

Original Article

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE (KAP) OF NUTRIVIGILANCE AMONG PHASE-2 MBBS AND POSTGRADUATE STUDENTS OF A TERTIARY CARE HOSPITAL-A CROSS-SECTIONAL OBSERVATIONAL STUDY

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ABSTRACT

Objective: Nutrivigilance is a new concept in India. Several adverse drug reactions (ADRs) arising due to the use of Nutraceuticals are undermined and under-reported by prescribers. Spontaneous reporting of ADRs forms the backbone of Nutrivigilance. This paper will examine the knowledge, attitude, and practice of nutrivigilance among medical students and postgraduate doctors and discuss the need, challenges, and opportunities for improving nutrivigilance in the future.

Methods: A Cross-sectional study was conducted between Phase-2 MBBS (UGs) and Postgraduates (PGs) of GMC, Ananthapuramu. The study tool was a validated questionnaire having 30 questions to evaluate KAP of Nutrivigilance. Data was collected in Google forms and was analyzed using SPSS 21 and P value<0.05 was taken as statistically significant.

Results: The results revealed poor knowledge on Nutrivigilance (UGs-16% and PGs-14%). The Attitude towards Nutrivigilance was equally positive (92%, 94%) in the two groups. Practice on Nutrivigilance was 54% and 52%, respectively. There was no significant difference in KAP on Nutrivigilance between the UGs and PGs.

Conclusion: UGs and PGs lack adequate knowledge and skill of reporting ADR, but both have a positive attitude towards Nutrivigilance programme. To increase awareness on the topic, Nutrivigilance and adverse reaction reporting of nutraceuticals must be added to the academic curriculum of undergraduate and postgraduates, thus improving the reporting and monitoring of ADRs by Nutraceuticals thus improving the health of the community.

Keywords: Nutrivigilance, Nutraceuticals, Phase-2 MBBS, Postgraduates, Knowledge, Attitude, Practice

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INTRODUCTION

Nutrivigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects related to the use of a food, dietary supplement, or medical food” as per Schmitz, *et al.* [1]. The term “Nutraceutical” is coined from “Nutrition,” which is a health-giving, beneficial dietary constituent and “pharmaceutical”, which means medicinal remedy, in 1989 by Dr. Stephen De Felice [2]. Nutraceuticals include dietary supplements, nutrients, herbal supplements, animal-based supplements, and functional foods [3].

Most population in India are malnourished. Instead of consuming fruits and vegetables, most people tend to use nutraceuticals to avert these deficiencies and diseases. Increasing health awareness, drift in population disease demographics where younger people furthermore affected, lifestyle alterations, escalated purchasers' opulence and elevated life expectancy are responsible for increasing market for nutraceuticals in India [4]. In India, multivitamins, multi-minerals, proteins, health drinks, herbs are the common dietary supplements sold in the form of tablets, liquids, powders, capsules, soft gels to improve one's well-being. Most of the common supplements are available without a prescription. An article published by ASSOCHAM under the title “Indian Nutraceuticals Market Study on the Current Scenario and Future trends” has shown an increased surge in usage of nutraceuticals over the past decade [5].

Lack of correct medical information or scientific support for these online-purchased products represents a major public health risk. Most of the nutraceuticals have excess quantities of nutrients than the recommended dietary allowance [4]. Though evidence suggests that few nutraceuticals enhance health in diverse ways, few adverse effects have been reported too [6]. The main problems of dietary supplements intake are represented by several adverse events (e. g.:

hepatic, cardiac, renal, metabolic disorders, neurotoxicity, teratogenicity etc.)

The conception of Nutrivigilance is new in India, unlike that of Pharmacovigilance for reporting adverse events due to medicines. Tools and guidelines for signal discovery need to be developed. The Pharmacovigilance Programme of India (PvPI) receives a veritably limited number of ADRs related to the use of nutraceuticals, health, and food supplements. Currently, the Food Safety and Standards Authority of India (FSSAI) regulates the standards for health supplements and nutraceuticals. The FSSAI defined regulatory guidelines for the approval of nutraceuticals in India. Several adverse drug reactions (ADRs) arising due to the use of Nutraceuticals are undermined and under-reported by prescribers [7].

