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KNOWLEDGE, ATTITUDE, PRACTICE AND PERCEPTION REGARDING NUTRIVIGILANCE AMONG MBBS STUDENTS

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Abstract

Background: Nutrivigilance is considered 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". Food Safety and Standards Authority of India (FASSI)- a regulatory guideline functioning since 2016 to regulate the adulteration of various foods, its adverse effects, bioavailability of Nutraceuticals. Although medical students understand the clinical and adverse events of these Nutraceuticals, we lack sufficient studies to provide evidences that project the therapeutic success of these foods; hence, it is essential to understand the integration of Nutrivigilance into standard clinical practice. Aim and Objectives: To assess the Knowledge, Attitude, Practice and Perception of Nutrivigilance among Phase-2 MBBS students. Methodology: A cross sectional study was conducted in a medical college involving 2nd year MBBS students using a Semi-structured questionnaireto assess their knowledge, Attitude, Practice and perception of Nutrivigilance and Nutraceuticals consumption. Results: A total of 166 medical undergraduates were recruited, and was observed thatknowledge of FSSAI expansion was 91.57% and that of Nutrivigilance was 86.75%. Adverse effects due to intake of food, nutritional supplements and medical foods were observed in 90.96%. Conclusion:There is sufficient knowledge regarding FASSI and Nutrivigilance among the students, but lack the motive to report due to barriers. There is a need 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.

Key Words: Nutrivigilance, Food Safety and Standards Authority of India, Nutraceuticals, Adverse effects

INTRODUCTION

Evolution of nutrition and diet have created a broad space in various sectors such as Nutraceuticals, food industries and so on, however, in a developing country like India, there is always a growing interest towards fancy beneficial dietary constituent that is readily available to give health benefits irrespective of its cons. Hence, to monitor all the activities occurring in such sectors one has established Nutrivigilance which is considered 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".[1, 2]Further development of this was undertaken by Food Safety and Standards Authority of India (FASSI)- a regulatory guideline functioning since 2016 to regulate the adulteration of various foods, its adverse effects, bioavailability of Nutraceuticals. Keeping these entire aside, it is essential to know and understand the nutritious benefits and correct medical information or scientific support and major public health risk associated with these dietary supplements intake are represented by several adverse events (e. g.: hepatic, cardiac, renal, metabolic disorders, neurotoxicity, teratogenicity etc.).[3, 4]

Although medical students understand the clinical and adverse events of these Nutraceuticals, we lack sufficient studies to provide evidences that project the therapeutic success of these foods; hence, it is essential to understand the integration of Nutrivigilance into standard clinical practice. The nutritional supplements contain macro and micro nutrients that aid

in boosting sports athletes, in some situations there could be a risky nature of the consumed Nutraceuticals which might accumulate more nutrition than necessary leading to some crucial disorders such as cardiovascular diseases, intestinal disorders and so on. Once they are exposed to such comorbidities, they rush to medical practioners for remedy and treatment who are unaware of such Nutraceuticalsproducts.[5, 6]It is essential for medical practitioners to be aware of Nutraceuticals products and its adverse effects. Hence this study was undertaken to evaluate the Knowledge and perception of Nutrivigilance among Phase-2 MBBS students.

METHODOLOGY

It is a cross-sectional questionnaire based study conducted at Sri Siddhartha Medical College, Tumakuru, Karnataka, India involving 166 MBBS students belonging to 2nd year during October to December 2023. The study was conducted after taking prior approval from the ethics committee and only participants who are willing to consent were enrolled. The study tool was a pre-designed, pre-tested, semi-structured questionnaire (data collection tool) that included socio-demographic profiles (age, gender, school language medium), details of postings, and precise objective and subjective internalization on Nutrivigilance. The questionnaire consisted of 19 questions involving knowledge (8), attitude (2), practice (5) and perception (4). The data obtained was entered into Microsoft Excel; frequencies and percentages were calculated.

RESULTS

Present study involving 166 students were assessed to understand their knowledge about the Nutrivigilance, its benefits,adverse effects, aware of FSSAI authorities, and controversies reported to FSSAI. Thedemographic characteristics like age, gender, school and language were recorded. There was no major difference in demographic data, with female preponderance; the age range is from 20 to 21.

