Review Article

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Exploring Concepts and Debates Surrounding Nutraceuticals in Nepal, A Scoping Review Article

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ABSTRACT

Background: Nutraceuticals are the products derived from herbs, dietary supplements, specific diets, and processed foods, offering health benefits beyond basic nutrition and even the potential to prevent or treat diseases. The global surge in nutraceutical usage has brought attention to both their potential benefits and scientific enquiry regarding their safety and efficacy. This article had tried to find out about the concepts and debates surrounding Nutraceuticals in Nepal.

Methods: The study reviewed 17 articles sourced from Google Scholar, Google, and PubMed between December 25, 2023, and January 25, 2024. It included a diverse array of sources such as cross-sectional and longitudinal studies, qualitative research, reviews, and other types of publications. Articles were managed using Zotero for de-duplication and assessment. All authors independently reviewed titles and abstracts, with discrepancies resolved through discussion and additional studies identified from reference lists.

Results: In Nepal, the nutraceutical sector is growing rapidly, driven by increased health consciousness, traditional herbal knowledge, and a rising demand for natural products. However, challenges such as adulteration, contamination, and mislabeling of products highlight the need for stringent regulations and robust quality control measures. The country's regulatory framework, guided by the Dietary Supplement Guideline and the Drug Act, aims to ensure consumer safety and product integrity. Despite these measures, implementation and enforcement issues persist, including limited resources, inadequate market surveillance, and the prevalence of unregistered products. Controversies regarding the scientific support for health claims, the integration of traditional knowledge, and the ethical implications of nutraceutical marketing persist.

Conclusion: This review emphasizes the need for comprehensive studies and regulatory improvements to validate the safety and efficacy of nutraceuticals in Nepal. By fostering collaboration among researchers, academia, and industry, and by enhancing consumer awareness and education, Nepal can effectively harness the potential of nutraceuticals to improve public health and well-being.

Key Words: Concepts, controversies, debate, nutraceuticals, Nepal

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BACKGROUND

Nutraceutical is a word formed by the combination of "nutrition" and "pharmaceuticals". They are the products extracted from sources like herbs, dietary supplements, specific diets, and processed foods. They provide health benefits in addition to basic nutrition and can even prevent or treat diseases. (1) The concept of nutraceuticals originated from Hippocrates' famous quote: "Let your food be your medicine and your medicine be your food (2)." They can be classified into different categories based on their nature and mode of action such as anti-cancer, antioxidant, anti-inflammatory and anti-lipid etc. (3). They have also been found to show positive affect on cardiovascular disease, can boost immune system and have a preventive role in infectious diseases (4).

In this article, Neutraceutical means, dietary supplements, fortified foods, and functional foods. Nutraceuticals, dietary supplements, and traditional herbal remedies are all related but separate ideas in the field of health and wellbeing, each with a specific function. Traditional herbal remedies, which have their roots in Ayurvedic medicine, are widely used in Nepalese culture to treat illnesses and promote overall health using plant-based materials (5). Dietary supplements are more modern and standardized which address specific nutrient deficiencies (6). Similarly, nutraceuticals, combining nutrition and pharmaceuticals, offer scientifically-backed health benefits beyond basic nutrition, bridging traditional and modern approaches (7).

Recently, use of nutraceutical has gained significant attention within the health and wellness domain and has been used globally (8). However, many health claims associated with these nutraceuticals may lack scientific support regarding their safety, efficacy, and impact on health conditions (9). Many studies conducted to explore the potential health benefits of nutraceuticals for specific pathological conditions found discrepancies in showing the exact mechanisms of action for reducing the pathological condition and improving the diseased condition (10). This has raised discussions among medical and scientific experts regarding the beneficial action of nutraceuticals (11). Different studies have shown that individuals with a balanced diet typically do not require nutraceuticals, and also there is a risk of adverse effects from over-supplementation (9,10). In developing countries, children may suffer from vitamin or mineral deficiencies due to inadequate nutrition, leading to the need for essential micronutrient supplementation like Vitamin A, iron, iodine, and zinc (14). Although vitamin and mineral supplements may offer benefits for specific deficiencies, recent studies have found no reduction in heart disease, stroke, or premature death with the use of multivitamins, Vitamin D, calcium, and Vitamin C supplements (12,15,16).

