

THE EFFECT OF β -HYDROXY β -METHYLBUTYRATE ON
MUSCULAR STRENGTH AND BODY COMPOSITION
IN COLLEGIATE FOOTBALL PLAYERS

By

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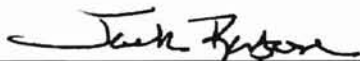
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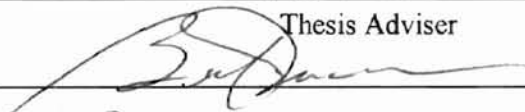
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LIST OF ABBREVIATIONS

BCAA: branched chain amino acid

CPK: creatine phosphokinase

HMB: β -hydroxy β -methylbutyrate

HMG-CoA: β -hydroxy β -methylglutaryl Coenzyme A

KIC: α -ketoisocaproate

Lb: one pound or 453.6 grams

RDA: Recommended Dietary Allowances

RM: repetition maximum

CHAPTER I

INTRODUCTION

Athletes are constantly searching for means of improving performance through dietary supplements that promise performance enhancing or ergogenic benefits. Currently, the most common dietary supplements on the market include creatine monohydrate, beta-hydroxy beta-methylbutyrate (HMB), antioxidant vitamins, amino acids, caffeine, and protein powder (1, 10, 15, 22, 37, 38). Sales of pills, powders, bars and beverages formulated to enhance athletic performance and recovery reached \$1.26 billion in 1997 and are expected to increase (34). In the last few years, HMB, a byproduct of the essential amino acid leucine, has become one of the best-selling sports supplements (3, 8, 37). Because it is found in both plant and animal foods, including catfish and grapefruit, and is a metabolite of an amino acid, HMB has been classified as a dietary supplement (10, 22, 37, 42). It has been estimated that a 70 kilogram human would produce from 0.2 to 0.4 g HMB per day (13). The Recommended Dietary Allowances (RDA) estimates leucine requirements at 14 mg/kg/day for adults or a dosage of approximately 1 g/day (12). However, the RDA's do not take into account the substantive evidence indicating that exercise increases protein requirements, which would in turn increase calorie requirements (4, 9, 40).

The proposed effects of HMB supplementation are numerous (3, 30, 36, 37). It has been hypothesized that HMB supplementation helps the body reduce catabolic effects of resistance training (3, 36, 37). Recent research has shown that intensely trained HMB-supplemented subjects (Ss) gain more strength and lean body mass than unsupplemented Ss (32). In addition, there has been a consistent decrease in LDL cholesterol, potentially

reducing the risk of cardiovascular disease (30). To date, no adverse effects have been seen in animals or humans supplemented with HMB (6, 24, 30, 36).

The exact mechanism whereby HMB influences muscle metabolism is not known; however, there are two hypotheses. HMB may act as a precursor to cellular muscle repair by stimulating proteinosis, which would increase collagen synthesis and connective tissues (37). The net effect of these actions would be a reduction in recovery time, which could potentially increase strength and lessen the risk of overtraining. The other hypothesis is that HMB may regulate enzymes responsible for muscle tissue breakdown. There is evidence that HMB supplementation decreases biochemical markers of muscle breakdown among weight trainers and directly decreases the degradation of muscle protein in vitro (3, 7, 30, 32, 33, 35).

Problem Statement

This study was designed to assess the effect of daily HMB supplementation on muscular strength and body composition among collegiate football players undergoing a strenuous exercise program.

Delimitations

The design of this experiment poses certain delimitations or boundaries that could affect the collection and interpretation of the data.

1. The Ss were competitive collegiate athletes residing in the Stillwater, Oklahoma area and participating on a volunteer basis.
2. Only male Ss were included in this study due to unavailability of female athletes and cost restraints.

3. Measurements were not taken during actual competition; they were taken during the practice sessions. It was not practical to test during actual competition; however, competitive situations were simulated to ensure maximal efforts.
4. Diet was not regulated. The athletes' diverse dietary practices and cost of a supervised meal program prevented controlling the diet.
5. The accuracy of the medical history, as reported by the Ss, was not verified due to the cost, time, and confidentiality.

Limitations

The effect of the delimitations and the ability to expand the scope of inference beyond the sample population influences the limitations. Generalizations made from the results are compromised by the following limitations:

1. The results of this investigation cannot be applied to those who are not well trained football players (ie. bodybuilders).
2. Using only experienced athletes limited the scope of inference to the population because of the athletes' advanced physiological status.
3. Care should be taken in generalizing the results to females, as physiological differences in response to HMB may exist between genders.
4. The level of work output by each S was dependent on degree of motivation, competitive spirit, and willingness to give maximal effort despite a non-competitive situation. For many athletes, the psychological component during actual competition plays an important role in the effort devoted to the exercise bout. To avoid the consequences of this, the Ss were paired to stimulate competitive situations.

5. Flaws in recall or truthfulness, as well as **ignorance** of a prior medical condition, may result in the inclusion of Ss with afflictions which could compromise the outcome of this investigation. The impact of an inaccurate medical history report was minimized by conducting a complete physical examination with a physician.

Assumptions

The basic assumptions for this study include:

1. The Ss were randomly distributed among the treatment groups.
2. The Ss consistently consumed HMB or placebo at the prescribed dosage (3 grams/day) throughout the entire supplementation period.
3. All Ss complied with the exercise training program as prescribed.
4. All Ss performed maximally in all tests.
5. The exercise tests were of sufficient intensity and duration to elicit differences, if present, between each of the test groups.
6. Provided HMB has an effect on muscular strength or body composition, the dosage and duration of the HMB supplementation in this study were sufficient to influence the test results.
6. All Ss followed a well balanced diet and came well nourished and hydrated to all tests.
7. All Ss completed the medical history accurately.

Null Hypotheses

H₀₁: There will be no significant differences between the placebo and experimental groups in muscular strength.

H₀₂: There will be no significant differences between the placebo and experimental groups in body composition.

The null hypotheses tested in this study pertain to the effect of HMB supplementation in collegiate football players based on: (1) treatment conditions: repeated factor where all Ss received HMB and placebo, (2) order of presentation: between Ss factor due to receipt of HMB before and after the placebo, or (3) the interaction between treatment and presentation when maximal strength values and body composition were controlled.