Knowledge of FSSAI expansion and reporting adverse effects related to food and nutritional supplements were 91.57% and 90.96% respectively, but poor for cosmetics, drugs and medical equipment. They were also aware of whom to report ADR (81.93%), complaint regarding Misleading claims and advertisement (84.94%);and food poisoning and allergic reactions (86.75%). (Table 1)

Although 63.86% of participants had concerns about the long term effects of nutraceuticals, there were multiple barriers to discourage reporting to the authorities like poor awareness, someone else will report, no interest and too much effort needed.(Table 2)

Out of 166 participants only 59 have consumed supplements (35.54%),and with prescription (59.64%). Adverse reactions were experienced by 42 participants (25.3%) but reporting was done only by 20 participants. More than half of the participants have never or rarely checked the FSSAI logo before buying. (Table 3)

The perception of the participants about the transparency of adverse effects should be on the manufacturer (84.94%) and any reactions should be reported by all; the doctors, consumers and manufacturers (68.67%). The importance of reaction reporting is agreed by majority of participants (85.54%) but simultaneously they suggested the lack of knowledge among the public is 71.69% which is high and needs orientation.

Although with several conflicting opinions, 71.69% were saying not to have any Nutrivigilance awareness among general public. 85.54% of students said that it is very important to report adverse effects. 40.96% students reported that several potential reasons and barriers discourage the reporting of adverse events related to nutrition products and majorly 63.86% of students were concerned about the potential of long term of consuming certain nutrition products.

TABLES AND CHARTS

Table 1: Knowledge of participants towards Nutrivigilance

Screening Parameters		Frequency	Percentage
Definition of Nutrivigilance	**Reporting adverse effects of cosmetics including beauty and skincare products**	9	5.42%
	Reporting adverse effects of drugs prescribed by medical professionals	3	1.81%
	Reporting adverse effects of food, nutritional supplements and medical foods	151	90.96%
	Reporting adverse effects of medical equipment used in hospitals	3	1.81%
Adverse effects reported to -	**FDA**	22	13.25%
	FSSAI	136	81.93%
	No such body	8	4.82%

Expansion of FSSAI	**Food Safety and Standards Authority of India**	152	91.57%
	Food Security Sincerity and Adverse effects Inquisition	13	7.83%
	Food Supplements, Savory food And Inedible items	1	0.60%
Issues can be reported to FSSAI	**Adulterated**	9	5.42%
	Misleading claims & advertisements	141	84.94%
	Unsafe food or substandard food	2	1.20%
	All of the above	14	8.43%
Responsible for ensuring the safety of food products and supplements	**Consumers**	44	26.5
	Manufacturers	106	63.85
	Medical professionals that promote the product	84	50.60
	Oneself	1	0.60
	Government	120	72.28
Complaints that may report to FSSAI	**Food poisoning and allergic reaction**	144	86.75%
	High price of vegetables	7	4.22%
	Inflation of product prices	4	2.41%
	Poor costumer service	11	6.63%
Difference between Pharmacovigilance and Nutrivigilance	**Pharmacovigilance is for doctors and Nutrivigilance is for consumers**	9	5.42%
	Pharmacovigilance is for drugs and Nutrivigilance is for food	121	72.89%
	Pharmacovigilance is more important than Nutrivigilance	4	2.41%
	All of the above	32	19.28%

Chart 1: Assessment of knowledge towards adverse events

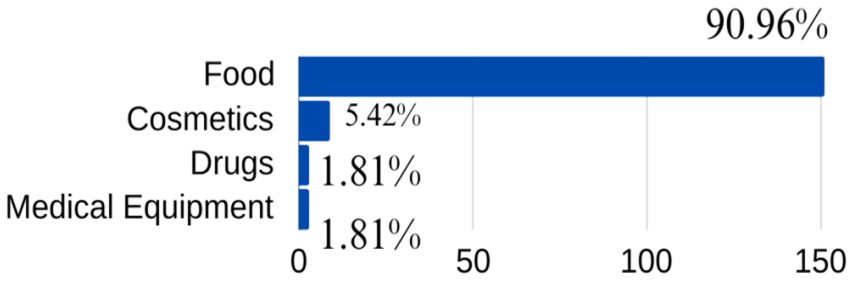


Table 2: Attitude of participants towards Nutrivigilance

Parameters		Frequency	Percentage
Barriers that discourage the reporting of adverse events related to nutrition products	**Lack of awareness**	38	22.89%
	Believing that someone else will report	33	19.88%
	Lack of interest	20	12.05%
	Too much effort	7	4.22%
	All of the above	68	40.96%
Concern about the potential of long term of consuming certain nutrition products	**Yes**	106	63.86%
	No	23	13.86%
	Not necessarily	37	22.29%

