

## Knowledge, Attitude and Practice Towards Pharmacovigilance and Adverse Drug Reaction Reporting Among Nurses in A Tertiary Care Hospital, Tirupati

R Rajalakshmi<sup>1\*</sup>, B Vasundara Devi<sup>2</sup>, T S Durga Prasad<sup>3</sup>, S Swetha<sup>3</sup>, B Dharini<sup>4</sup>

<sup>1</sup>Patient Safety Pharmacovigilance Associate (Pharmacovigilance Programme of India), ADR Monitoring Centre (AMC), S.V. Medical College, Tirupati-517507.

<sup>2</sup>S. V. Medical College, Tirupati-517507.

<sup>3</sup>Sri Padmavathi School of Pharmacy, Tiruchanoor, Tirupati

<sup>4</sup>Patient safety Pharmacovigilance Associate (Pharmacovigilance Programme of India), ADR Monitoring Centre (AMC), SDS Tuberculosis Research Centre & Rajiv Gandhi institute of Chest Diseases, Bengaluru

Received: 25<sup>th</sup> Sep, 17; Revised 18<sup>th</sup> Oct, 17, Accepted: 20<sup>th</sup> Nov, 17; Available Online: 25<sup>th</sup> Nov, 17

### ABSTRACT

Adverse drug reactions (ADRs) are adverse consequences of drug therapy and are ranked as some of the major causes of patient morbidity and mortality. ADRs are representing a major concern of health systems in terms of early recognition, proper management and prevention. Under reporting of ADRs is a common problem in Pharmacovigilance program and spontaneous reporting is important in improving patient safety. This study was done to evaluate the knowledge, attitude and practice of nurses towards pharmacovigilance and adverse drug reaction reporting. It was a cross-sectional questionnaire based study among the nurses of a tertiary care hospital. A predesigned self-assessed questionnaire evaluating knowledge, attitude and practice was distributed among nursing staff and filled questionnaire were collected and analysed. A total of 101 (73.7%) nurses completed the questionnaire. ADR reporting was considered important by most of the nurses and majority of the nurses had knowledge about serious ADRs (50%). Nurses had very significant and positive attitude towards pharmacovigilance but there is a need for enrichment in knowledge and practice of ADR reporting.

**Keywords:** Adverse drug reactions, attitude, knowledge, nurses, pharmacovigilance, practice.

### INTRODUCTION

Adverse drug reactions (ADRs) are adverse consequences of drug therapy and are ranked as some of the major causes of patient morbidity and mortality. Indians are one of the largest drug consuming populations in the world<sup>1</sup>. ADRs are one of the major health care problems occurring throughout the world. It is found that about 3.4% of hospital admissions in India were due to the ADRs<sup>2</sup>. Any drug or medicine in its normal therapeutic doses has a tendency to potentiate an adverse reaction<sup>2</sup>. Adverse drug reaction (ADR) is noxious and unintended response that occurs at normal doses used in humans for the prophylaxis, diagnosis, treatment or modification of physiological function. There is a need for continuous pharmacovigilance for all drugs including those existing for many years. Reporting adverse drug reactions (ADRs) spontaneously is considered as a cornerstone of pharmacovigilance. Pharmacovigilance detects previously unknown adverse reactions, identifies risk factors that pre-dispose to drug toxicity and investigates causality of the adverse reactions<sup>3</sup>. "Pharmacovigilance": Pharmakon (Greek word for 'drug') and vigilare (Latin word for 'to keep watch'). According to the World Health

Organization, Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem, particularly long term and short term adverse effects of medicines"<sup>4</sup>. Pharmacovigilance programme of India (PvPI) was launched with a broad objective to safeguard the health of 1.28 billion people of India. PvPI has survived the danger of infant mortality and it has completed 5 years and now it would grow as a healthy child to benefit the nation. At present 250 AMCs are engaged to monitor and report. Its success depends on co-operative and motivated health care professionals. It is found that only 6- 10% of all ADRs are reported. This high rate of underreporting is a matter of great concern which can delay detection of serious ADRs and consequently have a major negative impact on the public health. The factors such as poor understanding and lack of awareness contributes to the under reporting of the ADRs<sup>5,6,7</sup>. Nurses are the key persons who can observe the patient on admission in hospital. They can also educate the patients and caretakers about the symptoms of ADR to report immediately<sup>5</sup>. So the present study was