Significance of the Study

Throughout history, athletes have trained their bodies to the utmost limits. Nutritional means, such as HMB supplementation, may be beneficial in promoting improved performance. Research on HMB has shown that supplementation can build muscle and reduce body fat, as well as lower total and LDL cholesterol levels in blood and help to strengthen the immune system (13, 30, 31, 32, 33, 35, 45). Short-term studies (6, 24, 30, 36) indicate that HMB does not adversely affect hematological and metabolic profiles, as do anabolic steroids. This is important for athletes, and the knowledge gained in this study may also be of benefit in disease prevention. Placing stress on the body through exercise causes an increase in proteolysis that also occurs with chronic wasting diseases or acute stress (33).

DEFINITION OF TERMS

Endogenous - produced or synthesized within the organism or system (12)

Exogenous - not produced or synthesized within the organism or system (12)

Half-life - the time required for half the amount of a substance in or introduced into a living system to be eliminated by natural processes (12)

Oxidation - the act or process of combining with oxygen (12)

Proteolysis - the hydrolysis of proteins or peptides with formation of simpler and soluble products (12)

CHAPTER II

REVIEW OF RELATED LITERATURE

β -hydroxy β -methylbutyrate (HMB) is the metabolized form of leucine, a branched chain amino acid (BCAA). These BCAA's ultimately serve as the structure for protein building. The major metabolic pathway of HMB metabolism was described extensively between 1949 and 1955 (30). Nissen and colleagues (13, 32, 33, 35) found that the patented leucine metabolite HMB helps build muscles quicker than any supplement known. This discovery occurred after years of examining the branched-chain amino acid leucine's role in protein synthesis and anti-catabolism (37). The role of leucine, α -ketoisocaproate (KIC), and HMB were examined to help animals of commerce lead healthier lives and produce more efficiently. Consistent and reproducible research showed that animal health is consistently improved by HMB supplementation. This encouraged Nissen and his colleagues to see if HMB had similar benefits in humans (36). The patent rights are owned by the Iowa State University Research Foundation, and they have been licensed to Metabolic Technologies, Inc (MTI). In 1994, MTI licensed several companies to sell HMB, including Twin Laboratories Inc. and Experimental and Applied Sciences (EAS) under U.S. Patent # 5,348,979 (29).

HMB Metabolism

Leucine is one of the nine essential amino acids serving as a fundamental building block for structural proteins. The tissue supply of leucine is dependent on endogenous and exogenous sources. Meat and plants represent the greatest exogenous source of leucine, and ultimately HMB. Unfortunately, the ingestion of what research has shown to be an anabolic dosage of HMB would far exceed normal daily intake (32, 33). Following

ingestion of a meal, the liver is the primary site for the uptake of most of the amino acids. Leucine is classified as an indispensable amino acid due to the negative nitrogen balance which occurs whenever there is a deficiency. According to the needs of the body, the liver monitors and adjusts the rate of metabolism (14).

In vivo studies have shown that HMB is derived exclusively from the amino acid leucine via KIC (43). In the cytosol and mitochondria of muscle cell, leucine is transaminated to the ketoacid KIC (30). The production of HMB from KIC is made possible by the enzyme KIC-dioxygenase. Under normal conditions, about 5% of leucine is oxidized to HMB (Figure 1); the remaining 95% of leucine is oxidized by the classical dehydrogenase mechanism (43).

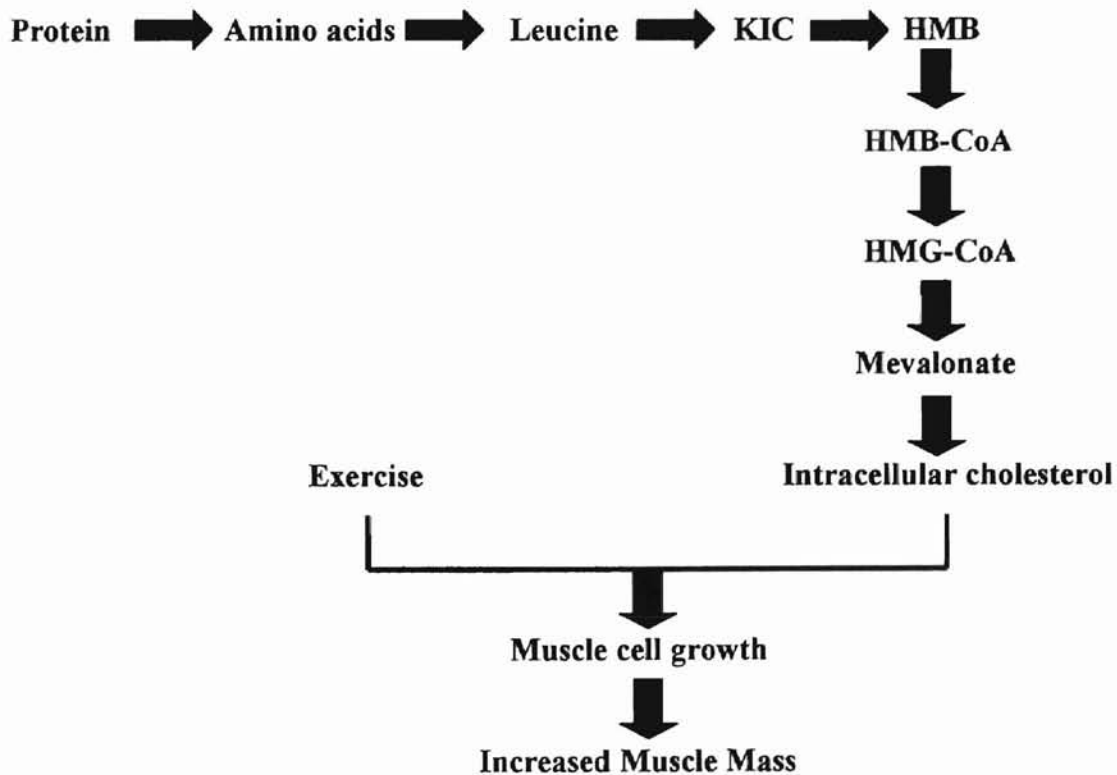


Figure 1 – Overview of HMB Metabolism in Mammals. Adapted from: Nissen, S.L., and N.N. Abumrad. Nutritional role of the leucine metabolite β -hydroxy β -methylbutyrate (HMB). *J Nutr Biochem.* 8:300-311, 1997.