Many nutraceuticals are marketed with questionable claims like improving brain function, supporting heart health, preventing aging, and reducing inflammation (4). Both consumers and health professionals encounter conflicting study results, potential side effects from overuse, and harmful interactions, highlighting the need for solid evidence (12). Critical issues such as how the body absorbs and processes these compounds, their safe dosages, and interactions with other drugs or supplements are not well-researched (17). The unknown safe levels and potential toxicity of ingredients used in nutraceuticals are also major concerns (18).

The rapid growth of the use of nutraceuticals is because of factors like increase in health consciousness among consumers, over-the-counter availability of the products, and growing demand for natural and organic products (19). A significant health risk has occurred due to the rapid use of these nutraceuticals (9). Adulteration, contamination, and mislabeling of nutraceutical products have been reported across various countries like Brazil and Germany, highlighting the need for enforcement of strict rules and regulations (20).

The global prevalence of prescribing nutraceutical products is well-established and also are being used without prescription. Similarly, these prescriptions by medical professionals have become a controversy (21). In many countries, nutraceuticals are being supplied illegally, which has increased the health risk. So realizing the fact, countries like Nepal, have banned such prescriptions (22). Those who are in favor of nutraceuticals, advocate for their potential to fill nutritional gaps, support immune function, and enhance overall health outcomes and those who are opponents are questioning the scientific evidence supporting these claims and raise concerns about the lack of proven data to support the usefulness, safety and efficacy of those products (23). Additionally, the industries involved in producing nutraceutical products are being criticized for practicing misleading marketing tactics, and the commodification of health, regulation challenges, and inconsistent quality standards leading to questions about the ethicality of promoting nutraceuticals as a solution for various health concerns (24).

In the context of Nepal to maximize the benefits derived from nutraceutical products, it is crucial to establish a robust regulatory framework that prioritizes the protection of consumer health and the integrity of these products. Recent ban of nutraceutical products by the Department of Drug Administration (DDA) due to concerns over safety, efficacy, or regulatory compliance, have sparked debates regarding the quality and reliability of such supplements. These actions reflect broader discussions within the country regarding the need for stricter regulations, enhanced surveillance, and greater consumer awareness regarding nutraceuticals.

Controversies surrounding the use of nutraceuticals and synthetic additives in nutraceutical formulations have generated debates over their safety and long-term health implications (25). So this review has been conducted to provide an overview of the use of nutraceuticals and the debate surrounding their uses (26). As this industry continues to expand in the context of Nepal, there is a pressing need to understand its uses and debate surrounding its uses for public health and well-being. Additionally, while there is a growing body of literature on nutraceuticals globally, there is a need of comprehensive studies and reviews specific to the Nepalese context.

METHODS

Research team

The research team comprised two faculty members with expertise in Masters in Public Health Nutrition and Masters in Health Promotion and Education, who brought a deep understanding of public health and nutritional aspects. Additionally, a pharmacy student contributed valuable insight into pharmaceutical perspectives related to nutraceuticals, enhancing the interdisciplinary nature of the article.

Procedures

The study adhered to the scoping review guidelines established by Arksey and O'Malley. We applied these guidelines to sift through the data within the databases and subsequently structured our report following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for scoping reviews (PRISMA – ScR). Following the Arksey and O'Malley Framework, we adhered to six stages for conducting a scoping review: (1) defining the research question; (2) finding relevant literature; (3) choosing studies; (4) extracting and mapping the data; (5) summarizing, synthesizing, and creating a report; and (6) consulting with experts. This scoping review aimed to address the following research question: What are the key concepts and debates surrounding nutraceuticals in Nepal?

Eligibility criteria: The study included all the articles like cross-sectional and longitudinal studies, qualitative studies, perspectives, reviews, systematic reviews, commentaries, case studies, conference proceedings, opinion pieces, and letters to the editor.

