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Review Article

Safety concerns of dietary and herbal supplements for typical patients

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ABSTRACT

The global dietary cum herbal supplements market crossed 140 billion U.S. dollars in 2020 already. Hence, it is evident that the supplements market is growing very fast globally, including India, one of the best potential markets. Market and marketing are always good for a country's better economy, but safety management is more critical, while health is a concern. This study aims to assess and understand the various safety concerns of dietary cum herbal supplements available globally, where India has focussed more. Some countries believe in the natural products often consumed as supplements without knowing their indications, contraindications, and drug interactions. Hence, this article was written to understand consumers' and typical patients' supplements consumption behaviors irrespective of authors' perception. Easy keywords and phrases such as 'common dietary supplements,' 'popular herbal supplements,' 'indications and contraindication of supplements' were used for the online searches. Many physicians, dietitians, and medical scientists have already shown the adverse effects of some supplements in pregnancy, lactation, and other critical conditions. Still, on the other hand, there are some positive effects in the chronic health issues, including skin and hair health issues, poor immunity, gastric problems, undernutrition. Selective supplements can also help post-operative recovery, muscle, bone, cognitive development, vitamin deficiency, endocrine disorders, and many more. The study has emphasized the government policies and regulations as applicable irrespective of the country. India is the 2^{nd} population-based country globally; hence more vigilance is needed at every level of supplement business for public health safety. Moreover, all authors have put their valuable summary that more awareness is required about indications and contraindications of various types of supplements, particularly for typical patients. It's not only doctors' or dietitians' job but everyone's concern.

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1. Introduction

Supplements are the additional synthetic food products consumed orally in tablets, capsules, powder, soft gels, or liquid. Vitamins, minerals, herbs or other botanicals, amino acids, enzymes, tissues from organs or glands, or extracts are among the dietary elements that are supplemented. Some dietary supplements may have some value, such as melatonin for jet lag, while ginkgo for dementia may have little or no benefit. Supplements purchased in stores or

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online may differ significantly from those examined in the research. The majority of evidence demonstrates that taking multivitamins unnecessarily does not prolong life, prevent cognitive decline, or reduce the risk of cancer, heart disease, or diabetes. $^{1-3}$

1.1. Actions and interaction of dietary supplements among patients

Dietary supplement interactions might be of two types. When the intrinsic action of a dietary supplement augments or antagonizes the activity of another medicine, this is

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known as pharmacodynamic interaction. Pharmacokinetic interactions occur when the active component of a dietary supplement or medicine changes metabolism, excretion, absorption, or protein binding. Such actions result in increased or decreased pharmacologic activity.²

1.2. Drug interactions

Critically ill or typical patients who are under cardiac, psychiatric medications must avoid consuming unwanted dietary supplements. Studies show that patients must avoid garlic, Ginkgo Biloba, ginseng while taking warfarin as anticoagulant medicine. HIV, Diabetic, and other allergic prone patients must also abstain from unwanted dietary supplements except for the doctors' or skilled dietitian's prescription. Nutritional supplements should be recommended only if they are mandatory or adequately applicable to that patient; otherwise, they should be avoided. The quacks, below category fitness trainers, push-sale companies, or sellers should not consume the products.²

2. Research Methods

This review study is based on India's most sold and gradual demand for dietary and herbal supplements and the current global scenario. The paper was written based on extensive digital searches of relevant open-access literature in good quality and reliable databases. Pubmed, Directory of Open Access Journals (DOAJ), Google Scholar, and other government portals of food and agriculture are the accessible databases used for searches. Keywords and phrases used for online searches: 'common dietary supplements' 'popular herbal supplements' 'indications, and contraindication of supplements,'

3. Discussions

3.1. Herbal medicines' indications and contraindication

Herbs are whole, fragmented, or powdered plant parts such as leaves, flowers, fruit, seeds, stalks, wood, bark, roots, rhizomes, or other plant components. Herbal medicines include herbs, materials, preparations, and finished herbal products. In some countries, herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin. Herbal preparations can comprise comminuted or powdered herbal components and extracts, tinctures, and fatty oils of herbal materials. Extraction, fractionation, purification, concentration, and other physical or biological procedures are used to make them. They also include herbal concoctions created by steeping or boiling herbs in alcoholic beverages, honey, or other substances. Herbal preparations created from one or more herbs are referred to as finished herbal products. ^{3,4}

Toxicity from the outside is contamination through harmful metals, adulteration, misidentification, adulteration, badly processed or produced products can all cause adverse consequences with herbal medications. Toxicity from the inside is that the toxicity is generated inside the body itself. The intrinsic toxicity of some herbs at regular therapeutic doses or in overdose is a direct factor. Adverse reactions to Aristolochia, Ephedra, and Aconitum have shown that people's herbal products could be toxic.⁵

3.2. WHO guidelines on safety monitoring of herbal medicines⁶

- 1. Some patients experienced corticosteroid-like adverse effects due to several herbal medicines were discovered to contain 100–300 mcg of betamethasone per capsule.
- Plant materials containing aristolochic acid were employed for making herbal remedies due to misidentification of therapeutic plant species, resulting in severe renal failure in patients in numerous countries.
- 3. Drug safety monitoring organizations have received reports of delayed prothrombin times, increased coagulation time, subcutaneous hematomas, and cerebral hemorrhage related to Ginkgo biloba use.
- When administered in concert with interferon, one of the most well-known traditional herbal treatments caused severe, sometimes fatal, episodes of interstitial pneumonia.