After HMB is produced in the body, it undergoes one of three fates. The most likely metabolic fate of HMB metabolism is direct conversion to β -hydroxy β -methylglutaryl CoA (HMG-CoA). The HMG-CoA produced serves as a key carbon source for cholesterol synthesis, which is necessary to maintain maximal cell function. During stimulated growth or differentiation, cholesterol synthesis may be rate-limited by HMG-CoA. Supplementation of HMB may provide a saturating source of HMG-CoA for cholesterol synthesis. Thus, the muscle cell membranes, which contain cholesterol, could be repaired after exercise-induced damage with an adequate supply of this substrate. The result may be a more rapid return to positive protein synthesis, allowing for maximal cell growth and function (30).

An alternate fate of HMB is excretion in the urine (3). Besides the production of HMB in the muscle and liver, the kidney is also believed to produce HMB; therefore, kidney excretion may partly account for the short half-life of HMB. About one-third of HMB fed to pigs and sheep is excreted in the urine (43). The half-life of HMB is about one hour in rats, 2 hours in pigs, and 3 hours in sheep. In human studies, up to one-half of HMB dosage was excreted in the urine (30).

The final possible fate of HMB may involve the regulation of enzymes responsible for muscle tissue breakdown. Current data supports that HMB supplies a source of HMG-CoA for cholesterol synthesis in muscle cells. Under demanding situations, these cells may need increased level of cholesterol synthesis for either the synthesis of new cell membranes or to recreate damaged membranes of existing cells (30). There is evidence that HMB supplementation decreases biochemical markers of muscle breakdown among

weightlifters and directly decreases the degradation of muscle protein in vitro (3, 7, 30, 35).

Metabolic Effects of β -hydroxy β -methylbutyrate

In vitro studies

In vitro studies have shown that HMB directly effects muscle metabolism (30). The rates of proteolysis and protein synthesis were measured in isolated muscle strips from rats and chicks exposed to various concentrations of HMB (35). In both rat and chick muscle, HMB stimulated protein synthesis by an average of 6%. At the same time, protein breakdown was decreased by an average of 18%. These results support human research that shows HMB suppresses muscle proteolysis.

In a study on rat and mouse muscle cells, HMB increased fatty acid oxidation (7). HMB treatment increased beta-oxidation of palmitate by 30%, decreased lactate dehydrogenase (LDH) by 25%, and increased cellular expression of creatine kinase by 25%. This data suggests that HMB exerts several effects on muscle cells, such as increasing the cell's oxidative capacity, stabilizing the membranes, and enhancing the expression of muscle-specific proteins. These HMB-induced changes may be beneficial in strength training as they would protect against some of the associated cellular injury. Also, the increase in fatty oxidation may explain some of the decrease in body fat observed with HMB supplementation in humans.

Animal studies

A variety of animal experiments have been conducted with HMB supplementation. A series of experiments (43) was conducted to determine whether leucine and KIC are converted to HMB in mammals. Young lambs infused with leucine showed levels of

leucine and HMB nearly identical to steady state, indicating that HMB is derived solely from leucine. In both lambs and pigs, only 34% of the injected HMB was excreted in the urine, suggesting that a portion of HMB is metabolized by the body.

The influence of HMB on protein metabolism has been studied in broiler chickens (30). Broiler growth and performance is improved by dietary supplementation with low levels of HMB. In addition, broiler mortality was decreased by 31%, resulting in increased body weight, hot carcass yield, and breast yield. Of note, lower doses were as effective as the higher doses in decreasing mortality. These findings suggest that HMB may be an important regulatory component affecting broiler growth.

In a toxicity study (30), three pigs were fed a diet supplemented with 100 grams of HMB for a period of 4 days, and two control pigs were fed an unsupplemented diet. This HMB dosage is approximately 100 times higher than what is normally fed to humans. At the end of the period, hematology, gross organ pathology, and histology measurements were made on each pig. None of the pigs experienced unfavorable signs related to HMB consumption. Across all animal studies, no adverse effects of HMB have been reported.

Human studies

Studies with humans have found that HMB supplementation can partly prevent exercise-induced proteolysis and/or muscle damage and result in larger gains in muscle function when combined with resistance training (33). One investigation (33) studied 41 male college-age volunteers, randomly placed into three levels of HMB supplementation (0, 1.5 or 3.0 g HMB/day) and two protein levels (normal, 117 g/day, or high, 175 g/day). Ss were excluded from the study if they had participated in a resistance training program in the last 3 months. The Ss weight lifted for 1.5 hours, 3 days/week for 3 weeks. With

HMB supplementation, the exercise-induced rise in muscle proteolysis was significantly decreased as measured by urine 3-methylhistidine, and creatine phosphokinase. Subjects gained lean body mass in a dose-responsive manner: 0.88 pounds for the group that received no HMB, 1.76 pounds for the group that ingested 1.5 g HMB/day, and 2.64 pounds in the group that ingested 3.0 g HMB/day. Also, total strength increased 8% in the unsupplemented group, 13% in the 1.5 g HMB/day group, and 18.4% in the 3 g HMB/day group. In the second study (33), 32 male volunteers, ages 19-22, were divided into two groups receiving either no HMB or 3.0 g HMB/day. They weight lifted for 2-3 hour/day, 6 days/week for 7 weeks. Compared with the unsupplemented subjects, at 2 and 4-6 weeks of the study, fat-free mass was significantly greater in the HMB-supplemented subjects.

The effect of HMB supplementation on strength and body composition of trained (experienced in weight training) and untrained (novices in weight training) males undergoing intense resistance training was tested in a 4-week double blind study (32). Twenty-three untrained and 17 trained males were randomly assigned to either placebo capsules or capsules containing HMB, 3 g/day in divided doses. All Ss completed resistance exercises 3 days/week for 4 weeks. Pre- and post-measurements were taken on body composition by underwater weighing. After 4 weeks of treatment, body fat significantly decreased and lean body mass increased in the HMB-supplemented subjects. The development of fat-free mass was reflected in a 55% greater gain in the bench press lift. These results indicate that benefits are reaped regardless of initial training status.

