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Regulating dietary supplements for athletes: An overview

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Abstract
Introduction: Dietary supplements are something added to the diet, mainly: vitamins, minerals, amino acids, herbs or botanicals, and metabolites/constituents/extracts, or combination of any of these ingredients.
Methodology: Survey of secondary literature is the prime methodology for preparing this research article.
Research Findings: There is a significant gap in research evaluating various aspects of dietary supplements and their impacts on Indian athletes. There is a need for multicentric, longitudinal studies evaluating various aspects of effects of dietary supplements. All such substances need to be approved by the Sports Authority of India (SAI) and should be given to the athletes under the supervision of SAI Certified Specialist Dietitian.
Conclusion: The most important factors affecting the adaptations to endurance training are the training stimuli volume and intensity. However, within a given training program, the appropriate use of dietary supplements may offer additional benefits.

Keywords: Dietary supplements, athletic performance, improving training adjustment, international Olympic committee

Introduction
Sports success is dependent primarily on genetic endowment in athletes with morphologic, psycho logic, physiologic, and metabolic traits specific to performance characteristics vital to their sport. Such genetically-endowed athletes must also receive optimal training to increase physical power, enhance mental strength, and provide a mechanical advantage. However, athletes often attempt to go beyond training and use substances and techniques, often referred to as ergogenic, in attempts to gain a competitive advantage. Pharmacological agents, such as anabolic steroids and amphetamines, have been used in the past, but such practices by athletes have led to the establishment of anti-doping legislation and effective testing protocols to help deter their use. Thus, many athletes have turned to various dietary strategies, including the use of various dietary supplements (sports supplements), which they presume to be effective, safe, and legal.
The use of dietary supplements is widespread among athletes globally. Dietary supplements are used by athletes worldwide. In the United States, the Dietary Supplement Health and Education Act has defined dietary supplements as something added to the diet, mainly (1) vitamins, (2) minerals, (3) amino acids, (4) herbs or botanicals, and (5) metabolites/constituents/extracts, or combination of any of these ingredients. In addition to actual food products targeted to athletes and physically-active individuals, numerous companies have marketed dietary supplements to athletes, often with the claim that sports performance may be enhanced. [1]

Major Dietary Supplements
Sports nutrition supplements include a variety of drinks, powders and pills designed to improve athletic performance and/or fill gaps in the diet of people who play sports or workout on a regular basis. It is important to talk to one's doctor before one takes any type of supplement, vitamin or medication. Some things one needs to consider before one takes a supplement include:

- Taking supplements do not make up for eating an unhealthy diet. No diet is perfect 365 days a year, so there may be times a supplement is helpful, such as during special training, illness, or when you have a medical condition (pregnancy, anemia, etc.).
- Many supplements have extensive research behind them to prove their benefit, but an even greater number do not have enough evidence to support their use. Your doctor or dietitian can help you understand which supplements are helpful for you.
- Unlike medication, supplements are not intended to treat, diagnose, prevent or cure diseases.

Major dietary supplements for athletes include sports drinks, protein powders and other performance-enhancing supplements:

- **Sports Drinks:** Sports drinks (electrolyte replacement drinks) are meant to keep you hydrated by replacing the sodium and potassium you lose when you sweat. They also keep blood glucose (sugar) levels stable so you can make the most of your energy during endurance or high-intensity exercise. Because they taste good, you are more likely to drink them and prevent dehydration. Sports drinks also prevent cramping. If you have postural orthostatic tachycardia syndrome (POTS), you need to have sports drinks when you exercise. Sports drinks are not for everyone, though. If you are more of a casual/recreational athlete, the drinks can give you extra calories and sodium that you do not need. Because of this, they are also not good for people with diabetes or heart failure. There are lower-calorie and zero-calorie versions, but both contain sodium.
- **Protein Supplements:** Powdered protein is a convenient, portable source of protein. Many types are easy to digest and are quickly absorbed by your body. However, these supplements can be expensive. And, like other supplements, they are not FDA- tested for safety and effectiveness.
- **Creatine:** Creatine can increase muscle strength and speed. This supplement can be expensive. It can also cause bloating, diarrhea, low blood pressure, and make you sweat more. Like other supplements, creatine supplements are not FDA- tested for safety and effectiveness.
- **Performance-Enhancing Supplements:** Performance-enhancing supplements like pre-workout powders and drinks, energy boosters and metabolism boosters often contain banned substances. They can lead to gastrointestinal problems, anxiety and nervousness. They also do not offer any proven benefits.