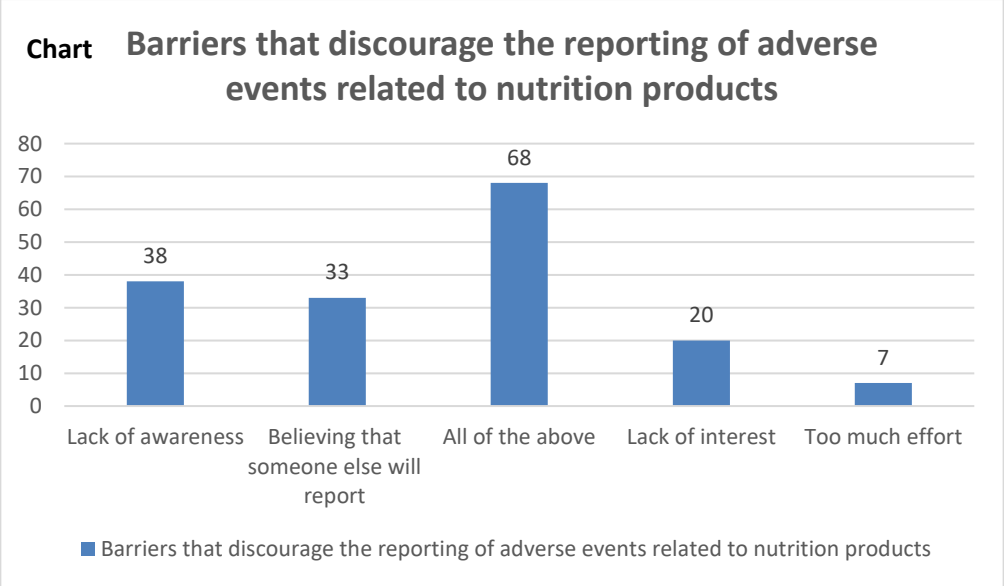


Table 3: Practice related distribution

Parameter		Frequency	Percentage
Taking Supplements	**Yes**	59	35.54%
	No	107	64.46%
Taking Supplements without prescription	**Yes**	67	40.36%
	No	99	59.64%
Experienced food reactions (rashes, food poisoning, allergies, etc.)	**Yes**	42	25.30%
	No	124	74.70%
Report Food reactions (42)	**Yes**	20	47.61%
	No	22	52.38%
Check FSSAI logo before buying food products	**Always**	22	13.25%
	Most of the times	55	33.13%
	Never	22	13.25%
	Sometimes	67	40.36%

Table 4: Perception of participants regarding Nutrivigilance

Parameters		Frequency	Percentage
Manufacturers should be transparent about adverse effects	**Neutral**	7	4.22%
	Somewhat important	18	10.84%
	Very important	141	84.94%
Ill effects of food to be reported to-	**Consumers**	35	21.08%
	Doctors	44	26.50%
	Manufacturers	34	20.48%
	All of the above	114	68.67%
Nutrivigilance awareness among general public	**Yes; awareness programs needed**	35	21.08%
	Yes; awareness programs not needed	6	3.61%
	No; awareness programs needed	119	71.69%
	No; awareness programs not needed	6	3.61%
Important to report adverse effects	**Neutral**	2	1.20%
	Somewhat important	21	12.65%
	Very important	142	85.54%
	Not important	1	0.60%

Chart 3: To whom should be reporting

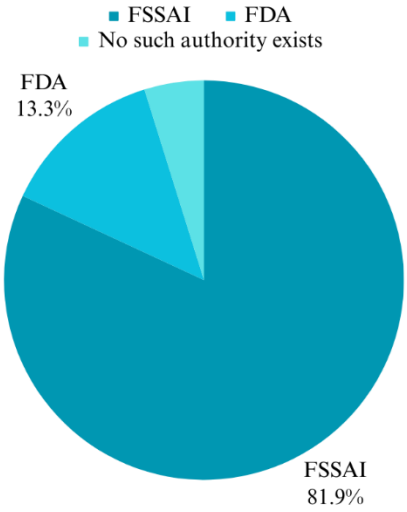
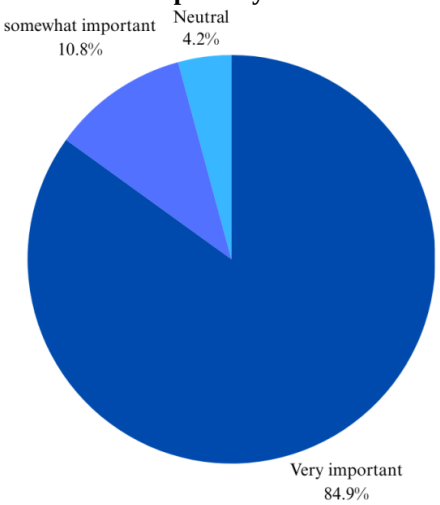