3.3. Safety regulation

The respective country's national pharmacovigilance centers will need to focus on understanding technical knowledge to control herbal medicines, mainly to analyze the causes of adverse outcomes. This will involve qualified professionals relevant to specialized areas and facilities to examine the items in question, which frequently lack sufficient knowledge and reliable information support. Many countries now lack this competence, especially regarding access to proper analytical laboratories. As a result, the Member States have advocated the development of regional laboratories specializing in analyzing herbal products. Consumers would get benefits from a regulatory framework for natural medications.

On the other contrary, Herbal medicines are regulated and specified differently in each country. Herbal medications were classified as dietary supplements, functional foods, health products, or drugs, resulting in a patchwork of regulations and a chaotic market. The World Health Organization should propose unified international planning, with global management and quality standards as an element. To ensure the quality and safety of herbal medicines, the WHO also focuses on the radical source of herbs, seed and seedling breeding, planting, harvesting,

 Table 1: Indication vs. contraindications of popular supplements

Name of supplement	Available Form	Indication	Contraindication
Multivitamins	Capsule/Tablet	Deficiency of vitamins, post-operative, fatigue, chronic and acute disorders	Excess or unwanted intake may cause bloating, stomach upset, headache, nausea. ^{7–9}
Multivitamins with minerals	Capsule/Tablet	Minerals and vitamin deficiency, post-operative, fatigue, chronic and acute disorders, muscle growth, and cognitive development	Excess or unwanted intake may cause constipation, bloating, stomach upset, headache, nausea, vomiting, dark stool. ^{7–9}
Probiotics	Sachets/Capsule/ Tablet	Diarrhea, irritable bowel syndrome, colic, and ulcerative colitis: Crohn's disease, lactose and gluten intolerance	Saccharomyces boulardii can cause adverse reactions in yeast allergies patients, and Lactobacillus-based probiotics can cause an infection in the inner lining of the heart chambers, heart valve, and blood infections. ¹⁰
Omega-3/fish oil	Capsule	Helps in oxidative stress, inflammation, skeletal and muscular system strengthening,	Stomach upset, fishy breath, loose stool, nausea. ¹¹
Chia seeds/flax seeds	Seeds	Both are rich in magnesium, fiber, and omega-3. Hence both the seeds can improve digestive health and help in constipation, help in dyslipidemia, reduce inflammation, atopic dermatitis, insulin level, and cancer.	Common contraindications are bloating, gas, indigestion, nausea. ¹²
Boswellia	Herbs used as ayurvedic medicine	Helps in osteoarthritis, rheumatoid arthritis, irritable bowel syndrome, asthma, etc.	Stomach ache, nausea, diarrhea, and an allergic rash indicate this herb (skin use). ¹³
Gotu kola	Herbs used as ayurvedic medicine	Cognitive and nervous system functions, reduce stress/anxiety, helps in skin and bones, and wound healing and total detoxifications	When applied to the skin, stomach discomfort, nausea, light sensitivity, and an allergic rash are all adverse effects of Gotu Kola. ¹⁴
Triphala	Herbs used ayurvedic medicine	Laxative action, boosting appetite, anti-inflammatory, antioxidant effects. It also has antimutagenic, anticancer, antineoplastic, and hypoglycemic properties.	Diarrhea and gastrointestinal distress, especially in large doses. ^{14,15}
Guggul	Herbs used as ayurvedic medicine	Weight loss, hypothyroidism, eczema, acne, psoriasis, osteoarthritis, and rheumatoid arthritis.	Stomach distress, headaches, nausea, vomiting, loose stools, diarrhea, belching, and hiccups. ^{14,15}
Chawanprush	Cooked mixture	Energy and immune-modulatory and rejuvenation effect, cough, and cold	Avoid diabetes and allergic patients. Not to consume during pregnancy and lactation period. ¹⁶
Aloe vera Juice	Syrup	Helpful in gastric health, constipation, laxative, skin and hair health	The excess laxative effect may cause diarrhea, abdominal cramps, potassium loss, arrhythmia, fatigue, and muscle weakness. ^{14,15}
Amla Juice	Syrup	Anti-aging, anti-inflammatory, benefits hair, skin, gastric health. It's a potent antioxidant and immunity booster food with various uses.	May cause hypoglycemia, liver disorders, acidity, and dehydration. ^{14,15}
Dashmularishta	Syrup	Helps in women's overall health and reproductive system. It also strengthens uterus muscles for better menstrual discharge. The tonic is helpful in indigestion, arthritis, stamina, and stress	Overdoses and improper intake may cause hypoglycemia, nausea, and G.I complications. ^{17–19}
Ashokarishta	Syrup	Digestive weakness and loss of appetite reduce menstrual pain and cramps	Overdosage may cause excessive menstrual bleeding, uterine contraction, nausea, high blood pressure, GERD, constipation, irregular menstruation, hypoglycemia, and indigestion. ²⁰

and storage, rational proceeding, manufacture, and quality standards. Furthermore, to improve the security of herbal medicine and play a more significant role in human maintaining health, and overall safety system based on accurate clinical settings and risk monitoring should be developed. ^{6,21}

4. Conclusions

All supplements have proper indications and contraindications and might have other interactions with food or drug for a patient. Herbal and dietary supplements often have myths and misconceptions that anyone can consume and get benefits, but that's not true. Particularly for a typical patient, a supplement should be rightly identified as per the diagnosis, and accordingly, an experienced physician and dietitian can only recommend that.

5. Conflict of Interest

None.

6. Source of Funding

None.

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