Still, there has not been much integration of nutrivigilance into standard clinical practice. There are insufficient number of studies done to assess the knowledge of nutrivigilance and usage of nutraceuticals in India. Considering that medical students are more equipped with the clinical knowledge of adverse events due to various drugs, the implications of nutrivigilance for therapeutic success are not well understood by many medical students. This study was taken up with the purpose of evaluating the Knowledge, Attitude, and Practices of Nutrivigilance among Phase-2 MBBS students and Postgraduates and remedial measures to be taken, if needed, to improve it, in order to avoid morbidity and mortality due to adverse drug reactions produced by nutraceuticals which are being consumed by more number of people nowadays.

MATERIALS AND METHODS

Study center

The study was conducted in the “Department of Pharmacology, Government Medical College, Anantapuramu.

Study time

The study was conducted in September 2023.

Study type

It was a questionnaire-based study. It was a cross-sectional study.

Sample size

50 phase-2 undergraduate MBBS (UG) students and 50 postgraduates (PG) willing to take part and give Written Informed Consent were taken into the study. Phase 2 UGs were chosen among all MBBS students as they are freshly exposed to pharmacology syllabus.

Questionnaire

A questionnaire was formulated based on earlier studies on pharmacovigilance and tested in a small group of students. Later, the corrected final questionnaire was given to participants. The questionnaire holds a total of 30 questions—4 for basic demographic data and consent for the study, 14 for testing knowledge, 5 for testing the attitude, and 7 for testing practice in both UG and PG students.

Methods

Before the study began, the questionnaire was viewed and peer-reviewed by our expert teaching staff. The questions in the questionnaire were structured and pre-validated to enable easy collection of data and usage as a tool for research. Study was started after obtaining clearance from the Institutional Ethics Committee (Protocol number: 1-7-23, dated 10/07/2023). After obtaining informed consent from the students, the questionnaire was given to the students via WhatsApp as a google form link. Each correct answer was given one mark and zero was given for the wrong answer. Data was calculated using MS Excel.

Statistical analysis

All statistical analysis was done using SPSS software version 21. Data is mentioned as numerical variables and percentages. Chi-square test was used to test the significance between the two groups. $P < 0.05$ was considered as statistically significant for all statistical analyses.

Google form questionnaire on KAP of nutravigilance

Demographic details—Name, Age/sex, Undergraduate/Postgraduate.

Are you willing to participate in the study—Yes/No

Section 1: Questions pertaining to knowledge on nutravigilance

1. What is Nutravigilance?

- Science and activities relating to detection, assessment, understanding and prevention of adverse events related to use of food, dietary supplement, or medical food
- Science and activities relating to detection, apprehension, understanding and protection of adverse events related to use of medical foods and dietary supplements
- Science and activities relating to assessment, understanding, and reporting of adverse events related to nutrients, dietary supplements, and medical foods

2. What is a Nutraceutical?

- Pharmaceutical alternative which claims physiological benefits
- A specific biological therapy intended to cure pathologies of body
- Any substance that is a food or a part of food and provides medical and health benefits, including the prevention or treatment of disease
- Both a and c

3. Who coined the term 'nutraceutical'?

- Dr Ramesh C Gupta
- Dr Natarajan

c. Dr Stephen DeFelice

4. Who is the father of Indian nutraceuticals?

- Muhammed Majeed
- Sir Ram Nath Chopra
- Oswald Schmiedeberg
- Sir Upendranath Bramachari