Table 1: Knowledge of study group towards Pharmacovigilance.

| S. No. | Questions  | Yes (%)    | No (%)     | Don't Know (%) |
|--------|--|------------|------------|----------------|
| 1      | Are you familiar with the term Pharmacovigilance?  | 66 (65.34) | 35 (34.66) | 0 (0)          |
| 2      | Pharmacovigilance is the study that relates to ADRs  | 16 (15.84) | 83 (82.17) | 2 (1.98)       |
| 3      | Do you believe all the drugs available in the market are safe?                                     | 80 (79.20) | 18 (17.82) | 3 (2.97)       |
| 4      | Do you think ADR reporting is important?   | 100 (99)   | 0 (0)      | 1 (0.99)       |
| 5      | The healthcare professionals are responsible for reporting ADR in a hospital?                      | 73 (72.27) | 28 (27.72) | 0(0)           |
| 6      | In India CDSCO is responsible for monitoring of ADRs?  | 20 (19.8)  | 70 (69.30) | 11 (10.89)     |
| 7      | Is there any nearby ADR reporting and monitoring center in your knowledge?                         | 60 (59.40) | 41(39.60)  | 0 (0)          |
| 8      | Are you aware of PvPI Android app and toll free number?  | 32 (31.68) | 67 (66.33) | 2 (1.98)       |
| 9.     | The purpose of Pharmacovigilance is to report ADRs due to allopathic and non- allopathic medicines | 71 (70.29) | 30 (29.70) | 0 (0)          |

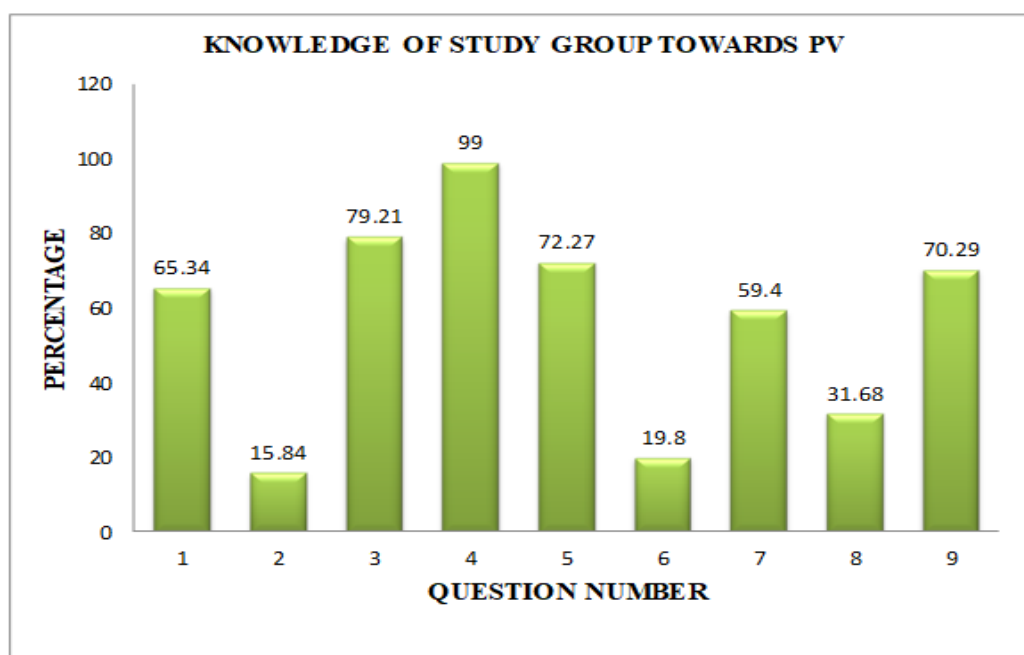


Figure 1: Knowledge of study group towards Pharmacovigilance.

aimed to assess the attitude of the nursing staff towards ADR reporting and to evaluate their knowledge of the spontaneous reporting system as well as to identify the reasons for under reporting rate so that suitable interventions may be planned in future in order to improve the reporting culture.