Athletes commonly take supplements, and a few supplements may have merit in the endurance world. Nitrates may help reduce oxygen cost and improve time to exhaustion, possibly cardiorespiratory performance at anaerobic threshold, and even VO2max. Studies are mixed however, and nitrate may preferentially benefit non-elite recreational athletes. Antioxidants may help an athlete who has already peaked in terms of training adaptation, where the main goal is facilitating recovery and earlier return to competition in multi-stage events. Caffeine has a very large body of research behind its ergogenic effects, with side effects being the main limiting factor. There is a paucity of quality research on probiotics for athletes, but chronic URI and GI symptoms common in endurance athletes may potentially be attenuated with Lactobacillus and Bifidobacterium supplementation. Additionally, as with any supplement, since the US Food and Drug Administration (FDA) is not authorized to review dietary supplement products for safety and effectiveness before they are marketed, there is the risk of contaminants and illicit substances in commercial supplements. These substances may not only present a safety risk but may be on a banned substance list for professional athletes. While it is recommended that athletes obtain nutrition from whole foods, we acknowledge that athletes may take supplements and recommend they choose from trusted sources. [2]

Table: Selected Ingredients in Dietary Supplements for Exercise and Athletic Performance*

Ingredient	Proposed Mechanism of Action	Evidence of Efficacy**	Evidence of Safety**
Antioxidants (vitamin C, vitamin E, and coenzyme Q_{10})	Minimize free-radical damage to skeletal muscle, thereby reducing muscle fatigue, inflammation, and soreness	Several small clinical trials Research findings: Do not directly improve performance; appear to hinder some physiological and physical exercise-induced adaptations	Safe at recommended intakes; some safety concerns reported with high doses Reported adverse effects: Potential for diarrhoea, nausea, abdominal cramps, and other gastrointestinal disturbances with vitamin C intakes of more than 2,000 mg/day in adults; increased risk of haemorrhagic effects with vitamin E intakes of more than 1,500 IU/day (natural form) or 1,100 IU/day (synthetic form) in adults; nausea, heartburn, and other side effects with coenzyme Q_{10}
Arginine	Increases blood flow and delivery of oxygen and nutrients to skeletal muscle; serves as a substrate for creatine production; increases secretion of human growth hormone to stimulate muscle growth	Limited clinical trials with conflicting results Research findings: Little to no effect on vasodilation, blood flow, or exercise metabolites; little evidence of increases in muscle creatine content	No safety concerns reported for use of up to 9 g/day for weeks; adverse effects possible with larger doses Reported adverse effects: Gastrointestinal effects, such as diarrhoea and nausea
Beetroot or beet juice	Dilates blood vessels in exercising muscle, reduces oxygen use, and improves energy production	Limited clinical trials with conflicting results Research findings: Might improve performance and endurance to some degree in time trials and time-to-exhaustion tests among runners, swimmers, rowers,	No safety concerns reported for short-term use at commonly recommended amounts (approximately 2 cups) Reported adverse effects: None known

