report the adverse drug reactions .This could be one of the methods to improve the rate of reporting adverse drug reactions in our country. [2]

The department of pharmacology, Kasturba Medical College, Manipal established a pharmacovigilance cell in 2010. The main objective of this cell was to collect the ADRs from the hospital and report them. But due to lack of awareness among the prescribers, there was underreporting of ADRs. In view of this, the

department found it imperative to impart to the medical students the methodology of reporting the ADRs to the undergraduates. Hence a workshop was organized to conduct the same.

## METHODOLOGY

The Pharmacovigilance training workshop was conducted for the second year (4th semester) undergraduate medical students at Kasturba Medical College, Manipal, during the month of January 2010. One month prior to the training workshop, the students were intimated and only those interested were asked to enroll. A total of 56 students enrolled themselves for the training programme. It was conducted in the medical education department, where the students were divided into 8 groups and each group comprised of 3-4 members of both genders. The training programme was divided into three sessions each of half an hour duration. The first session focused on the need for pharmacovigilance and reporting of adverse drug reactions. The definition, types of ADR's and the severity assessment was covered in the second session. The third session dealt with the reporting of ADRs, filling an ADR- CDSCO form and causality assessment with emphasis on Naranjo's algorithm. [3] At the end of the third session the students were given the following two cases and were asked to fill the CDSCO form, assess the causality as well as severity.

Case 1: A 40 year old laborer AJ presented with itching and scaly lesions on the dorsum of both hands, erythematous papules and macules on face, neck, both arms and chest which worsened on exposure to sun . He had been prescribed tablet levofloxacin 400 mgonce a day for five days for respiratory infection.
He developed the above lesions on day 3 of therapy. Patient never had history of drug allergy to fluoroquinolones since he had received ciprofloxacin in the past. Levofloxacin was stopped. The lesions subsided. On detailed overview of his previous prescriptions, it was found that the patient had developed a similar reaction to levofloxacin in the past.

Case 2: A 35 year old male SKdiagnosed to be suffering from schizophrenia was prescribed tab olanzapine 5 mg. Later the dose was gradually increased to 7.5 mg. when the patient came for follow up after a month, his condition had improved but some symptoms persisted. So the dose was increased to 15 mg.
Patient complained of swelling in his feet on his next follow up after a month. On examination his cardiac parameters, liver and renal function tests were normal.
Since no other reason was found, the dose of olanzapine was tapered and stopped. The pedal edema subsided on reduction of dosage. Patient was then prescribed olanzapine 15 mg again for his illness. Patient developed pedal edema again within 20 days. A literature review revealed two cases in the past of edema due to olanzapine.

## RESULTS

The students were able to fill the CDSCO form . All the 8 groups of students discussed amongst themselves and filled the forms. Severity was correctly assessed by 93% and causality by 95% students. The individual scores for each question in Naranjo' algorithm[3] has been shown in the table below.

| | Questions | Case 1 | Case 2 |
|---|---|---|---|
| 1 | Are there previous conclusive reports on this reaction? | 1 | 1 |
| 2 | Did the ADR appear after the suspected drug was administered? | 2 | 2 |
| 3 | Did the ADR improve when the drug was discontinued? | 1 | 1 |
| 4 | Did the ADR appear with re-challenge? | 0 | 2 |
| 5 | Are there alternative causes for the ADR? | 0 | 2 |
| 6 | Did the reaction appear when placebo was given? | 0 | 0 |
| 7 | Was the drug detected in blood at toxic levels? | 0 | 0 |
| 8 | Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? | 0 | 1 |
| 9 | Did the patient have a similar reaction to the same or similar drug in any previous exposure? | 1 | 0 |
| 10 | Was the ADR confirmed by any objective evidence? | 0 | 0 |
| | TOTAL SCORE | 5 | 9 |

## DISCUSSION

The students enthusiastically participated in this training programme. The filling up of CDSCO forms though a difficult task was made an easy one by group discussion.

Naranjo's algorithm was designed by Naranjo et al [3] to assess the causality. It determines the likelihood of whether an ADR is actually due to the drug or due to other factors. Probability is assigned via a score termed definite, probable, possible or doubtful. It is also called the Naranjo Scale or Naranjo Score.The Naranjo's s score for the case 1 was five which suggests that the adverse drug reaction could be 'possible' whereas the score for case 2 was nine which suggests that the adverse drug reaction could be definite.

Hartwigscale [4] categorises ADRs into seven levels as per their severity. Severity of ADR is categorized as mild, moderate or severe. When an ADR does not require an antidote, therapy or prolongation of hospitalization it is categorized to be of mild severity. When a change in therapy, specific treatment or an increase in hospitalization by at least one day is required it is of moderate severity. Severe ADR includes all potentially life threatening reactions causing permanentdamage or requiring intensive medical care. Lethal reactions are those which may lead to death of the patient. In both the cases severity was assessed according to Hartwig scale. It was of moderate (Level 3) severity as the ADR required that suspected drug be withheld and there was no increase in length of stay

The Pharmacovigilance centre was established in the department in the year 2010. But the rate of reporting ADR was very less. In view of this, we planned to educate the undergraduates about pharmacovigilance. This workshop proved very beneficial as the ADR reporting improved thereafter. The students too found the sessions informative and interesting. We also plan to conduct such workshops for the postgraduates in various disciplines. We hope that our experience will be of interest to researchers and teaches of various medical colleges. This study provides a module to how Pharmacovigilance training can be imparted to medical students.

## REFERENCES


1. http:// cdsco.nic.in/pharmacovigilance_intro.htm
2. Ravishanker P, Subish P, Mishra P, Dubey AK. Teaching Pharmacovigilance to medical students and doctors. Indian Journal of Pharmacology 2006;38(5):316-319
3. Naranjo CA, Busto U, Sellars EM, Sandor P, Ruiz I, Roberts EA andJanecek E. Method for Estimating the Probability of Adverse Drug Reactions. ClinPharmacolTher. 1981;30:239–45.
4. Hartwig SC, Siegel J and Schneider PJ. Preventability and Severity Assessment in Reporting Adverse Drug reactions. American Journal of Hospital Pharmacy. 1992;49:2229-31.


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