## MATERIALS AND METHODS

### Study design and site

A cross-sectional study was conducted among nursing staff working at a 1200 bedded tertiary care hospital Tirupati, India.

### Source of data

The required information for the study was collected from the nurses through a pre-designed self-administered questionnaire about the knowledge, attitude and practice towards pharmacovigilance and ADR reporting. The questionnaire consisted of questions included in previous local and international studies that examined the knowledge, attitude and practice (KAP) of health care professionals.

### Study sample

A total of 137 nursing staff participated in the study, of which 101 nurses returned the filled questionnaire within the stipulated time frame.

### Study period

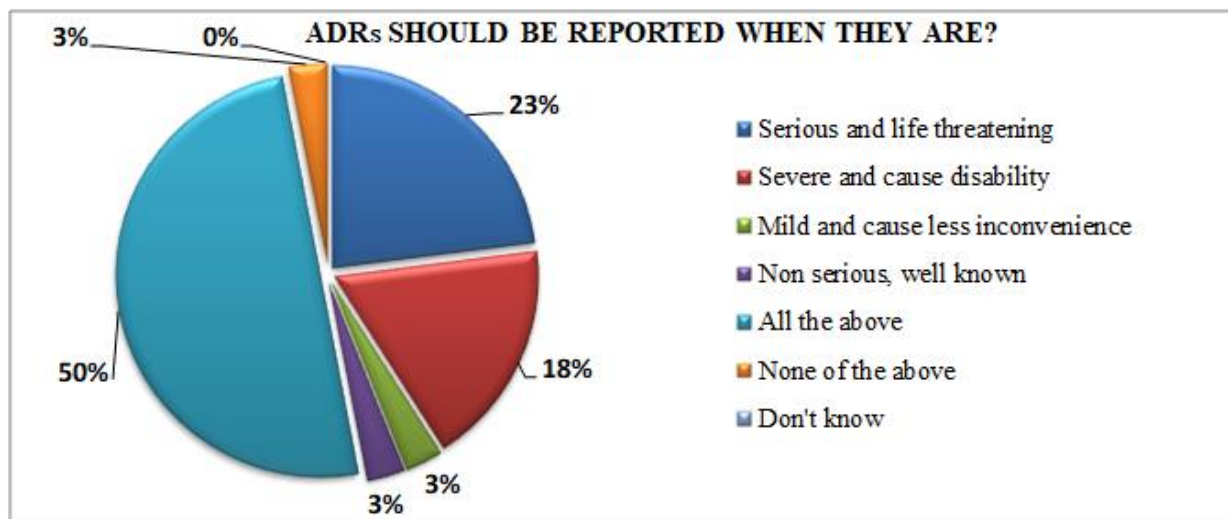


Figure 2: Knowledge about ADR reporting.

Table 2: Knowledge about ADR reporting.

| ADRs should be reported when they are? | Percentage (%) |
|--|----------------|
| A Serious and life threatening         | 23             |
| B Severe and cause disability          | 18             |
| C Mild and cause less inconvenience    | 3              |
| D Non serious, well known              | 3              |
| E All the above                        | 50             |
| F None of the above                    | 3              |
| G Don't know                           | 0              |

Table 3: Attitude of Study group towards PV.

| Sl. No. | Questions  | Yes (%)    | No (%)     | Don't Know (%) |
|---------|--|------------|------------|----------------|
| 11      | Do you feel that ADR reporting is time consuming activity with no outcome?             | 61 (60.39) | 25 (24.75) | 15 (14.85)     |
| 12      | Do you think reporting adverse drug reaction will increase patient safety?             | 91 (90.09) | 8 (7.9)    | 2 (1.98)       |
| 13      | Do you worry about legal problems while you think of ADR reporting?                    | 60 (50.40) | 41 (40.59) | 0 (0)          |
| 14      | Do you think Pharmacovigilance should be taught in detail to healthcare professionals? | 101 (100)  | 0 (0)      | 0 (0)          |