Exclusion criteria: The study excluded articles published in other than English language, non-peer reviewed, and unpublished articles.

Information sources and search strategy

Between December 25, 2023, and January 25, 2024, we conducted a search in PubMed and Google Scholar for relevant literature. RB crafted the search strategy in line with the study's primary objective, which CKP reviewed. RB, RP, and CKP jointly identified relevant databases and keywords essential for the study. They selected suitable free-text keywords such as "nutraceuticals," "concepts," "debates," and "Nepal." The search strategy ((((nutraceuticals) AND (concepts)) AND (debates))) was initially crafted in PubMed and then applied across all databases.

Selection of relevant studies

The search outcomes were transferred to the Zotero reference manager for de-duplication and assessment. RB, RP and CKP separately reviewed titles and abstracts based on the eligibility criteria. Articles lacking sufficient details in the title and abstract underwent full-text screening for potential inclusion. RB and CKP then deliberated on the screening outcomes, addressing any disparities through discussion. Additionally, they scanned the reference lists of chosen articles to identify further relevant studies for inclusion.

Data extraction/charting

All the authors were involved in extracting the data from the included studies in word tables. Information was placed into tables for data extraction. The reviewers extracted information about the concept of nutraceuticals, its debate, and regulatory mechanism. Reviewers also recorded their comments separately in a notes column that was incorporated into the main content while preparing the manuscript.

Summarizing, synthesizing, and creating a report

The main author (RB) organized and combined information from studies and drafted the manuscript. The other authors checked and improved the summary. Important points required for the manuscript were included after consultation with experts.

RESULTS

Initially, 37 papers were found in PubMed, and 7850 more were identified from other sources like Google scholar and Google totaling 19413 papers. After a thorough review, 19248 papers were excluded for being duplicates leaving 165 papers for full-text analysis. Further screening removed 49 papers in the first round and 37 more in the second round and 62 at third round. So after filtering the papers based on inclusion criteria, all together 17 articles are included in this paper which is shown as in figure below