To validate previous research demonstrating that HMB increases fat free mass and strength during resistance training and to determine if additional benefits are gained

by supplementing with higher doses of HMB during resistance training, 37 untrained collegiate males were assigned to one of three groups (0, 36, and 76 mg HMB/kg/day) (33). Resistance training consisted of 10 different exercises performed 3 days/week at 80% of 1-repetition maximum (1RM). Among the groups, no differences were observed in 1 RM strength, but lower body strength increased by 14% and 10% for the 38 and 76 mg/kg/day groups respectively, as compared to the 0 mg/kg/day group. No differences were observed in body fat among the groups, but the 38 mg/kg/day group exhibited a greater increase in fat free mass. At 48 hours after the initial training bout, the 0mg/kg/day group demonstrated a greater increase in creatine phosphokinase (CPK) activity (an estimator of muscle breakdown) than either the 38 or 76mg/kg/day groups. Despite the fact 1 RM strength gains were not significantly different among the groups, HMB appears to inhibit muscle breakdown and increase fat free mass. Also, strength or fat free mass gains do not appear to be enhanced by higher doses of HMB (>38 mg/kg/day).

The effect of HMB supplementation on muscle soreness and strength following downhill running was tested on young physically active males 48 hours after 30 minutes of downhill running (5). The tests were performed before and after 28 days of dietary supplementation with 3g/day HMB. On a scale from 0 to 10 (maximum soreness), muscle soreness resulting from downhill running was reduced after supplementation of HMB as compared to before supplementation (1.9 ± 0.8 versus 2.7 ± 0.5 , $p < 0.05$). Strength was less negatively affected following HMB ingestion, as compared to placebo, in those individuals who lost strength following downhill running prior to supplementation.

These data indicate that individuals who are susceptible to strength loss following eccentric exercise may benefit from HMB.

To determine if the same effect of HMB supplementation on men occurs in women, a 2-part study was carried out (31). In experiment one, 36 non-exercising women were given either a placebo or 3g HMB/day for four weeks. In experiment two, 37 women were also supplemented with a placebo or 3g HMB/day combined with a supervised, three times a week weight training program. Body composition was measured at the beginning and end by underwater weighing. There was no effect of HMB on the sedentary women, but combined with weight training, the HMB-supplemented women experienced increases in lean mass and strength. The investigators suggest that the endogenous production of HMB may not be adequate to meet the needs of muscles during vigorous weight training.

Studies in young adults (33) have demonstrated that HMB supplementation can increase strength and lean mass, so a study was conducted to determine if HMB supplementation would be beneficial in older adults. In the 8-week double blind study (45), thirty-one elderly men and women were randomly assigned to either placebo capsules or HMB capsules. After four weeks of training, leg strength was increased in the HMB-supplemented group. After eight weeks, the HMB subjects gained more lean mass and lost more fat mass compared to the placebo group. When supplemented with HMB daily, older adults appear to make significant gains in muscular strength and lean mass similar to younger adults. These findings are similar to studies conducted on younger adults.

In humans, little is known about the long-term effects of HMB supplementation on hematological and metabolic markers. The short-term effects of ingesting 1, 3, or 6 g/day of HMB on urine and serum HMB concentrations and clinical chemistry profiles were examined in 40 experienced resistance-trained athletes (24). In this double blind and randomized study, the athletes were matched according to training volume and weight and assigned to supplement their diet with HMB for 28 days. The HMB supplementation resulted in significant increases in serum and urinary HMB. Compared to the unsupplemented group, changes in creatine kinase levels tended to be lower in the 6g/day group. No other significant differences were found among groups in the chemistry profile. These results indicate that HMB does not adversely affect hematological and metabolic profiles over the short-term.

In a longer investigation, 37 untrained collegiate males were assigned to one of three groups (0, 36, and 76 mg HMB/kg/day) to compare hematology, hepatic and renal function during 8 weeks of resistance training (6). Blood and urine was collected prior to resistance training, 48 hours after the initial session, and at 1, 2, 4, and 8 weeks of resistance training. At 48 hours, the unsupplemented group demonstrated a greater increase in creatine phosphokinase (CPK) activity (an estimator of muscle breakdown) than either the 38 or 76mg/kg/day groups. At 4 and 8 weeks, the 38mg/kg/day group had a greater increase in basophils compared to the unsupplemented or 76mg/kg/day groups. At all time points, plasma HMB concentration was greater for 38mg/kg/day versus no supplementation and 76mg/kg/day was greater than 38mg/kg/day. Urinary recovery was similar in the 38 and 76mg/kg/day groups. No adverse effects on hepatic enzyme function, lipid profile, renal function or the immune system were found. Therefore, 8

weeks of HMB supplementation up to 76mg/kg/day during resistance training appears to be safe.

CHAPTER III

METHODOLOGY

The major objective of this study was to assess the effects of daily β -hydroxy- β -methylbutyrate (HMB) supplementation on muscular strength and body composition among collegiate football players. Those who joined the study ingested either capsules of HMB (3g/day) or a similar amount of capsules that do not contain HMB for the 8-week supplementation period. This study employed a crossover design where the subjects ingested HMB for four weeks and placebo for 4 weeks with a one week washout period. A battery of tests involving muscular strength and body composition was performed at the beginning of the study, at the end of the first supplementation period, and at the end of the study. All physical tests were preceded by a 10-minute warm-up and stretching period. Strength tests included bench press, power cleans, and squats. Body composition was assessed using weight and skinfold calipers.

Setting

The testing was performed during three sessions at the Oklahoma State University athletic facilities in Stillwater, Oklahoma.

Subjects

The subjects ($n=35$) were collegiate football players training under the supervision of certified strength coaches. All Ss (21.3 ± 1.2 yr, 72.1 ± 0.2 "', 97.6 ± 18.8 kg, and $12.4 \pm 7.0\%$ body fat) had at least 4 years of weight training experience. They adhered to the same regimen of intensity and average 20 hours of weekly exercise. These Ss were asked to participate in the study. The main incentives for participation were that Ss received information regarding their physiological status and receive possible performance-

enhancing supplements at no charge. Those who identify themselves as prospective Ss were required to give their informed written consent (Appendix A) and to complete a physical evaluation and medical history questionnaire (Appendix B) designed to evaluate health status, medication, and medical history. A licensed physician evaluated this information. Participation in the study required that Ss be in apparently good health. Any indication of a possible health problem that might compromise the safety of Ss or the validity of the study constituted grounds for exclusion (Appendix C). The Ss were assigned randomly to one of two experimental groups.