The study was conducted for a period of 3 months from April 2016 to June 2016.  
 Design of Questionnaire

Table 4: Opinion about establishing ADR monitoring centre in every hospital.

| 15. Opinion about establishing AMC                | Percentage (%) |
|---|----------------|
| a) Should be in every hospital                    | 92             |
| b) Not necessary in every hospital                | 0              |
| c) One in a city is sufficient                    | 0              |
| d) Depends on number of bed size in the hospitals | 8              |

Table 5: Practice of Study group towards PV.

| Sl. No. | Name of the question   | Yes (%)    | No (%)     | Don't Know (%) |
|---------|--|------------|------------|----------------|
| 16.     | Have you ever experienced an adverse drug reaction (ADR) in patients during your practice? | 74 (73.26) | 27 (26.73) | 0 (0)          |
| 17.     | Have you ever reported ADR to the PV center?   | 29 (28.71) | 72 (71.28) | 0 (0)          |
| 18.     | Have you ever counseled patients regarding ADRs?   | 40 (39.60) | 50 (49.50) | 11 (10.89)     |

The 20 item questionnaire consisted of information about knowledge, attitude and practice of ADR reporting, factors that may likely affect their reporting of ADR and suggestions towards better methods in ADR reporting culture was prepared in English and used on nursing staff. The questionnaire was divided into three sections of

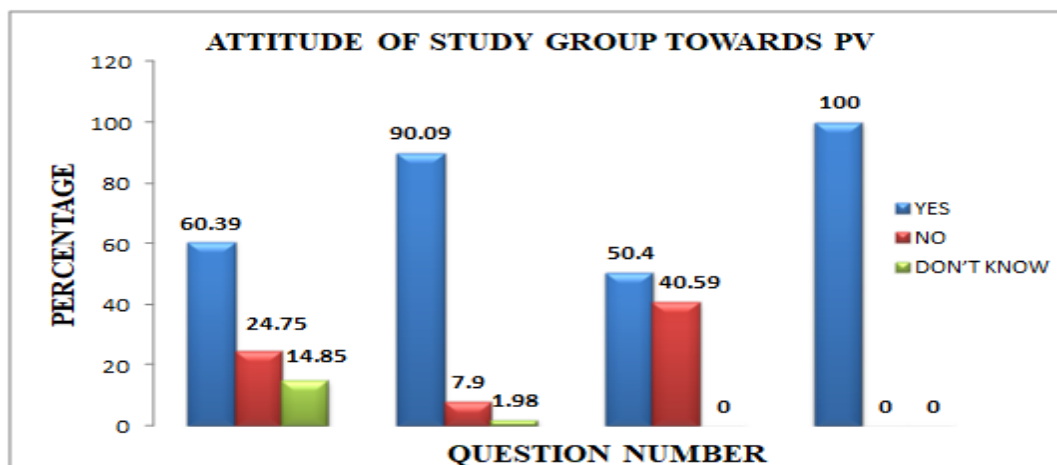


Figure 3: Attitude of Study group towards PV.

