



Original Article

Knowledge, Attitude and Practices (Kap) Regarding Nutrivigilance Among Postgraduate Students and Clinicians of A Tertiary Care Teaching Hospital: A Cross- Sectional Observational Study.

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ABSTRACT

Background: Nutrivigilance is a discipline focused on the detection, assessment, and prevention of adverse effects associated with dietary supplements and nutraceuticals. In spite of increasing consumption of these products, awareness, reporting practices among healthcare professionals is suboptimal.

Aim: To assess the knowledge, attitude, and practices (KAP) regarding nutrivigilance among postgraduate students and clinicians in a tertiary care teaching hospital.

Methods: A hospital-based cross-sectional observational study was done among 500 postgraduate students and clinicians using a pre-validated, structured questionnaire. The questionnaire assessed sociodemographic details and KAP domains.

Results: Among 500 participants, 50.6% showed moderate knowledge. 25.4% had good knowledge and 24.0% had poor knowledge regarding nutrivigilance. Awareness of nutrivigilance was reported by 63.4%. 52.8% were aware of existing reporting systems. A positive attitude towards nutrivigilance was seen in 65.4% of participants. 74.6% had prescribed nutraceuticals and 33.6% had encountered adverse events, but only 13.2% reported these events. 56.8% showed poor practice levels.

Conclusion: In spite of positive attitude, there is significant gap in the knowledge and reporting practices related to nutrivigilance. Structured educational interventions and strengthened reporting mechanisms are needed to enhance safety surveillance of nutraceuticals and promote patient safety.

Keywords: Nutrivigilance, Nutraceuticals, Knowledge Attitude Practice, Adverse Event Reporting, Healthcare Professionals.

INTRODUCTION

Nutrivigilance is a field that deals with systematic detection, assessment, understanding, and prevention of adverse effects related to the use of dietary supplements, functional foods, and nutraceutical products. It applies principles similar to pharmacovigilance to non-prescription food-derived products that are commonly used for health enhancement but are usually perceived as inherently safe by consumers and healthcare providers alike.¹

The global market for dietary supplements and nutraceuticals has expanded rapidly in recent years. But regulatory frameworks in many regions do not mandate pre-marketing safety studies comparable to those required for pharmaceuticals, and post-marketing surveillance systems for these products remain underdeveloped. This creates a risk for unrecognized adverse events, drug-supplement interactions, and public health issues due to underreporting and lack of systematic monitoring.²

Nutrivigilance fills this gap by encouraging adverse event reporting from stakeholders, including consumers, clinicians, manufacturers, and regulatory bodies, thereby enhancing product safety and protecting public health.³ In Europe and the United States, voluntary and country-specific surveillance systems have showed the feasibility and value of nutrivigilance in capturing suspected adverse reactions related to supplement use.

Awareness and implementation of nutrivigilance practices among healthcare professionals and trainees are limited, especially in developing countries where the prevalence of dietary supplement use is high and regulatory oversight may be less stringent. Lack of structured education and reporting culture can lead to missed opportunities for identifying safety signals and improving patient outcomes.⁴

Assessing the knowledge, attitudes, and practices (KAP) regarding nutrivigilance among postgraduate students and practicing clinicians at tertiary care teaching hospitals is needed to identify gaps, inform educational interventions, and strengthen surveillance mechanisms.⁵ To date, few studies have evaluated KAP in this domain, especially in the Indian context where nutraceutical consumption is increasing but formal nutrivigilance systems are still nascent.^{6,7}

This study helps to fill that gap by evaluating how postgraduate students and clinicians perceive nutrivigilance, their level of awareness about adverse effect reporting related to nutraceuticals, and their actual reporting behaviors in a tertiary care setting.

AIM AND OBJECTIVES

Aim

To assess the knowledge, attitude, and practices regarding nutrivigilance among postgraduate students and clinicians working in a tertiary care teaching hospital.