5. All the following come under nutraceuticals. Except?

- Probiotics
- Energy drinks
- Food additives
- Vaccines

6. Match the Nutraceutical with its adverse effect.

- Aloe vera - hepatotoxicity
- Omega-3 fatty acids - Prostate cancer
- Green tea - Arrhythmias
- Vitamin e - dysgeusia

a. A-ii, B-iv, C-iii, D-i

b. A-iii, B-iv, C-i, D-ii

c. A-iv, B-iii, C-ii, D-i

d. A-i, B-iv, C-ii, D-ii

7. Choose the correct definition for Adverse drug reaction.

a. A response which is noxious and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function

b. An intended response which occurs at doses that exceed the normal therapeutic dosage used in humans for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function

c. Any allergic or anaphylactic reactions that occur at doses less than the therapeutic dosage used in humans for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function

8. Are adverse drug event and Adverse drug reaction the same? Yes/No

9. Who can report ADR?

- Doctor
- Pharmacologist
- Patient
- All the above

10. ADR reporting is mandatory. True/false?

11. Which method is commonly used for causality assessment of ADRs?

- WHO-UMC scale
- Naranjo scale
- Karch and Lasagna scale

12. Nutraceuticals are regulated by which authority in India?

- Drug Controller General of India
- Food Standards Safety Authority of India
- Drugs and Cosmetics act

13. Pharmacovigilance, Nutrivigilance, Materiovigilance, Cosmetovigilance, Hemovigilance, Biovigilance and Phyto pharmacovigilance are reported to which center in India?

- National Drug Formulary
- National Pharmacopoeia Commission
- National Coordination Center

14. Expand the acronym CDSCO

- Centre for Drugs Standard Controller Organization
- Central Drugs Standard Control Organization
- Committee for Drugs Standard Control and Organization

Section 2: Questions pertaining to attitude on nutravigilance

- ADR reporting on Nutraceuticals is mandatory. Agree/disagree
- Do you think ADR reporting on Nutraceuticals benefits both patients and Doctors? Yes/No
- Should Nutrivigilance be included under the Pharmacology CBME practical curriculum? Yes/No
- Do you think medical students and postgraduates could play a role in ADR reporting of Nutraceuticals? Yes/No
- Do you think collecting box at all clinical departments is helpful for proper reporting of adverse events? Agree/Disagree

Section 3: Questions pertaining to practice on nutravigilance

- Have you ever consumed any Nutraceuticals in your life? Yes/No
- Name the nutraceutical used by you.

Dietary supplements

- Standard nutrients–Vitamins, amino acids, proteins, fatty acids, minerals
- Herbal supplements–Herbal tea, plant extracts, alkaloids
- Animal-based supplements–Shark cartilage, glucosamine and chondroitin, digestive enzymes (lipase and pepsin)

Functional foods and beverages

- Functional foods–Prebiotics, probiotics, mushroom extracts, protein bars, fortified omega-3 fatty acids
- Functional beverages–Energy drinks, sports drinks, fortified juices

Answer: _____

- Have you seen an adverse drug reporting form by CDSCO? Yes/No

4. Have you ever seen a case of ADR with Nutraceuticals? Yes/No

5. Have you ever reported any ADR due to nutraceuticals from your institution? Yes/No

6. Have you ever visited any ADR monitoring center? Yes/No

7. Have you ever given advice to anyone regarding nutraceuticals and nutravigilance? Yes/No

RESULTS

From the data analyzed, there is almost equal participation of both genders in this study i. e, Males–51%, Females–49% [table 1].

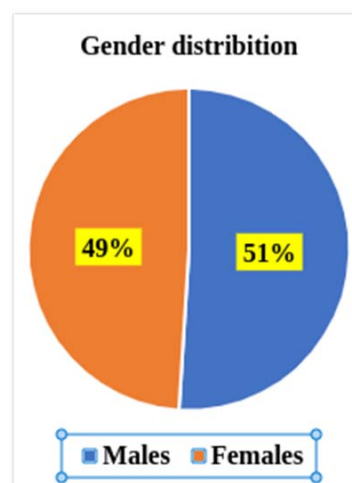


Fig. 1: Pie diagram showing gender distribution in the study

Knowledge on nutravigilance

Only 8 undergraduates (16%) and 7 postgraduates (14%) had adequate knowledge about Nutraceutical and nutravigilance. The basic terminologies of 'Adverse drug reaction', expansion of CDSCO, Regulatory authority of Pharmacovigilance, cosmetovigilance, etc are not known to majority of students [table 2].