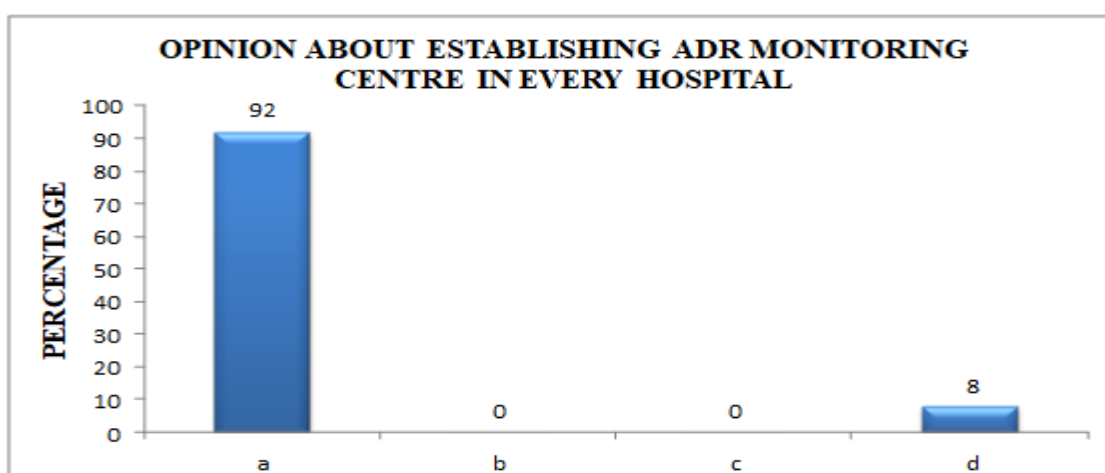


Figure 4: Opinion about establishing ADR monitoring centre in every hospital.

Table 6: Reasons for under-reporting of ADRs.

| Reason for under-reporting of ADRs?               | Percentage (%) |
|---|----------------|
| Reporting does not influence the treatment scheme | 7.90           |
| Busy schedule                                     | 7.90           |
| Lack of incentives                                | 16.83          |
| ADR is known only to physician                    | 43.56          |
| Don't know whom to report                         | 23.76          |
| Waste of time                                     | 3.96           |
| Insufficient clinical knowledge                   | 50.49          |
| Thinking one report doesn't make any difference   | 18.81          |
| Difficult to point out suspected drug             | 32.67          |
| Others (please specify)                           | 0.00           |

knowledge (10 questions), attitude (5 questions) and practice (5 questions).

*Data collection*

Initially KAP questionnaire was administered and briefed to all participants about the purpose of the study and asked to submit the same within 30 minutes.

*Responses of nurses on knowledge related questions*

There were 10 knowledge related questions. Among the respondents, 66(65.34%) nurses were familiar with the

term pharmacovigilance and 16(15.34%) nurses knew that it is the study that relates to ADRs. About 80 (79.20%) nurses believe that all the available drugs in market were safe. Almost all of the respondent's 100 (99%) thought that ADR reporting is important and most of them (72.27%) were aware that health care professionals were responsible for reporting ADR in a hospital. Most of the nurses (59.40%) had awareness that there is an ADR reporting and monitoring centre nearby but most of respondent nurses (69.30%) were unaware about CDSCO. About 67(66.33%) respondents were unaware of PvPI android app and toll free number. About 71(70.29%) respondents were aware that ADRs due to allopathic and non- allopathic medicines can be reported to Pharmacovigilance. Half of the respondents (50%) felt that serious, severe, mild and non-serious ADRs can be reported where other responders felt that only serious (23%), severe (18%), mild (3%) and non-serious (3%) ADRs should be reported.

*Responses of nurses on attitude related questions*

There were 5 attitude related questions. About 60(60.39%) respondent nurses felt that ADR reporting is time consuming activity with no outcome and 91(90.09%) nurses thought that ADR reporting increases patient safety. About 50.40% of respondent nurses were