Research Design

This study was experimental in nature and followed a double blind crossover, placebo design. In the first supplementation period, 16 of the 35 Ss were supplemented with 3 grams of HMB per day for 4 weeks; the other 19 received placebo. There was a one-week washout period and the Ss received the other supplement for 4 weeks. Comparisons between the placebo and HMB treatments were made using a randomized split-plot factorial analysis of covariance (ANCOVA). Post-hoc analyses were performed to determine the differences between means using a significance level of .05.

Internal Validity

An attempt was made to ensure that the results would not be influenced by factors other than the independent variables. The groups were created by random assignment of Ss. History and maturation should have affected both groups equally because all Ss were highly-trained collegiate athletes in football and weight training. Possible procedural and instrumentation confounding variables were controlled for during each exercise testing bout and body composition analysis. This was accomplished by following identical

protocols and instrumentation procedures. The capsule administration was prescribed identically for each group throughout the investigative period.

An uncontrollable threat to internal validity is morbidity. However, the chance of Ss withdrawing from this project for reasons other than injury was minimal due to its relatively short duration and there was no required change in lifestyle, diet, or activity level. Furthermore, the investigators encouraged compliance by stressing the importance of this research prior to and during the study. In addition, continuous feedback was provided and competition among the Ss was encouraged during testing.

External Validity

The ability to generalize from the results of this study is limited by several factors. Since all Ss were homogeneously well trained athletes from a specific area and participating on a volunteer basis, generalizations beyond the scope of this investigation will not be attempted. To control for reactive arrangements and the placebo effect, the placebo capsules were identical in color, composition, size, and texture to the capsules of HMB.

Exercise Training

Exercise sessions (Appendix D) were held 4 days/week for approximately 4 hours/day. A warm-up consisting of 10 minutes jogging and 10 minutes stretching preceded each practice session. Both strength and speed endurance exercises were performed each day of practice. Strength exercises were done at 10 exercises/session, with 8-12 sets/exercise, and 2-10 reps/set. The speed and tempo endurance drills were performed with 26-30 seconds recovery time between repetitions and full recovery between sets.

Testing Procedures

All Ss reported to the test site prior to initiating the treatment schedules to complete a health history questionnaire, a release of pertinent demographic information (Appendix E), and a medical examination performed by a licensed medical physician (Appendix B). A dietary analysis (Appendix F) was performed via a food frequency questionnaire (46) to assess the Ss dietary intake. When cleared for participation, each S received a thorough explanation of the experimental procedures before commencing the treatment. Permission to conduct the study was granted by the Oklahoma State University Institutional Review Board (Appendix G).

The nine-week double blind, crossover design required two stages of supplementation: (1) HMB and (2) placebo. One full week lapsed between the end of the first 4-week treatment period and the switch to the second 4-week treatment period. Consequently, each S underwent both treatments with an intervening washout period of 7 days. Following the washout period, Ss crossed over to the other treatment and the protocol was repeated.

In the first supplementation period, Ss were asked to ingest either 750 mg capsules of HMB or placebo capsules containing an inert substance (methylcellulose) for a period of 28 days which was consumed at a rate of four capsules per day or 3g of HMB/day. There was a one-week washout period and the Ss then received the other supplement for 4 weeks. The optimal uptake and utilization of HMB is unknown in regard to time of day, food intake, or other conditions. However, multiple doses per day and smaller dose sizes are believed preferable (16). The Ss were instructed to take four capsules a day;

two with breakfast, one with lunch, and one with dinner. The rationale of taking the capsules with meals was to enhance compliance and to have small, multiple doses.

The supplements were distributed at the beginning and two weeks into each supplementation period. Therefore, 56 capsules were distributed four times: at the beginning and midway through both supplementation periods. Constant verbal reinforcement was given to ensure the Ss adhered to the protocol. All capsules were disguised and controlled by the nutritional supplement manufacturer (Twin Labs, Inc., Hauppauge, NY).

Prior to supplementation and on the day following each 28-day supplementation period, S reported to the testing site at the scheduled time, having been instructed not to eat for 3 hours prior to testing. The Ss were instructed to not alter their lifestyles or dietary practices during the investigation. In addition, they were asked to report whether or not there were any side effects. In order to receive the most accurate and maximal exercise effort, vigorous physical activity was discouraged for 24 hours prior to the scheduled test appointment. Ss were instructed to report to the testing site well hydrated and nourished. Also, a full night's sleep was strongly recommended.

A battery of tests involving muscular strength and body composition was performed at the beginning of the study, at the end of the first supplementation period, and at the end of the study. Subjects were tested in groups and competition was stressed. A 10-minute warm-up and stretching period preceded each testing session. All strength tests used 3-5 repetition maximal efforts and the 1 repetition maximal effort was predicted. Strength tests included bench press, power cleans, and squats, recorded to the nearest pound. Body composition was assessed using body weight and Lange skinfold

calipers, computed from total skinfold measurements in millimeters for statistical analysis. The Jackson and Pollock (thigh, chest, abdominal) equations were used to determine body density for healthy male athletes (19). The exercise testing sessions and body composition analyses were conducted during similar times of day and days of the week for each S.

Statistical Analysis

To maintain the crossover design, Ss switched to either HMB or placebo. The second stage of the study was conducted in the same manner as the first stage. The pre-test data generated in this investigation originated from health history questionnaires (Appendix B) and the testing data form (Appendix E). The data was used to describe the tested sample in terms of health and physical fitness status. Mean, standard deviation, and range calculations describe demographic information gathered from health questionnaires.

The exercise testing bout consisted of maximal strength values, body weight, and percent body fat. The three testing sessions were compared by analysis of covariance (ANCOVA). Tukey post hoc analyses were performed to test the significance of observed mean differences.

The hypothesis tested in this study pertains to the effect of HMB supplementation in collegiate football players based on: (1) treatment conditions: repeated factor with all Ss receiving HMB and placebo, (2) order of presentation: between Ss factor of receiving HMB before and after the placebo, or (3) the interaction between treatment and presentation when maximal strength values and body composition (covariate) are controlled.