Objectives

1. To evaluate the level of knowledge about nutrivigilance, including its definition, scope, reporting systems, and regulatory framework among postgraduate students and clinicians.
2. To assess the attitudes of postgraduate students and clinicians towards the importance of nutrivigilance and adverse event reporting related to nutraceuticals and dietary supplements.
3. To determine the current practices of adverse event reporting related to nutraceuticals among postgraduate students and clinicians.

MATERIALS AND METHODS

Study Design

Hospital-based, cross-sectional observational study.

Study Setting

The study was done at tertiary care teaching hospital, including various clinical and para-clinical departments.

Study Population

Postgraduate students and clinicians working in the tertiary care teaching hospital.

Sample Size Calculation

The sample size was calculated using the formula for estimating proportion in a cross-sectional study:

$$n = 4PQ / L^2$$

Therefore:

$$P = 50$$

$$Q = 100 - 50 = 50$$

$$L = 5\%$$

Thus, the minimum required sample size was 400.

Considering a 20% non-response rate:

$$20\% \text{ of } 400 = 80$$

$$\text{Adjusted sample size} = 400 + 80 = 480$$

To improve representativeness and ensure adequate statistical power, the final sample size was rounded to 500 participants.

Therefore, the final sample size for the study was 500.

Sampling Technique

A stratified random sampling method was used. Participants were stratified into:

- Postgraduate students
- Senior residents
- Consultants / faculty

Proportionate sampling was applied to ensure representation from different departments.

Inclusion Criteria

- Postgraduate students (all years)
- Senior residents and consultants

Exclusion Criteria

- Interns and undergraduate students
- Healthcare professionals not directly involved in patient care
- Incomplete questionnaire responses

Study Tool

Data were collected using a pre-validated, structured, self-administered questionnaire consisting of four sections:

1. Sociodemographic details (age, gender, department, designation, years of experience)
2. Knowledge domain (definition, scope, adverse event reporting, regulatory awareness)
3. Attitude domain (Likert scale-based statements regarding importance and responsibility)
4. Practice domain (experience with prescribing nutraceuticals, reporting adverse events)

The questionnaire was a pilot tested on 10% of the sample (not included in final analysis) to assess clarity and reliability.

Data Collection Procedure

After obtaining approval from the Institutional Ethics Committee, participants were approached in their respective departments. The purpose of the study was explained, and written informed consent was obtained.

The questionnaire was distributed either in printed form or electronically (Google Forms). Confidentiality and anonymity was maintained.

Outcome Measures

- Level of knowledge (categorized as poor / moderate / good based on scoring)
- Attitude towards nutrivigilance (positive / neutral / negative)
- Reporting practices of adverse events related to nutraceuticals

Data Analysis

- Data were entered into Microsoft Excel and analyzed using SPSS version 17.0. Descriptive statistics: frequency, percentage, mean, and standard deviation.
- Chi-square test was used to assess association between demographic variables and KAP scores.

A p-value < 0.05 was considered statistically significant.

RESULTS

Knowledge Level Regarding Nutrivigilance:

More than half of the subjects (50.6%) showed moderate knowledge, while only 25.4% had good knowledge. Awareness of nutrivigilance was reported by 63.4% of participants, and 52.8% were aware of existing reporting systems.

Table 1: Knowledge domain assessment among subjects

Knowledge Variable	Frequency (n)	Percentage (%)
Knowledge Level		
Poor	120	24.0
Moderate	253	50.6
Good	127	25.4
Awareness of Nutrivigilance		
Yes	317	63.4
No	183	36.6
Awareness of Reporting System		
Yes	264	52.8

Knowledge Variable	Frequency (n)	Percentage (%)
No	236	47.2

Attitude Towards Nutrivigilance: 65.4% of the subjects had positive attitude toward nutrivigilance.

Table 2: Attitude domain assessment among subjects

Category	Frequency	Percent
Negative	62	12.4
Neutral	111	22.2
Positive	327	65.4

Practice domain

74.6% of participants had prescribed nutraceuticals and 33.6% had encountered adverse events, but only 13.2% reported such events. More than half (56.8%) showed poor overall practice levels.