Chart 4:Importance of transparency on behalf of manufacturers



DISCUSSION

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. In our study, students having knowledge of FSSAI expansion and reporting adverse effects related to food and nutritional supplements were 91.57% and 90.96% respectively, but poor for cosmetics, drugs and medical equipment. They were also aware of whom to report ADR (81.93%), complaint regarding Misleading claims and advertisement (84.94%); and food poisoning and allergic reactions (86.75%). (Table 1) In accordance to our study, S. Arun et al has Cross-sectional study was conducted between Phase-2 MBBS (UGs) and Postgraduates (PGs) of GMC, Ananthapuram[7]. 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. In our study, 63.86% of participants had concerns about the long term effects of Nutraceuticals, there were multiple barriers to discourage reporting to the authorities like poor awareness, someone else will report, no interest and too much effort needed. (Table 2). However, in S. Arun et al study there was no significant difference in KAP on Nutrivigilance between the UGs and PGs. 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.

In our study, out of 166 participants only 59 have consumed supplements (35.54%), and with prescription (59.64%). Adverse reactions were experienced by 42 participants (25.3%) but reporting was done only by 20 participants. More than half of the participants have never or rarely checked the FSSAI logo before buying. (Table 3) In a study conducted by Singh, Sruthi et al[8], out of total 273 (65.8%) participants had good knowledge and only 47 (11.3%) had positive attitude. About 68.7% medical students and 82.7% nursing students felt that regular intake of Nutraceuticals has a

positive role in protecting against COVID-19 (p-value=0.007). Out of 415, 264 participants (63.6%) had used Nutraceuticals. About 156 (58.9%) medical students and 103 (68.7%) nursing students felt that the safety of Nutraceuticals is a grave concern. Two- fifth of the participants (202, 48.7%) had consumed a dietary supplement to maintain good health. Although the knowledge score was good, but positive attitude was lacking. Thus, Healthcare Personnels (HCP)s should be trained regarding proper usage and recommendations of Nutraceuticals.

Similarly, Redhwan A. A et al[9] in their study found that majority of the participants were medical students and they were asked about food allergy perceptions and opinions and found that 40 (67%) mentioned that the common symptoms of food allergy are: skin rashes, swollen lips, diarrhea, vomiting, bronchospasm, redness, itchiness, difficulty in breathing, stomach ache and fever. Majority of participants mentioned that seafood is the food that can cause most food allergies 52 (87%), followed by tree nuts 25 (42%), peanuts and dairy products 19 (32%). Regarding the most allergenic food named by the participants are seafood 23 (38%); followed by milk and dairy products 5 (8%) and nuts 5 (8%). The majority of participants mentioned that food allergy can be fatal 48 (80%), a child can catch food allergy 57 (95%), and 10 of 100 people would have food allergy 31 (52%). Half of the participants 30 (50%) mentioned that it is very hard to care for children with food allergy. The majority of participants mentioned that food allergies do run in families 50 (83%), avoiding allergenic food is the best preventive methods 36 (60%) and that food allergy can be treated and will go away and 32 (53%). This study showed that in spite of sufficient knowledge among medical students about food allergy, some misconceptions still exist such as the high prevalence of food allergy and that food allergy can be treated and will go away. Therefore, there is a need for improving the continuous medical education among medical students with regard to food allergy because they are our future physicians.

Further, Annamalai et al[10] in their study evaluated the knowledge, attitudes, and utilization of food labels among undergraduate medical students in a medical college in Chennai. A cross-sectional survey was conducted of 200 students studying in the 1st to 3rd year in a medical college through an online Google Forms survey, self-administered by the students after online informed consent was obtained. Gathered information on their knowledge, attitudes, and utilization of food labels. It was observed that out of 400 students approached, 200 responded to the online survey. They had good knowledge about food labels. Female students had 3.4 (1.59 to 7.25) times better knowledge compared to men. The students had a positive attitude toward food labels, and a majority thought that the food labels are useful. Utilization of food labels to understand the nutritive content (55%), additives (57%), and manufacturer details (47%) was poor. Utilization of food labels was 2.7 times more (1.142–6.587) among those who did regular exercise, and it was 0.2 (0.09 to 0.9) times less among those who were on a strict diet. Therefore it was concluded that Medical students had a sound knowledge and good attitude toward food labels, but their food label utilization patterns were still poor. There is a need to incorporate food labelling in the undergraduate medical curriculum and inculcate better food label utilization behavior.

CONCLUSION

Present study concludes that phase-2 undergraduates still require more adequate knowledge and skill of reporting ADR from Nutraceuticals, but they have a positive attitude towards Nutrivigilance programme. There is a need, scope, and importance of Nutrivigilance to be improved to understand 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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