The dependent variables in this study are maximal strength values, body weight, and sum of body fat skinfolds following each supplementation period. The independent variables are: (1) the placebo or the HMB supplement and (2) the order of presentation (supplement first of second). The repeated factor is treatment in reference to HMB/placebo and order of testing. The covariates were maximal strength values, body weight, and sum of body fat skinfolds. A split-plot factorial analysis of covariance design was used for the primary analysis. A separate analysis was performed for each variable. The alpha level was set at $p \leq .05$ for all analyses.

CHAPTER IV

MANUSCRIPT

Athletes are constantly searching for means of improving performance through dietary supplements that promise performance enhancing or ergogenic benefits. The most common dietary supplements on the market include creatine monohydrate, β -hydroxy β -methylbutyrate (HMB), antioxidant vitamins, amino acids, caffeine, and protein powder (1, 10, 15, 22, 37, 38). Sales of pills, powders, bars and beverages formulated to enhance athletic performance and recovery reached \$1.26 billion in 1997 and are expected to increase (34). In the last few years, HMB, a byproduct of the essential amino acid leucine, has become one of the best-selling sports supplements (3, 8, 37). Because it is found in both plant and animal foods, including catfish and grapefruit, and is a metabolite of an amino acid, HMB has been classified as a dietary supplement (10, 22, 37, 42). It has been estimated that a 70 kilogram human would produce from 0.2 to 0.4 g HMB per day (13). The Recommended Dietary Allowances (RDA) estimates leucine requirements at 14 mg/kg/day for adults or a dosage of approximately 1 g/day (12). However, the RDA's do not take into account the substantive evidence indicating that exercise increases protein requirements (4, 9, 40).

The proposed effects of HMB supplementation are numerous (3, 30, 36, 37). It has been hypothesized that HMB supplementation helps the body reduce catabolic effects of resistance training (3, 36, 37). Recent investigations have shown that intensely trained HMB-supplemented Ss significantly gain more strength and lean body mass than unsupplemented Ss (32). In addition, there has been a consistent decrease in LDL cholesterol, potentially reducing the risk of cardiovascular disease (30). To date, no

adverse effects have been seen in animals or humans supplemented with HMB (6, 24, 30, 36).

The effect of HMB supplementation on strength and body composition of males undergoing intense resistance training has been tested (32). Body fat significantly decreased, and lean body mass increased in the HMB-supplemented Ss. The development of fat-free mass was reflected in a 55% greater gain in the bench press lift. Body fat between pretest and HMB in the present investigation decreased by an average of 7.3% (.9% body fat). Although body composition results were not significantly different, further investigation regarding the potential effect of HMB on body composition needs to be explored.

The effect of HMB on body fat has been validated in a few animal and human studies (7, 32). HMB treatment has increased beta-oxidation of palmitate by 30%, decreased lactate dehydrogenase (LDH) by 25%, and increased cellular expression of creatine kinase by 25%. These data suggest that HMB exerts several effects on muscle cells, potentially increasing the cell's oxidative capacity, stabilization of cell membrane, and enhancing the expression of muscle-specific proteins. Also, the increase in fatty acid oxidation may explain some of the decrease in muscle fat observed with HMB supplementation in humans.

The exact mechanism whereby HMB influences muscle metabolism is not known; however, there are two hypotheses. HMB may act as a precursor to cellular muscle repair by stimulating proteinosis, which would increase collagen synthesis and connective tissues (37). The net effect of these actions would be a reduction in recovery time, which could potentially increase strength and lessen the risk of overtraining. The

other hypothesis is that HMB may regulate enzymes responsible for muscle tissue breakdown (37). There is evidence that HMB supplementation decreases biochemical markers of muscle breakdown among weight trainers and directly decreases the degradation of muscle protein in vitro (3, 7, 30, 32, 33, 35). The objective of this research was to conduct a randomized controlled trial to evaluate the effects of daily HMB supplementation on muscular strength and body composition among collegiate football players undergoing a strenuous exercise program.

METHODS

Subjects

The Ss ($n=35$) were collegiate football players training under the supervision of certified strength coaches. All Ss (Table 1) had at least 4 years of weight training experience and adhered to the same regimen of intensity, averaging 20 hours of weekly exercise.

Table 1 Demographic Data

Age	Height	Weight	Body Fat
X = 21.3 ± 1.2yr range = 19.2-23.6yr	72.1 ± 0.2" range = 69.0-75.0"	97.6 ± 18.8kg range = 74.1-138.6kg	12.4 ± 7.0% range = 3.8-28.5%

Note. All values are at pretest.

Each S gave their written, informed consent to participate in these experiments after the purpose, procedures, and known risks of the tests were explained in accordance with the University Institutional Review Board. Each S completed a physical evaluation and medical history questionnaire designed to evaluate health status, medication, and

previous injury status. Participation in the study required that Ss be in apparently good health. Any indication of a possible health problem that might compromise the safety of Ss or the validity of the study excluded the individual from the present investigation. The Ss were assigned randomly to one of two experimental groups.

Experimental Design

This study was experimental in nature and followed a randomized double blind crossover, placebo design. In the first supplementation period, 16 of the 35 Ss were supplemented with 3 grams of HMB per day for 4 weeks; the other 19 received placebo. There was a one-week washout period and the Ss received the other supplement for 4 weeks.

Exercise Training

Each S participated in supervised exercise sessions (Table 2) held 4 days/week for approximately 4 hours/day throughout the 9 week period of supplementation. A warm-up consisting of 10 minutes jogging and 10 minutes stretching preceded each practice session. Both strength and endurance exercises were performed each day of practice. Strength exercises were done at 10 exercises/session, with 8 to 12 sets/exercise, and 2 to 10 reps/set. The endurance drills consisted of speed and tempo exercises; they were performed with 26 to 30 seconds recovery time between repetitions and full recovery between sets.

