Pharmacovigilance and adverse drug reaction reporting perspectives among interns and postgraduates of a teaching hospital

Sir,

Pharmacovigilance (PV) is the branch dealing with adverse drug reactions (ADRs), their recognition, and reporting. ADR is defined by the World Health Organization (WHO) as a response to a drug that is noxious, unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of a physiological function. PV is defined by the WHO as a science, with activities that relate to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.[1] The literature depicts the incidence of ADR to be 2.4-6.5% even in western countries, with only 6-10% of all ADRs being reported.[2] Issues and challenges in PV, in India, are gross underreporting of ADR mainly due to lack of adequately skilled resources and inadequate awareness of PV among physicians.[3] However, there are no studies involving particularly interns and postgraduates (PGs) to know their PV and ADR reporting preparedness, as they are the first to attend any ADR in a teaching medical college setup thus playing a pivotal role in healthcare delivery. Hence, in the present study we analyzed the PV knowledge, ADR reporting behavior, and deterrents for ADR reporting, among interns and PGs from a medical college hospital, to understand the current status and need for future improvement.

This prospective observational questionnaire-based study, comprising of 24 objective questions, was conducted at a medical college hospital after obtaining ethical clearance. One hundred and fifty-four respondents participated in the study by answering the questionnaire independently without consulting each other. Data analysis using the SPSS software involved mean ± SD, percentages (%), and independent t-test. A P < 0.05 was considered statistically significant. The respondents were grouped and compared using the above statistical measures. The results and conclusions were drawn from the data analysis.

The present study included 154 respondents (60 interns and 94 postgraduates), aged 22-39 years (SD 2.44). Male: Female gender distribution was 37:23 among interns and 63:31 among PGs. Among interns 29 (48%), 41 (68%), 32 (53%), and 40 (67%) had completed medicine, surgery, obstetrics and gynecology (OBG), and ancillary internship postings, respectively. Among the PGs 38 (40%) belonged to the medicine and allied group and 56 (60%) belonged to the surgery and allied group.

Observations from the present study were as follows:

Our present study involved interns and PGs as there was a paucity of data pertaining to PV and ADR reporting among the same.

In the present study it was evident that the interns and PGs of both genders were equally poor in ADR reporting, as >65% had not reported any ADR. It is alarming and disheartening to note that, they have demonstrated the same trend seen among physicians and consultant prescribers.[4,5]

Factors like ignorance, indifference, and complacency have been attributed to poor ADR reporting among professionals and consultants.[6] Our present study involving interns and PGs revealed a difficulty to decide the occurrence of ADR as the major factor discouraging ADR reporting, while other factors included lack of time to report and non-remuneration for reporting.

Our present study confirmed the fact that routine clinical training during clinical postings and possessing a positive attitude toward PV, ADR reporting did not have much impact on spontaneous ADR reporting by interns and PGs, as there was no statistically significant difference of the mean pharmacovigilance score among the four subgroups of interns and two subgroups of PGs, as illustrated in [Tables 1 and 2].

Finally, we conclude that there is an absolute need for exclusive pharmacovigilance and ADR reporting training for interns and PGs of medical colleges to enhance their pharmacovigilance efficiency.
Research Letter