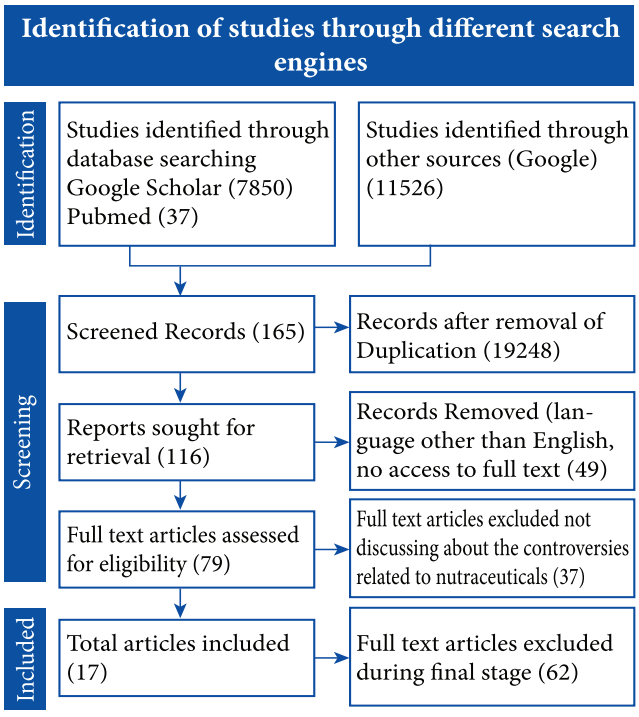

Figure 1 PRISMA Flow Diagram

Regulatory framework

In Nepal, the oversight and regulation of dietary supplements are governed by the Dietary Supplement Guideline (2016), mandated by the Food Act of 1967, administered under the Department of Food Technology and Quality Control within the Ministry of Agriculture and Livestock Development (27). This guideline serves to safeguard consumer health and ensure customer satisfaction by controlling and guaranteeing the composition and purity of products, while also establishing quality standards for nutritional supplementary food. Also Drug Act 1978 and various regulation under it provides the legal framework for registration, licensing, importation, manufacturing, labeling, advertising, and quality control of nutraceuticals (28). Nutraceutical products must undergo registration with the DDA, involving the submission of detailed documentation on product composition, safety data, manufacturing processes, and labeling information, leading to the issuance of a registration certificate upon successful compliance (29). Labeling requirements ensure comprehensive information on product name, ingredients, dosage instructions, storage conditions, batch number, manufacturing, and expiry dates, promoting consumer safety and transparency (30). Advertising guidelines mandate ethical standards, prohibiting misleading or unsubstantiated claims about product efficacy or health benefits (31). Quality control measures enforce adherence to Good Manufacturing Practices (GMP) and quality testing of raw materials and finished products, with periodic inspections and audits conducted by regulatory authorities to ensure compliance (32). Surveillance and monitoring activities, conducted by agencies like the DDA, oversee the market, identify non-compliant products, and take enforcement actions, including routine inspections of manufacturing facilities, sampling, testing, and investigation of consumer complaints, ensuring the safety, purity, and efficacy of nutraceuticals in Nepal (33).

Despite the existence of regulatory provisions, challenges persist in the implementation and enforcement of the regulatory framework for nutraceuticals in Nepal. These challenges include limited resources and capacity within regulatory agencies, inadequate surveillance and monitoring of the nutraceutical market, proliferation of unregistered and counterfeit products, and ambiguity in regulatory requirements (34). Due to a lack of resources, regulatory agencies are unable to enforce compliance or carry out efficient inspections, which permits the sale of inferior goods (35). Manufacturers struggle with high compliance costs and quality control challenges, especially small and medium-sized businesses (36). Inadequate labeling and marketing frequently deceive consumers, and trustworthy safety and efficacy data are unavailable to healthcare providers (37).

Nutraceutical consumption patterns

Nutraceutical consumption practices in Nepal has been influenced by a diverse mix of traditional practices and socio-economic background, cultural beliefs, and healthcare access (38). Accurate data on nutraceutical consumption in Nepal is limited, however, it has been found that people are showing a growing interest in dietary supplements, herbal remedies, and functional foods as part of everyday health maintenance (22). A study conducted in the far-western part of Nepal found that a significant portion of the Nepalese population relies on traditional herbal medicines for managing various health conditions, with common ingredients including ginger, garlic, turmeric, and neem (5). Similarly, a hospital-based study found over 80% of patients were discovered to be self-administering nutraceuticals (9). The most commonly recommended types of nutraceuticals included vitamins (40.7%), minerals (23.7%), enzymes (21.1%), proteins (8.8%), probiotics (4.2%), and herbal supplements (2.0%) (9). Additionally, a survey revealed a notable increase in the consumption of dietary supplements, particularly among urban residents and affluent demographics, driven by perceived health benefits and lifestyle choices (39). Also, in Nepal, cultural preferences and beliefs shape consumption patterns, with Ayurvedic and traditional remedies remaining popular alongside modern nutraceuticals (40).

Production and marketing

Studies have highlighted the significant role of local herbal resources and traditional knowledge systems in the manufacturing of nutraceutical products (41). In terms of marketing, a report by the United Nations highlighted a growing trend of direct-to-consumer marketing channels, including online platforms and health food stores, to promote nutraceutical products (42). According to the International Partnership for the Satoyama Initiative, Nepal is home to over 1,600 species of medicinal plants, which form the raw materials for nutraceutical production (43). Key players in the industry have capitalized on these resources, producing a variety of products such as herbal supplements, fortified foods, and natural remedies (44). The domestic market for nutraceuticals has expanded by approximately 12% annually, fueled by rising consumer awareness and the integration of traditional Ayurvedic practices with modern nutritional science (45). Additionally, Nepal's nutraceutical exports have also increased, particularly to markets in India, China, and Europe, with export revenues reaching approximately $30 million in the last fiscal year (46).