Table 2 Exercise Program

Type of Exercise	Drill/Lift	Distance	Recovery
Warm-up Every session	10 minutes jogging 10 minutes stretching		
Endurance (Speed) 2x/week	Parachute Surgical tubing Stadium steps Box jumps Foot ladder Medicine ball Metabolic Training (position specific running patterns)	4 x 40 yards 4 x 50 yards 4 flights 2 x 20 sec. 4 x 20 yards 2 x 10 yards 6 x 50 yards	Full between sets, 26-30 sec. between reps
Endurance (Tempo) 2x/week	50-yard dash Metabolic Training	2 x 5 6 x 50 yards	Full between sets, 26-30 sec. between reps
Strength 4x/week 70-90% RM 10 lifts/session	Snatch pulls, Power pulls, Push press, Split snatches, Incline plyometric push-ups, Step- ups, Jump squats, Seated power pass, Leg curls, Squats, Bench press, 2-way E-Z curls, Front squats, Incline bench, Upright row, Step-ups, Sumo deadlift, Military press, Leg curls, 2-way latissimus pulldown, 2-way E-Z curls, Triceps pushdown, Close grip, Hang clean, Up-right row, Pullover press, Dumbbell rows	8-12 sets 2-10 reps	Full between sets. 1-2 minutes between reps

Note. Not all drills/lifts performed at each exercise session.

Testing Procedures

The nine-week double blind, crossover design required two stages of supplementation: 1) HMB and 2) placebo. One full week lapsed between the end of the first 4-week treatment period and the switch to the second 4-week treatment period. Consequently, each S underwent both treatments with an intervening washout period of 7 days. Following the washout period, Ss crossed over to the other treatment and the protocol was repeated. All Ss reported to the test site prior to initiating the treatment schedules to complete a release of pertinent demographic information. In addition, a dietary analysis via a food frequency questionnaire (46) was performed to assess the Ss

dietary intake (Appendix H) and subsequently evaluated by a registered and licensed dietitian (2).

In the first supplementation period, Ss were asked to ingest either 750 mg capsules of HMB or placebo capsules containing an inert substance (methylcellulose) for a period of 28 days, which was consumed at a rate of four capsules per day or 3g of HMB/day. The Ss were instructed to take four capsules a day; two with breakfast, one with lunch, and one with dinner. The optimal uptake and utilization of HMB is unknown in regard to time of day, food intake, or other conditions. However, multiple doses per day and smaller dose sizes are believed preferable (16). In addition, the rationale of taking the capsules with meals was to enhance compliance. The supplements were distributed at the beginning and two weeks into each supplementation period. Therefore, 56 capsules were given four times: at the beginning and midway through both supplementation periods. Constant verbal reinforcement was given to ensure the Ss adhered to the protocol. All capsules were disguised and controlled by the nutritional supplement manufacturer (Twin Labs, Inc., Hauppauge, NY).

Prior to supplementation and on the day following each 28-day supplementation period, S reported to the testing site at the scheduled time, having been instructed not to eat for 3 hours prior to testing. The Ss were instructed to not alter their lifestyles or dietary practices during the investigation. In addition, they were asked to report whether there were any side effects. To receive the most accurate and maximal exercise effort, vigorous physical activity was discouraged for 24 hours prior to the scheduled test appointment. Ss were instructed to report to the testing site well hydrated, nourished and a full night's sleep was strongly recommended.

A battery of tests involving muscular strength and body composition was performed at the beginning of the study, at the end of the washout period, and at the end of the study. Ss were tested in groups and competition was stressed. A 10-minute warm-up and stretching period preceded each testing session. All strength tests used 3 to 5 repetition maximal efforts allowing prediction of 1 repetition maximal effort (26). Strength tests included the bench press, power cleans, and squats, recorded to the nearest pound. Body composition was assessed using body weight and the Jackson and Pollock (thigh, chest, abdominal) equations to determine body density for healthy male athlete's (19).

For the dietary analysis, the food frequency questionnaires were evaluated using the American Diabetes Association, Inc. and the American Dietetic Association's Exchange Lists for Meal Planning (41). The Exchange Lists are the basis of a meal planning system based on principles of good nutrition that apply to everyone. They contain foods that are alike; each choice contains about the same amount of carbohydrate, protein, fat, and calories.

Statistical Analysis

Comparisons between the placebo and HMB treatments were made using a randomized split-plot factorial analysis of covariance (ANCOVA) to compare the mean differences between tests. Tukey post-hoc analyses were performed to determine the differences between means using a level of significance set at 0.05. The repeated factor was treatment in reference to HMB/placebo and order of testing. The covariates are maximal strength values, body weight, and sum of body fat skinfolds.

RESULTS

There was no difference for muscular strength, including bench press, power cleans, and squats; or body composition, including body weight and body fat. Muscular strength was not significant, bench press ($F=.402, p>.05$), power cleans ($F=.807, p>.05$), and squats ($F=1.235, p>.05$). In addition, there was no significance for body composition (Table 3), body fat ($F=2.002, p>.05$) or weight ($F=.478, p>.05$). Although not significant, body fat during HMB supplementation decreased compared to body fat at pretest (Table 3). The repeated factor of treatment in reference to HMB/placebo and order of testing was not significant ($p>.05$). The means for all tests are listed in Appendix I.

Table 3 Body Composition Results

Weight			Body Fat		
Pretest	HMB Post-test	Placebo Post-test	Pretest	HMB Post-test	Placebo Post-test
215lb	215lb	216lb	12.4%	11.5%*	12.2%

Note. *Body fat during HMB supplementation decreased compared to body fat at pretest.

The food frequency questionnaire was evaluated using the American Diabetes Association, Inc. and the American Dietetic Association's Exchange Lists for Meal Planning (41). Reported mean intake was 2600 calories, consisting of 43-45% carbohydrate, 21-23% protein, and 33-35% fat.

DISCUSSION

In the present study, we examined the effects of daily HMB supplementation on muscular strength and body composition among collegiate football players undergoing a

strenuous exercise program. There were no significant changes in muscular strength, including bench press, squats, and power cleans, among the collegiate football players participating in this 8-week supplementation of both HMB and placebo. In addition, there were no significant changes in body composition, including body weight and percent body fat.