Attitude on nutravigilance

A total of 46 Undergraduates (92%) and 47 postgraduates (94%) showed positive attitude towards nutravigilance and willingness to report adverse events arising due to nutraceuticals [table 3].

Table 1: Gender distribution in the study

Graduation	Number of participants in the study		Total (n)
	Male	Female	
Undergraduates	28	22	50
Postgraduates	23	27	50
Total	51	49	100

Table 2: Percentage of students having knowledge on Nutravigilance based on scores

Graduation	Knowledge scores<7		Knowledge score>7		P value
	Number	Percentage	Number	Percentage	
Undergraduates (n=50)	42	84%	8	16%	0.7794
Postgraduates (n=50)	43	86%	7	14%	NS

Total 14 questions were given in the section of knowledge. Correct answers were given 1 mark and wrong answer zero mark. Students who scored more than 7 marks out of 14 were considered as having adequate knowledge on Nutravigilance. 'P' indicates significance at values<0.05; NS–Not significant, Chi-square statistic is 0.0784

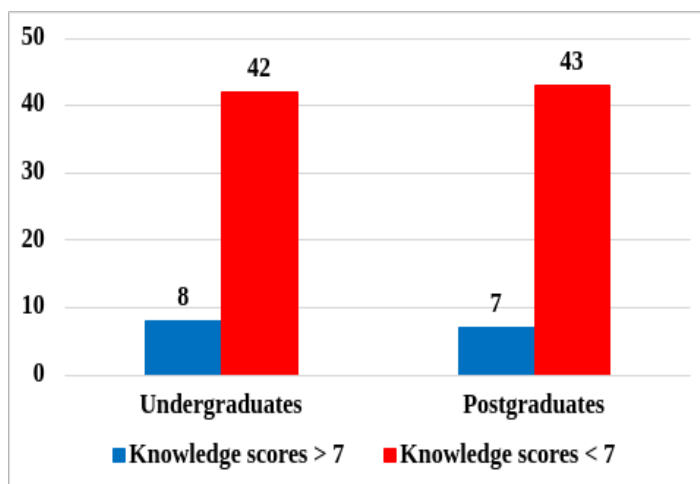


Fig. 2: Bar diagram showing number of students with their scores on knowledge pertaining to Nutrivigilance

Table 3: Percentage of students having positive and negative attitude towards Nutrivigilance

Graduation	Positive attitude (Answers like 'yes', 'agree')		Negative attitude (Answers like 'no', 'disagree')		P value
	Number	Percentage	Number	Percentage	
Undergraduates (n=50)	46	92%	4	8%	0.6951
Postgraduates (n=50)	47	94%	3	6%	NS

Total 5 questions were given in the section of attitude. Responses like 'yes' and 'agree' were considered as positive attitude and responses like 'no' and 'disagree' were considered as negative attitude, 'P' indicates significance at values<0.05; NS-Not significant, Chi square statistic is 0.1536

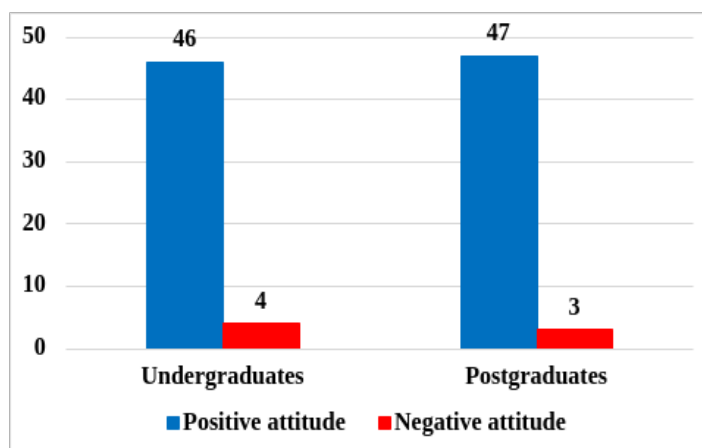


Fig. 3: Bar diagram showing number of students with positive and negative attitude towards Nutrivigilance