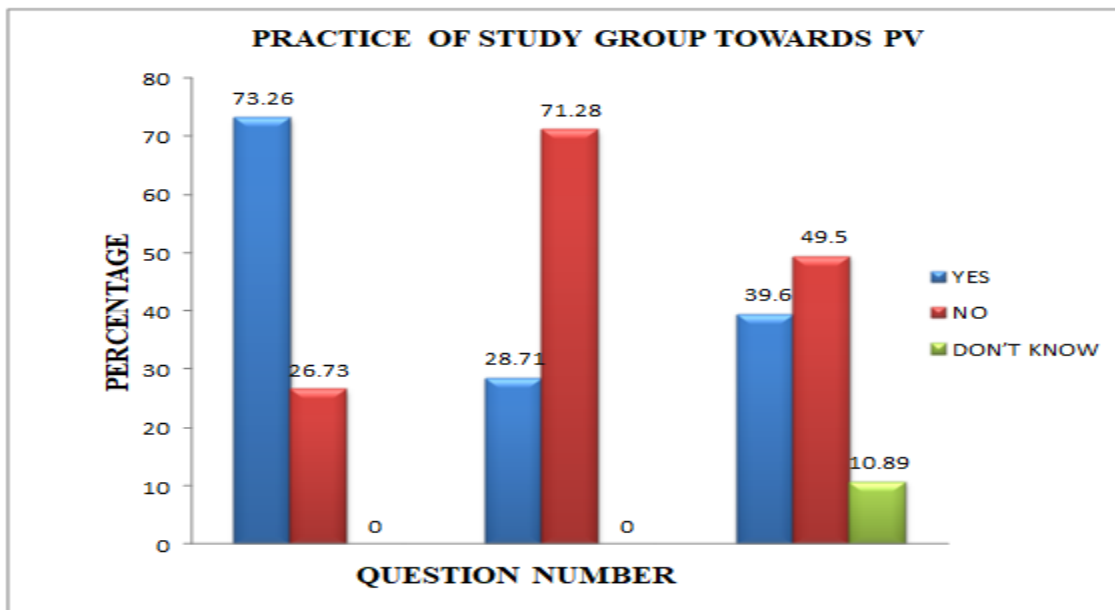


Figure 5: Practice of Study group towards PV.

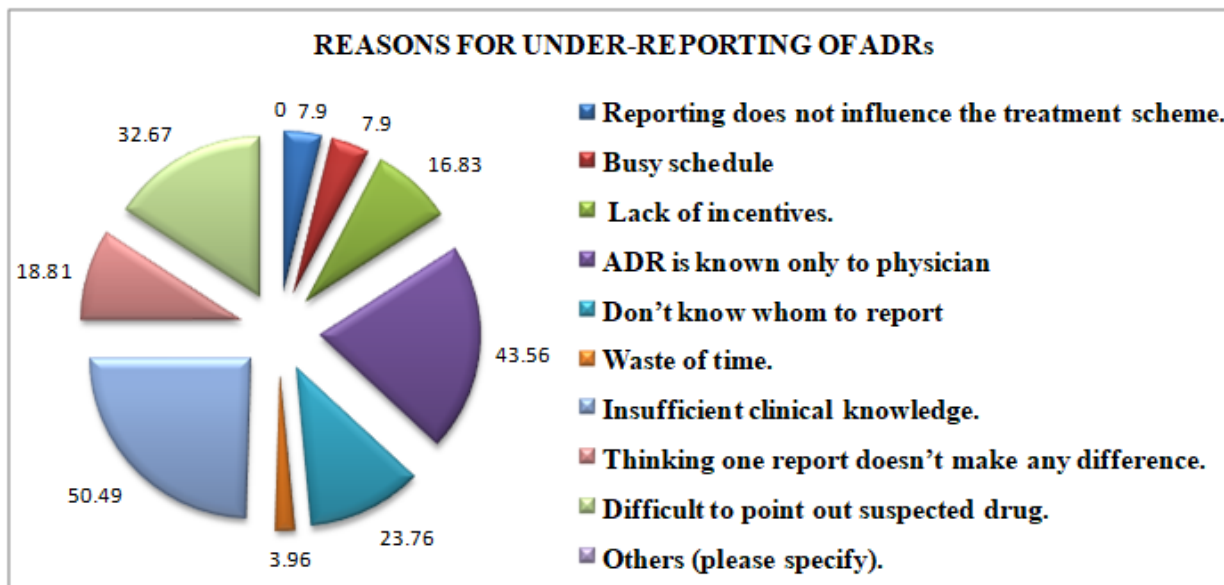


Figure 6: Reasons for under-reporting of ADRs.

Table 7: Preferable method to report ADRs.

| Which method would you prefer to send adverse drug reaction to ADR reporting center | Percentage (%) |
|---|----------------|
| Direct Contact  | 50.49          |
| Telephone   | 39.60          |
| Android application   | 0              |
| Post  | 2.97           |
| E-mail  | 4.95           |
| others  | 1.98           |

worried about the legal problems while ADR reporting. All of the nurses agreed that it should be taught in detail to healthcare professionals.