		and cyclists; appears to be most effective in recreationally active non-athletes	
Beta-alanine	Increases synthesis of carnosine, a dipeptide that buffers changes in muscle pH, thereby reducing muscle fatigue and loss of force production; considerable individual variation in associated muscle carnosine synthesis	Numerous clinical trials with conflicting results Research findings: Inconsistent effects on performance in competitive events requiring high-intensity effort over a short period, such as team sports; little or no performance benefit in activities lasting more than 10 minutes	No safety concerns reported for use of 1.6–6.4 g/day for up to 8 weeks Reported adverse effects: Paraesthesia (tingling) in face, neck, back of hands, and upper trunk with at least 800 mg or over 10 mg/kg body mass; pruritus (itchy skin)
Beta-hydroxy-beta-methyl butyrate (HMB)	Helps stressed and damaged skeletal muscle cells restore their structure and function	Numerous clinical trials with conflicting results Research findings: Might help speed up recovery from exercise of sufficient amount and intensity to induce skeletal muscle damage	No safety concerns reported for typical dose of 3 g/day for up to 2 months Reported adverse effects: None known
Betaine	Might increase creatine production, blood nitric-acid levels, or water retention in cells	Limited clinical trials in men with conflicting results Research findings: Potential but modest strength and power-based performance improvements in bodybuilders and cyclists	No safety concerns reported for 2–5 g/day for up to 15 days Reported adverse effects: None known
Branched-chain amino acids (leucine, isoleucine, and valine)	Can be metabolized by mitochondria in skeletal muscle to provide energy during exercise	Limited number of short-term clinical trials Research findings: Little evidence of improved performance in endurance-related aerobic events; possibility of greater gains in muscle mass and strength during training	No safety concerns reported for 20 g/day or less for up to 6 weeks Reported adverse effects: None known
Caffeine	Blocks activity of the neuromodulator adenosine; reduces perceived pain and exertion	Numerous clinical trials with mostly consistent results Research findings: Might enhance performance in endurance-type activities (e.g., running) and intermittent, long-duration activities (e.g., soccer) when taken before activity	Reasonably safe at up to 400–500 mg/day for adults Reported adverse effects: Insomnia, restlessness, nausea, vomiting, tachycardia, and arrhythmia; risk of death with acute oral dose of approximately 10–14 g pure caffeine (150–200 mg/kg)
Citrulline	Dilates blood vessels to increase delivery of oxygen and nutrients to skeletal muscle	Few clinical trials with conflicting results Research findings: Little research support for use to enhance performance	Few safety concerns reported for up to 9 g for 1 day or 6 g/day for up to 16 days Reported adverse effects: Gastrointestinal discomfort
Creatine	Helps supply muscles with energy for short-term, predominantly anaerobic activity	Numerous clinical trials generally showing a benefit for high-intensity, intermittent activity; potential variation in individual responses Research findings: May increase strength, power, and work from maximal effort muscle contractions; over time helps body adapt to athlete-training regimens; of little value for endurance sports	Few safety concerns reported at typical dose (e.g., loading dose of 20 g/day for up to 7 days and 3–5 g/day for up to 12 weeks) Reported adverse effects: Weight gain due to water retention; anecdotal reports of nausea, diarrhoea, muscle cramps, muscle stiffness, heat intolerance
Deer antler velvet	Contains growth factors (such as insulin-like growth factor-1 [IGF-1]) that could promote muscle tissue growth	Few short-term clinical trials that show no benefit for physical performance Research findings: No evidence for improving aerobic or anaerobic performance, muscular strength, or endurance	Safety not well studied Reported adverse effects: Hypoglycaemia, headache, oedema, and joint pain (from prescription IGF-1); banned in professional athletic competition
Dehydroepiandrosterone (DHEA)	Steroid hormone that can be converted into testosterone and	Small number of clinical trials that show no benefit for	Safety not well studied; no safety concerns reported for up to 150 mg/day for 6–12 weeks

	oestradiol	physical performance Research findings: No evidence of increases in strength, aerobic capacity, lean body mass, or testosterone levels in men	Reported adverse effects: Over several months, raises testosterone levels in women, which can cause acne and growth of facial hair
Ginseng	Unknown mechanism of action; *Panax* ginseng used in traditional Chinese medicine as a tonic for stamina and vitality; Siberian ginseng used to reduce fatigue	Numerous small clinical trials, most showing no benefit for physical performance Research findings: In various doses and types of preparations, no effects on peak power output, time to exhaustion, perceived exertion, recovery from intense activity, oxygen consumption, or heart rate	Few safety concerns reported with short-term use Reported adverse effects: For *Panax* ginseng: headache, sleep disturbances, and gastrointestinal disorders; for Siberian ginseng: none known
Glutamine	Involved in metabolism and energy production; contributes nitrogen for many critical biochemical reactions	Few studies of use to enhance performance directly Research findings: In adult weightlifters, no effect on muscle performance, body composition, or muscle-protein degradation; may help with recovery of muscle strength and reduce muscle soreness after exercise	No safety concerns reported with about 45 g/day for 6 weeks; safe use of up to 0.42 g/kg body weight (e.g., 30 g/day in a person weighing 154 lb) by many patients with serious conditions (e.g., infections, intestinal diseases, and burns) Reported adverse effects: None known
Iron	Increases oxygen uptake, reduces heart rate, and decreases lactate concentrations during exercise	Numerous clinical trials with conflicting results Research findings: Improved work capacity with correction of iron deficiency anaemia; conflicting evidence on whether milder iron deficiency without anaemia impairs exercise performance	No safety concerns reported for use at recommended intakes (8 mg/day for healthy men and postmenopausal women and 18 mg/day for healthy premenopausal women) Reported adverse effects: Gastric upset, constipation, nausea, abdominal pain, vomiting, and fainting at intakes above 45 mg/day
Protein	Builds, maintains, and repairs muscle	Numerous clinical trials Research findings: Optimizes muscle training response during exercise and subsequent recovery period	No safety concerns reported at daily recommended intakes for athletes of up to about 2.0 g/kg body weight (e.g., 136 g for a person weighing 150 lb) Reported adverse effects: None known
Quercetin	Increases mitochondria in muscle, reduces oxidative stress, decreases inflammation, and improves blood flow	Numerous small, short-term clinical trials Research findings: Little to no effect on endurance performance or maximal oxygen consumption	No safety concerns reported for 1,000 mg/day or less for up to 8 weeks Reported adverse effects: None known
Ribose	Involved in production of adenosine triphosphate (ATP)	A few small, short-term, clinical trials Research findings: Little to no effect on exercise capacity in both trained and untrained adults	Safety as a dietary supplement not well studied; no safety concerns reported for up to 10 g/day for 8 weeks Reported adverse effects: None known
Sodium bicarbonate	Enhances disposal of hydrogen ions generated from intense muscle activity, thereby reducing metabolic acidosis, and resulting fatigue	Many small, short-term clinical trials Research findings: Might provide minor to moderate performance benefit for short-term and intermittent high-intensity activity, especially in trained athletes	No safety concerns reported for short-term use of up to 300 mg/kg body weight Reported adverse effects: Nausea, stomach pain, diarrhoea, and vomiting
Tart or sour cherry	Phytochemicals in tart cherries may facilitate exercise recovery by reducing pain and inflammation	A few clinical trials with conflicting results Research findings: Variable results for aiding muscle strength recovery, reducing soreness, or reducing inflammatory effects on lungs after exercise; insufficient research on ability to improve aerobic performance	No safety concerns reported for about 1/2 quart of juice or 480 mg freeze-dried Montmorency tart-cherry-skin powder per day for up to 2 weeks Reported adverse effects: None known
Tribulus terrestris	Increases serum testosterone and	A few small, short-term	Safety not well studied; no safety concerns