Practice on nutrivigilance

About 27 undergraduates (54%) and 26 postgraduates (52%) had shown moderate practice. About 76% of both the groups have an idea about the ADR monitoring center (AMC), located in the Department of Pharmacology, Government Medical College, Ananthapuramu.

Comparison between the variables

From this study, it is clear that there is significant difference between the knowledge and attitude percentages of Undergraduates (16% and 92%) and Postgraduates (14% and 94%) respectively towards nutrivigilance, but it is statistically not significant fig. 5.

Table 4: Percentage of students having good and bad practice towards Nutrivigilance

Graduation	Good practice		Bad practice		P value
	Number	Percentage	Number	Percentage	
Undergraduates (n=50)	27	54%	23	46%	0.8411
Postgraduates (n=50)	26	52%	24	48%	NS

Total 7 questions were given in the section of practice. Correct answers regarding nutraceuticals and nutrivigilance including awareness on such, were taken as good practice. 'P' indicates significance at values<0.05; NS-Not significant, Chi-square statistic is 0.0401

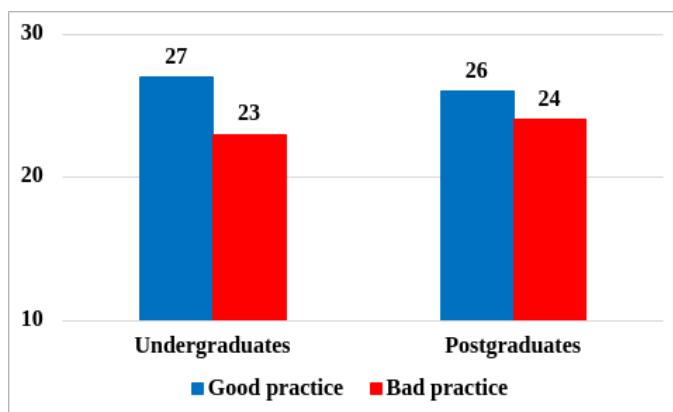


Fig. 4: Bar diagram showing number of students with good and bad practice towards Nutrivigilance

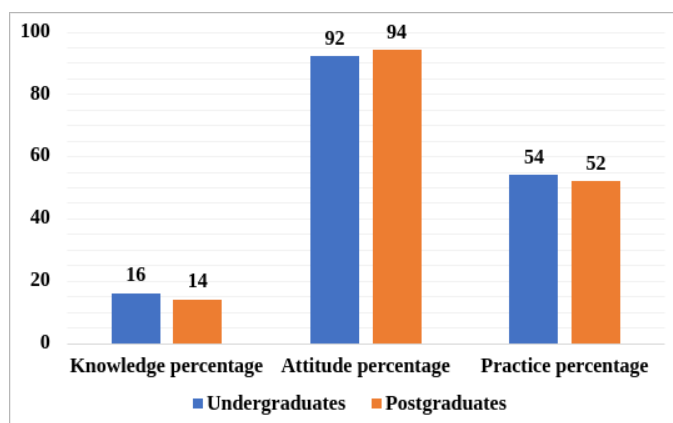


Fig. 5: Knowledge, attitudes, and practices (KAP) domains of UG and PG students regarding Nutrivigilance

DISCUSSION

Nutrivigilance programme should be considered as a part of the health-care system. The objective of nutrivigilance is to incorporate monitoring schemes to discern or identify the adverse effects caused by nutraceuticals for consumer safety. For nutrivigilance to succeed, and especially focused on post-market analysis, there must be a fully committed national surveillance system for nutraceuticals and consumers must have awareness of the spontaneous reporting system. The regulatory authorities, health providers and patients should observe the adverse effects of the nutraceuticals and they need to proactively report the adverse effects related to their consumption.