*Responses of nurses on practice related questions*

There were 5 practice related questions. Most of the nurses (73.26%) had seen patients experiencing ADR. It was found that only 29(28.71%) nurses had reported ADR to the PV centre but about 40(39.60%) respondent nurses counselled patients regarding ADRs. About 50.49% of the nurses preferred direct contact method to send ADR to ADR monitoring centre. The most common reasons for under reporting of ADRs by the nurses were insufficient clinical knowledge (50.49%), ADR is known only to physician (43.56%), Difficult to point out suspected drug (32.67%), don't know whom to report (23.76%), Thinking one report doesn't make any difference (18.81%) and others.

**DISCUSSION**



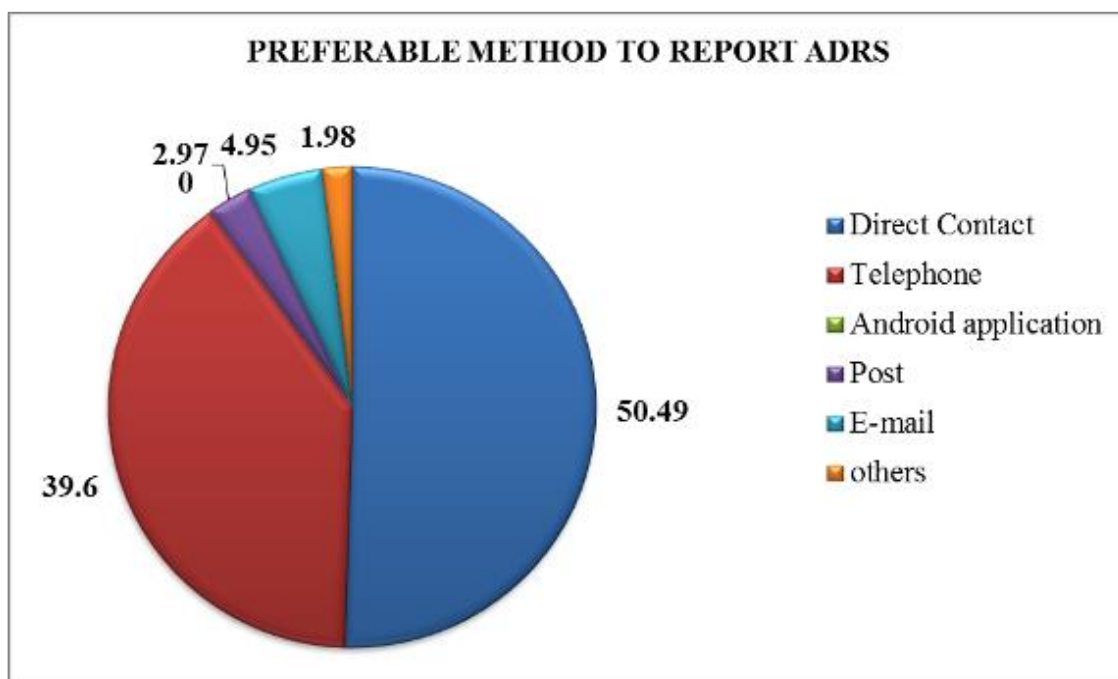


Figure 7: Preferable method to report ADRs.

The present study was a questionnaire based study that included 137 nurses working in a tertiary care teaching hospital. Among 137 nurses, 101 nurses returned the filled questionnaire and were selected for analysis. The response rate was 73.72%. Most of the nurses (65.34%) were familiar about the term pharmacovigilance. But they were not able to relate it to ADRs (15.84%). Majority of the nurses (79.2%) felt that all of the available drugs were not safe and reporting should be must (99%) especially for serious, severe, mild and non-serious ADRs similar to the findings made by rehan H.S<sup>8</sup> and Khan et al<sup>6</sup>. Though majority of nurses were aware about ADR monitoring and reporting (59.40%) only few of them knew that the centre is CDSCO (19.8%). 71% of nurses perceived that ADRs due to allopathic and non-allopathic medicines should be reported and health care professionals are responsible for reporting them (72%) the results were similar to findings made by Gupta et al<sup>9</sup>. About 66 % of nurses were unaware of the PvPI android app and toll free number.