	luteinizing hormone concentrations, thereby promoting skeletal muscle hypertrophy	clinical trials Research findings: No effect on strength, lean body mass, or sex hormone levels	reported at up to 3.21 mg/kg/day for 8 weeks Reported adverse effects: One case report of harm from product labelled but not confirmed to contain *Tribulus terrestris*

* References to support statements in Table 1 are provided in subsequent text.
** The evidence of efficacy and safety is for the individual ingredients. The efficacy and safety of these ingredients might be different when they are combined with other ingredients in a product or training plan.

Regulatory Mechanism

Although the use of some dietary supplements for athletes may have added benefits in terms of improving body composition, sports performance and overall health, the risk to benefit ratio needs to be carefully considered before embarking on the widespread use of supplements. The product safety and purity claimed benefits and safety of the supplement for short- and long-term, needs to be considered carefully before it is taken. Poor quality control of supplements on sale in pharmacies and supermarkets can also potentially increase the likelihood of athletes obtaining negative results in doping tests.

But the use of (Food for Special Dietary Uses) FSDU for sportspersons by sportspersons is a serious concern because in many countries the manufacturing and labelling of supplements do not follow strict rules, which may lead to a supplement containing an undeclared substance that is prohibited under anti-doping regulations. A significant number of positive tests have been attributed to the misuse of food supplements and attributing an Adverse Analytical Finding to a poorly labelled dietary supplement is not an adequate defence in a doping hearing. The risks of taking FSDU for sportspersons should be weighed against the potential benefit that may be obtained, and athletes must appreciate the negative consequences of an Anti-Doping Rule Violation because of taking a contaminated supplement. Using FSDU for sportspersons that has been subjected to one of the available quality assurance schemes can help to reduce, but not eliminate, the risk of an inadvertent doping infringement.

Poor hygiene and lack of good manufacturing practices can result in supplements containing impurities such as lead, broken glass, and animal faeces, which carries obvious health risks for athletes and other users. Direct or deliberate, and indirect contamination of dietary supplements with undeclared and unlabelled anabolic steroids also places supplement users in a difficult position. Some supplements may not contain the exact amount of ingredients that are listed on the label as a marketing tool. Athletes may be unaware of the potential negative effects of using these supplements. Currently, the World Anti-Doping Agency (WADA) does not distinguish between deliberate cheating and inadvertent doping, and the responsibility and future athletic career of the individual rests solely with the athlete. For further reading on banned substances in sports, readers are referred to the latest WADA code, as well as South African Institute for Drug-Free Sport.

Dietary supplements are poorly regulated in South Africa and other countries. Although the manufacturers of these products are not allowed to state that a supplement can prevent or treat any illness or disease without sufficient scientific evidence, monitoring is not thorough. Regulation of supplements is also further complicated by the widespread sale thereof on the Internet. This promotes the use of supplements from unidentified sources.