Despite the debate about benefits, nutraceuticals consumption is constantly growing, especially for students [8]. The evaluation of intake risks can be achieved employing some models used for drugs but adapted to dietary supplements, which include WHO scale, FDA algorithm, the Naranjo scale, Kramer scale or Liverpool scale [4]. Ide *et al.*, have adapted the FDA algorithm to estimate a causality relationship between adverse events and dietary supplements usage [9]. Palet *et al.*, proposed that the adverse events' reporting system must be strongly encouraged all over the world [10]. Researchers confirmed that primary motivation for consuming such nutraceuticals include maintaining good health, increasing energy, muscle strength and enhancing physical performance [6]. It was reported that higher education levels were associated with higher dietary supplements usage [11].

In a study done by Eric A. Klein *et al.*, it has been found that, there is a risk of development of prostate cancer in males on long-term consumption of vitamin E [12]. Similarly, in another study done by Shreena S Patel *et al.*, Green tea extract caused hepatotoxicity in a 16-year-old male [13]. In a study done in Saudi by Mashaal Abdullah Alowais *et al.*, many of health sciences students do not have accurate information about dietary supplements [14]. In a study done by S

Afina *et al.*, students had low objective knowledge of functional foods, but had a positive attitude towards it [15]. Another study done by Singh S *et al.*, to assess the KAP on nutraceuticals among nursing students and medical students showed that medical students have increased knowledge and positive attitude towards nutraceuticals usage [16].

This study presents some aspects that encourage the development of nutrivigilance as a main activity in the dietary supplements field. Spontaneous reporting forms the key of Nutrivigilance programme. The current study suggests that both undergraduate medical students (16%) and postgraduate students (14%) lack sufficient knowledge and have a positive attitude (92%, 94%) towards the role of nutraceuticals in human health and the Nutrivigilance programme. This result does not correlate with previous studies done on KAP of dietary supplements and nutraceuticals in the general population. But, there are no studies to assess the KAP of Nutrivigilance in India.

This study showed that there is no statistically significant difference between the two groups' knowledge, attitudes, or practices; nonetheless, the groups' perceptions of nutrivigilance attitudes are more favorable than their awareness and application.

CONCLUSION

This study concludes that phase-2 undergraduates and PGs lack adequate knowledge and skill of reporting ADR from Nutraceuticals, but both have a positive attitude towards Nutrivigilance programme. There is a wide variation in the knowledge and attitude aspect of both the groups.

Awareness among the healthcare fraternity is to be created to minimize the use of nutraceuticals and to be used whenever essential. The need, scope, and importance of Nutrivigilance is to

improve the process of adverse events reporting in the country due to the recent surge in the growth of nutraceuticals. More strict vigilant measures need to be implemented to raise concerns regarding nutraceuticals. Reducing the over-the-counter availability of nutraceuticals will reduce the excess unwanted intake by student communities who hope for the miracle of improving their health and physical fitness by alternate means. More number of community outreach programmes, Continuing Medical Education (CME) on Nutrivigilance can be conducted among UG and PG students during their study period. More of orientation programmes, foundation courses to medical, nursing and practicing doctors can be given to enrich their knowledge and increase the practice. It is important to strengthen the health science curriculum concerning this topic and access to scientific and unbiased information with the aim of producing better-informed future health professionals.

It is recommended to carry on more studies across India to correlate with the findings and to assess the knowledge aspect among students of various geographical zones within the country.

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Nil

AUTHORS CONTRIBUTIONS

All authors have contributed equally.

CONFLICT OF INTERESTS

Declared none

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