#### Attitude

Most of the nurses agreed that ADR reporting increases the patient safety (90%), but their attitude towards it is time consuming with no outcome (61%). This needs an educational intervention to change their attitude towards ADR reporting. In our study we found that all the nurses who completed the questionnaire in the study expressed their opinion that PV should be taught in detail to health care professionals this was similar to the study conducted by Gupta et al<sup>9</sup>. About 92% of the nurses agreed that ADR monitoring centre should be present in every hospital which was comparable to the findings made by Gupta et al<sup>9</sup>.

#### Practice

More than 70% of the nurses have experienced an ADR in patients during their practice but only 39% have counselled patients regarding ADRs. About 28% of the nurses have reported ADRs in our study where as 9% in the study conducted by Hanafi S et al<sup>10</sup>. The factors responsible for under-reporting of ADRs were found to be insufficient clinical knowledge, ADR is known only to physician, difficult to point out suspected drug, indifference, lack of incentives and others similar to the results of Tandon et al<sup>11</sup>. These findings reveals that there is improvement in the knowledge and attitude of ADR reporting. But the practice of ADR reporting is lacking among the nursing staff. So the intervention is required to generate awareness on how to report, what to report and also the reporting techniques through their most preferable methods that is by direct contact (50%) and telephone (39%).

#### CONCLUSION

This study shows that the nursing fraternities were moderately aware about the pharmacovigilance and ADR reporting system. The major cause for under reporting was poor clinical knowledge on ADRs. Therefore, it is necessary to create awareness in order to improve ADR reporting, since they are in closer contact with the patients for a longer duration. They can play an important role in making the pharmacovigilance programs more efficacious. Number of training sessions and workshops must be conducted in hospitals to healthcare professionals in order to improve their knowledge on pharmacovigilance, filling the spontaneous ADR reporting forms and mode of reporting criteria. The ADR reporting should be made an integral part of the clinical activities in order to improve the patient safety.

## ACKNOWLEDGEMENT

We thank Principal, Sri Venkateswara Medical College, Tirupati. We also express our sincere thanks for technical & logistic support of NCC-PvPI, IPC, Ghaziabad.

## REFERENCES

1. Bhagavathula A, Elnour A, Jamshed S, Shehab A. Health Professionals' Knowledge, Attitude and Practices about Pharmacovigilance in India: A Systematic Review and Meta-Analysis. *PLOS ONE*. 2016; 11(3): 1-15.
2. Kharkar M, Bowalekar S. Knowledge, attitude and perception/practices (KAP) of medical practitioners in India towards adverse drug reaction (ADR) reporting. *Perspectives in Clinical Research*. 2012; 3(3):90-4.
3. Ahmad A, Balkrishnan R, Manna P, Mohanta G, Patel I. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study. *Perspectives in Clinical Research*. 2013; 4(4):204-210.
4. Olsson S. The need for pharmacovigilance. In: Gupta SK. *Pharmacology and Therapeutics in the New Millennium*. New Delhi: Narosa Publishing House; 2001.502-508.
5. Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharmacy Practice (Internet)* 2011 Oct-Dec; 9(4):228-235.
6. 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. *Journal of natural science, Biology and Medicine*. 2013; 4:191-6.
7. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions amongst resident doctors. *Journal of Pharmaceutical sciences and research*. 2011; 3:1064-9.
8. 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 Journal of Pharmacology*. 2012; 44(6):699-703.
9. Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. *Perspectives in Clinical Research*. 2015;6(1):45-52.
10. Hanafi S, Torkamandi H, Hayatshahi A, Gholami K, Javadi M. Knowledge, attitudes and practice of nurse regarding adverse drug reaction reporting. *Iranian Journal of Nursing and Midwifery Research*. 2012;17(1):21-25.
11. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under reporting of adverse drug reactions: A challenge for pharmacovigilance in India. *Indian journal of Pharmacology* 2015;47:65-71.