In 1994, the US President Bill Clinton signed in to law the dietary supplement Health and Education Act (DSHEA), which allows manufacturers/companies/brands to make structure function claim, the law strictly prohibits disease claims for dietary supplements. In U.S.A. Food and Drug Administration (FDA) does not have the ability to check the safety and effectiveness of supplements before they hit the market. To make sure you choose safe products, buy only products that are certified as safe by a third party company like National Safety Foundation or Informed Choice. These groups have strict certification guidelines to prevent tampering, verify label claims against the contents, and make sure they do not contain banned substances.

In India, FSSAI has issued a guidance note on Foods for Special Dietary Uses for Sportspersons (FSDUS). This document is applicable to the sports fraternity, manufacturers, importers, retailers and the general public. The Foods for Special Dietary Uses (FSDU) is covered in the Food, Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods, and Novel Food) Regulations, 2016, which covers eight categories of foods, namely health supplements, nutraceuticals, food for special dietary use, foods for special medical purposes, specialty foods containing plants or botanicals, foods containing probiotics, foods containing prebiotics and novel foods. FSSAI stated, “Requirements for such foods as detailed in these regulations pertain to essential composition, claims and labelling provisions. These standards also include the essential composition, requirements related to claims, labelling, permitted use of additives and the permissible limits of contaminants, toxins and residues.” “The regulations do not allow the use of hormones or steroids or psychotropic ingredients in any of the articles of food. Furthermore, these regulations provide various Schedules dealing with use of vitamins and minerals, amino acids, ingredients of plants or botanical origin, nutraceuticals, probiotics and prebiotics in these products,” it added, stating, “The sub-category under FSDU shall cover FSDU for Sportspersons considering their special needs.” Offering the industry point of view on the guidance note, Dr Bindu Maurya of AFST (I), who is also a food and beverage industry veteran, stated, “The norms directed in the guidance note have been covered extensively and they seem to address everything that was needed.” According to the guidance note, the FBOs are required to adopt the following practices: Registration and licensing of manufacturer with FSSAI: The manufacturer (domestic or international) should have an Indian registered office with local contact details for addressing consumer grievances. The manufacturing facility should be periodically audited as per the FSSAI Regulations.

- **Labels and claims:** FBOs should ensure that the following declarations are printed on label of the package containing FSDU for Sportspersons:

“For sportspersons only”, “Recommended to be used under medical advice or dietetic supervision only”, “The product is not to be used by pregnant, nursing and lactating women or by infants, children under five years and elderly, except when medically advised”, “The food is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet for the article of food specially prepared for sportsperson”,

"The food should be used in conjunction with an appropriate physical training or exercise regime" and "For oral consumption only".

- **Authenticity:** The manufacturer's product authentication for the consumer (each individual pack should have an independent marking which the end user can validate on their own); the manufacturer should also ensure that packing is tamper-proof/tamper-evident. The manufacturer should authenticate the sellers/distributors and should publish details of authorized seller through their website or advertisements.
- **Traceability:** The manufacturer should provide complete visibility of the entire supply chain. Date marking: The manufacturer should ensure visibility of expiry/best before date when selling products through online marketplaces.

The guidance note also stated that the following precautions must be taken before claiming that FSDU for sportspersons does not contain any prohibited substance as per WADA:

- Periodical tests, preferably bi-annually, should be conducted by FBO through FSSAI approved labs;
- Repository of Certificate of Analysis (COAs) of periodical tests should be maintained by FBO for ready reference & Control samples should be properly preserved and stored as per the FSS Regulations;
- All FBOs or importers must exercise due diligence and self-regulation while importing FSDU for sportspersons into the country. The importer must ensure that they import only such products which comply with FSSAI-specified standards and regulations," said the guideline

Conclusion

The most important factors affecting the adaptations to endurance training are the training stimuli volume and intensity. However, within a given training program, the appropriate use of dietary supplements may offer additional benefits. [3]

Vitamins and supplements can be a safe way for athletes to try to improve their performance, but more research is necessary to determine the effectiveness of some supplements. It is crucial to speak to a doctor before starting to take any new vitamins or other supplements. These substances can interact with other medications that a person might be taking. Taking too much of some supplements, such as iron, can cause adverse side effects. Also, some vitamins may be ineffective unless a person has an existing deficiency. A doctor can test for vitamin deficiencies and advise on how to correct them if necessary. People who feel as though they have low energy despite exercising regularly may wish to consider other aspects of their routine before taking supplements. Eating a balanced, nutritious diet and getting enough sleep may also boost athletic performance. Athletes following vegetarian and vegan diets may need to take particular care to ensure that they are obtaining enough of the above nutrients through their diet.

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