Debates

Food supplements containing essential micronutrients can be utilized to enhance the health of individuals with specific needs (47). However, many health claims

associated with these supplements may lack scientific support regarding their safety, efficacy, and impact on health conditions (48). Studies often lack rigor in exploring the mechanisms of action and potential health benefits of nutraceuticals for specific pathological conditions (9). Controversies regarding nutraceutical persist around the integration of traditional knowledge and indigenous practices into commercial nutraceutical formulations, with debates over cultural appropriation, intellectual property rights, and equitable benefit-sharing (49). Divergent opinions among healthcare professionals, policymakers, and industry stakeholders regarding the therapeutic value and appropriate use of nutraceuticals contribute to ongoing debates and controversies within the nutraceutical sector (26). While individuals with a balanced diet typically do not require supplements, there is a risk of adverse effects from over-supplementation. Some studies indicate that vitamin and mineral supplements can benefit specific groups, such as children and the elderly, by improving bone density or reducing birth defects (50–52). Certain dietary supplements and nutraceuticals have demonstrated therapeutic and preventive benefits (3). Some are associated with reduced immunopathology, antiviral and anti-inflammatory effects, and even the prevention of acute respiratory distress syndrome (ARDS) (53–55). On the other side, recent large-scale studies have found no significant reduction in heart disease, stroke, or premature death associated with the use of multivitamins, Vitamin D, calcium, and Vitamin C supplements (56–58). Also, legislation concerning the prescription of nutraceuticals by qualified medical professionals remains contentious, with some countries banning their prescription altogether (22). Safety and efficacy concerns surrounding nutraceuticals have sparked debate among medical and scientific professionals (59).

Future direction

The regulatory framework in Nepal must align with ongoing research efforts to ensure adherence to standards of quality, safety, and efficacy, given the widespread use of nutraceuticals. Comprehensive studies on the medicinal properties of native plants and traditional treatments are essential to validate the effectiveness and safety of nutraceuticals through rigorous research, clinical trials, and testing. Collaborative efforts among researchers, academia, and industry are crucial for developing evidence-based nutraceutical formulations tailored to the unique health needs of the Nepalese population. Consequently, stringent regulations for product registration, manufacturing processes, labeling, and advertising must be implemented. Additionally, surveillance and monitoring mechanisms should be strengthened to promptly address any instances of noncompliance. Additionally, nurturing consumer awareness and education regarding nutraceuticals is indispensable in empowering individuals to make informed decisions for their health and well-being. Disseminating accurate information on nutraceutical benefits, risks, and appropriate usage can cultivate confidence and encourage responsible consumption practices among the people, thereby contributing to the cultivation of a healthier society.

Limitations

The review faced limitations due to language barriers and restricted access to full texts, which may have led to the omission of relevant studies. Additionally, the focused search strategy may have excluded some valuable resources. Despite these constraints, the selected studies offer a comprehensive overview within the accessible scope.

CONCLUSION

The term "nutraceuticals," encompassing products derived from sources such as herbs, dietary supplements, specific diets, and processed foods offering health benefits beyond basic nutrition, holds significant promise in Nepal's healthcare setting. As the industry is emerging globally, Nepal too witnesses a rapid evolution in nutraceutical consumption and production, driven by heightened health consciousness, demand for natural remedies, and preventive healthcare trends. However, alongside their potential, nutraceuticals in Nepal also lead numerous debates and controversies regarding their safety, efficacy, regulation, and ethical considerations. The growing popularity of nutraceuticals has also led to challenges, including the risk of adulteration, misleading marketing practices, and variability in product quality. Despite the challenges, the future direction for nutraceuticals in Nepal appears promising, with opportunities to align regulatory frameworks with ongoing research, foster industry growth through innovation and investment, and promote consumer awareness and education. By addressing these aspects, Nepal can harness the potential of nutraceuticals to advance public health and well-being despite the complexities inherent in this burgeoning industry.

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Conflict of interest

All the authors declare no conflict of interest. We assure that we have no conflicts of interest associated with this publication and there has been no significant financial support for this work that could be have influenced its outcome.

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