Table 3: Practice domain assessment among students

Practice Variable	Frequency (n)	Percentage (%)
Ever Prescribed Nutraceuticals		
Yes	373	74.6
No	127	25.4
Encountered Adverse Events		
Yes	168	33.6
No	332	66.4
Reported Adverse Events		
Yes	66	13.2
No	434	86.8
Overall Practice Level		
Poor	284	56.8
Good	216	43.2

DISCUSSION

This cross-sectional study assessed knowledge, attitude, and practices regarding Nutri vigilance among postgraduate students and clinicians in a tertiary care teaching hospital. The findings showed gaps in awareness and reporting practices in spite of positive attitude.

In this study, only about one-quarter of participants showed *good knowledge* of nutrivigilance concepts. This is consistent with previous assessments in related domains showing limited awareness of safety reporting systems among health professionals. Studies on pharmacovigilance have similarly shown significant gaps in knowledge of adverse event reporting systems among clinicians and allied healthcare workers, with many participants unaware of national programs or reporting procedures.¹ These findings indicate that new surveillance fields like nutrivigilance, which combine elements of pharmacovigilance with food supplement safety, are usually under-recognized by providers.

Attitude toward nutrivigilance was mainly positive, and most participants agreeing on the importance of reporting adverse events. This is similar with the literature on pharmacovigilance KAP, where healthcare professionals express a favourable view toward the concept of safety surveillance but still fail to translate it into practice. In India, a meta-analysis of pharmacovigilance awareness found that many clinicians believed ADR reporting was necessary, but large percentage had never reported an event.⁸ The positive attitude seen in the current study shows willingness to engage with post-marketing safety measures if training and systems support are improved.

In spite of positive attitudes, actual *practices* of reporting adverse events related to nutraceuticals were low in our study. This underreporting shows trends seen in pharmacovigilance and nutrivigilance contexts. Spontaneous reporting in established nutrivigilance systems, like those tracking red yeast rice supplement reactions, has shown low case reporting rates relative to the consumer exposure population, showing the broader challenge of capturing adverse event data for non-

regulated products.⁹ Underreporting reduces the ability to detect safety signals and protect public health, and implies the need for structured training and dedicated reporting mechanisms.

Limited knowledge and practice seen in this study may also be affected by the relative novelty of nutravigilance as a defined discipline. Compared with pharmacovigilance, nutravigilance frameworks are less established globally and lack clear regulatory mandates or reporting pathways in many countries. Studies have noted that existing systems for dietary product adverse event reporting operate in a fragmented manner without standardized vigilance procedures.¹⁰ This regulatory doubt may contribute to hesitancy or confusion among clinicians regarding their role in monitoring nutraceutical safety.

Due to high and increasing consumption of dietary supplements and nutraceuticals worldwide, strengthening nutravigilance systems is critical. Poorly monitored supplements can pose risks like mild gastrointestinal symptoms to severe reactions, which is evidenced by international audits of supplement-related adverse events. Enhancing awareness and training among clinicians is essential to improve reporting rates and to integrate nutravigilance into routine clinical practice.^{11,12} The study's strengths include a large sample size and representation of both trainees and practicing clinicians.

Limitations include:

Self-reported data that may be affected by recall bias and the single-institution setting, which may limit generalizability. Future research should consider multi-centre studies and interventions like educational modules and simplified reporting tools to improve nutravigilance engagement.¹³

CONCLUSION

Postgraduate students and clinicians showed positive attitude toward nutravigilance and recognized its importance in ensuring patient safety, significant gaps exist in their knowledge and actual reporting practices. But more participants had only moderate or poor awareness of nutravigilance concepts, reporting systems, and regulatory frameworks. These findings indicate a clear gap between awareness and implementation of nutravigilance practices in clinical settings. Underreporting of adverse events related to dietary supplements may compromise early detection of safety signals and limit public health protection. So, there is a need for structured educational interventions, inclusion of nutravigilance training in postgraduate curricula, and establishment of clear, accessible reporting mechanisms within healthcare institutions. Strengthening institutional and national nutravigilance systems will promote a culture of safety monitoring and improve patient care outcomes related to nutraceutical use

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