| Questionnaire questions | Answer | Interns n=60 (%) | Postgraduates n=94 (%) |
|-------------------------|--------|------------------|------------------------|
| ADR definition          | Correct| 46 (77)          | 78 (83)                |
|                         | Incorrect| 14 (23)         | 16 (17)                |
| Dose and ADR            | Correct| 50 (83)          | 80 (85)                |
|                         | Incorrect| 10 (17)         | 14 (15)                |
| Molecular weight and ADR| Correct| 10 (17)          | 16 (17)                |
|                         | Incorrect| 50 (83)         | 78 (83)                |
| Genetic basis and ADR   | Correct| 53 (88)          | 78 (83)                |
|                         | Incorrect| 07 (12)         | 16 (17)                |
| Classification of ADR   | Correct| 10 (17)          | 18 (19)                |
|                         | Incorrect| 50 (83)         | 76 (81)                |
| Most common organ involvement in ADR | Correct| 41 (68)        | 65 (69)                |
|                         | Incorrect| 19 (32)        | 29 (31)                |
| ADR regulatory body in India | Correct| 49 (82)        | 49 (52)                |
|                         | Incorrect| 11 (18)        | 45 (48)                |
| Location of the central ADR monitoring cell in India | Correct| 13 (22)        | 15 (16)                |
|                         | Incorrect| 47 (78)        | 79 (84)                |
| Necessity of ADR reporting | Yes/positive attitude| 58 (97)   | 92 (98)                |
|                         | No/negative attitude| 02 (3)     | 02 (2)                 |
| ADR reporting as a professional obligation | Yes/positive attitude| 53 (88)   | 75 (80)                |
|                         | No/negative attitude| 07 (12)    | 19 (20)                |
| Teaching pharmacovigilance in academic curriculum | Yes/positive attitude| 56 (93)   | 82 (87)                |
|                         | No/negative attitude| 04 (7)     | 12 (13)                |
| Willing to attend pharmacovigilance training workshop | Yes/positive attitude| 54 (90)   | 75 (80)                |
|                         | No/negative attitude| 06 (10)    | 19 (20)                |
| Personally seen ADR     | Yes    | 15 (25)          | 40 (43)                |
|                         | No     | 45 (75)          | 54 (57)                |
| Shall consider ADR as a D/D even if not reported earlier by others | Yes    | 53 (88)          | 69 (73)                |
|                         | No     | 07 (12)          | 25 (27)                |
| Undergone ADR reporting training | Yes    | 13 (22)          | 17 (18)                |
|                         | No     | 47 (78)          | 77 (82)                |
| Number of ADRs reported personally | None    | 41 (68)          | 61 (65)                |
|                         | <5     | 19 (32)          | 33 (35)                |
| Factors discouraging ADR reporting | Difficulty to decide occurrence of ADR| 50 (83)  | 51 (54)                |
|                         | Lack of time to report| 26 (43)   | 28 (30)                |
|                         | Non-remuneration for reporting| 24 (40)   | 24 (26)                |
|                         | Un reporting may not affect data base| 15 (25)  | 08 (9)                 |

ADR=Adverse drug reaction
Table 2: Pharmacovigilance score among interns and postgraduates

|                      | Interns       |     |     |
|----------------------|---------------|-----|-----|
| Completed medicine postings |               |     |     |
| Yes                  | 15.14         | 3.64|     |
| No                   | 15.32         | 3.32|     |
| Completed surgery posting |             |     |     |
| Yes                  | 14.98         | 3.86|     |
| No                   | 15.79         | 2.35|     |
| Completed OBG posting  |               |     |     |
| Yes                  | 15.38         | 2.70|     |
| No                   | 15.07         | 4.20|     |
| Completed ancillary posting |           |     |     |
| Yes                  | 15.08         | 4.03|     |
| No                   | 15.60         | 2.06|     |
| Postgraduates        |               |     |     |
| PGs of medicine and allied departments |           |     |     |
| Yes                  | 13.79         | 2.90|     |
| No                   | 13.70         | 2.68|     |
| Gender               |               |     |     |
| Males                | 14.20         | 3.52|     |
| Females              | 14.53         | 2.20|     |

OBG=Obstetrics and gynecology, SD=Standard deviation

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Raghava Sharma, Adithi Kellarai
Department of Medicine, KS Hegde Medical Academy, Mangalore, Karnataka, India

REFERENCES

1. World Health Organization (WHO) (A) World Health Organization. The Importance on Pharmacovigilance. Safety Monitoring on Medicinal Products. Geneva, Switzerland: Office of Publications; 2002 WHO/EDM/QSM/2002.
2. Smith CC, Bennett PM, Pearce HM, Harrison PI, Reynolds DJ, Aronson JK, et al. Adverse drug reactions in a hospital general medical unit meriting notification to committee on safety of medicines. Br J Clin Pharmacol 1996;42:423‑9.
3. Biswas P. Pharmacovigilance in Asia. J Pharmacol Pharmacother 2013;4 Suppl 1:S7‑19.
4. Rishi RK, Patel RK, Bhandari A. Opinion of physicians towards adverse drug reaction reporting results of pilot study. Journal of Community Medicine and Health 2012;1:25‑9.
5. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. BMC Clin Pharmacol 2009;9:14.
6. Lopez‑Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under‑reporting of adverse drug reactions: A systematic review. Drug Saf 2009;32:19‑31.

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