In short-term recall situations, the food frequency questionnaire has the potential to underestimate energy and nutrient intake (21). Other limitations of food frequency questionnaires include intake data being compromised when multiple foods are grouped within single listings and they are dependent on the ability of the subject to describe their diet (25). Athletes tend to focus more on eating and body composition than non-athletes (27). Consequently, desire for weight change and level of dietary consciousness may also severely bias reported food intake in food frequency questionnaires (20). Based on a review of the literature on intake requirement for football players (27), the average total caloric need in this study's Ss was 4310 calories/day. Therefore, the reported mean intake of total calories consumed (2600 calories/day) during this study is much lower than the football players' needs. Hence, it is believed that the mean reported caloric intake in this study is underreported.

The traditional nutritional intake requirement for football players includes an average percentage of total calories for each macronutrient resulted in values of 43.4% to 44.9% carbohydrate, 16.3% to 18.1% protein, and 38.5% to 38.8% fat. Depending on several factors, such as metabolic rate, activity level, and football position, the total caloric needs range from 39.0 to 45.7 calories/kilogram/day (27). The breakdown of macronutrients (43 to 45% carbohydrate, 21 to 23% protein, and 33 to 35% fat)

consumed by the football players in this study is fairly consistent with their needs as reported in the literature (27). Therefore, the subjects appear to have been adequately nourished to fulfill their increased needs due to intense exercise.

There were no significant changes in muscular strength, including bench press, squats, and power cleans, among the collegiate football players participating in this 8-week supplementation of both HMB and placebo. No change in strength variables among the HMB group and the decrease in some strength variables among the placebo group compared to pretest scores may indicate that overtraining has occurred.

Overtraining is a multifaceted syndrome with many causes as well as symptoms. A major symptom of overtraining that appeared to effect this investigation is decreased performance despite an increased training load (23). Many factors might have contributed to the potential overtraining effect of the involved Ss (17, 44). Hooper et al. (18) suggests that volume of training, rather than intensity, may be the major contributing factor in the development of the overtraining syndrome. If the body is unable to cope with the alarm responses of the overtraining stressors and consistent with Selye's Model of Distress (39), a reduction in the anabolic hormone and an increase in catabolic hormone will result. These factors may have lead to the lack of expected strength gains following 9 weeks of intensive exercise training and decreased the potential metabolic effect of HMB. The volume of exercise in this study was higher than most other HMB supplementation studies. This high volume of exercise combined with the high athletic ability of the subjects may have hindered any potential strength gains.

The present investigation had 8 Ss forced to withdraw from the study due to injury. Proper application of stress during the training program, with sufficient rest

periods, helps decrease the incidence of overtraining and injury. In addition, knowledge of the athlete's other life stresses enable the coach to modify the training schedule accordingly, reducing the incidence of overtraining.

SUMMARY

Athletes are constantly searching for means of improving performance through dietary supplements that promise performance enhancing or ergogenic benefits. The proposed affects of HMB supplementation are numerous. It has been hypothesized that HMB supplementation helps the body reduce catabolic effects of resistance training. Recent research has shown that intensely trained HMB-supplemented subjects significantly gain more strength and lean body mass than unsupplemented Ss (32).

This study was designed to assess the effect of daily HMB supplementation on muscular strength and body composition among collegiate football players undergoing a strenuous exercise program. Recognizing that caution should be observed in generalizing from this study's results, it was concluded that supplementation of HMB as provided in this study had no effect on muscular strength or body composition during an intensive strength and conditioning program on well-trained collegiate football players.

Future research needs to be performed on HMB to adequately assess the potential ergogenic effect of HMB. Very little clinical evidence exists for supplementing HMB in the athletic population. Even though short-term studies show that HMB is safe, the long-term effects remain unknown. Athletic staff considering supplementing HMB to their athletes should proceed with caution and consider the amount of HMB (leucine) an athlete is already receiving through an oral diet. More research needs to be conducted to

understand the mechanisms of how HMB works, so that researchers can develop better methods of helping athletes reach their full potential.

The following recommendations for future research are made: 1) using both male and female subjects, 2) using a longer supplementation period, 3) using untrained subjects, 4) inclusion of an endurance training scheme, and 5) assessing the HMB effect in an overtraining scenario with identification of stress indicators which do not return to baseline following a period of regeneration.

CHAPTER V

CONCLUSIONS, APPLICATIONS, RECOMMENDATIONS

Athletes are constantly searching for means of improving performance through dietary supplements that promise performance enhancing or ergogenic benefits. The proposed affects of HMB supplementation are numerous. It has been hypothesized that HMB supplementation helps the body reduce catabolic effects of resistance training. Recent research has shown that intensely trained HMB-supplemented subjects significantly gain more strength and lean body mass than unsupplemented Ss (32).

This study was designed to assess the effect of daily HMB supplementation on muscular strength and body composition among collegiate football players undergoing a strenuous exercise program. The null hypotheses were as follows:

H₀₁: There will be no significant differences between the placebo and experimental groups in muscular strength.

H₀₂: There will be no significant differences between the placebo and experimental groups in body composition.

Recognizing that caution should be observed in generalizing from this study's results, it was concluded that supplementation of HMB as provided in this study had no effect on muscular strength or body composition during an intensive strength and conditioning program on well-trained collegiate football players. Therefore, the null hypotheses have been accepted.

Future research needs to be performed on HMB to adequately assess the potential ergogenic effect of HMB. Very little clinical evidence exists for supplementing HMB in the athletic population. Even though short-term studies show that HMB is safe, the long-

term effects remain unknown. Athletic staff considering supplementing HMB to their athletes should proceed with caution and consider the amount of HMB (leucine) an athlete is already receiving through an oral diet. More research needs to be conducted to understand the mechanisms of how HMB works, so that researchers can develop better methods of helping athletes reach their full potential.

The following recommendations for future research are made: 1) using both male and female subjects, 2) using a longer supplementation period, 3) using untrained subjects, 4) inclusion of an endurance training scheme, and 5) assessing the HMB effect in an overtraining scenario with identification of stress indicators which do not return to baseline following a period of regeneration.

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Appendix A

OSU INSTITUTIONAL REVIEW BOARD CONSENT FORM GUIDELINE

The Effect of β -hydroxy β -methylbutyrate on Body Composition, Strength and Speed in Collegiate Football Players

I, _____, voluntarily agree to participate in this investigation directed by Dr. Jack Ransone and Kerri Neighbors at Oklahoma State University. I know that while the research study will be supervised by these individuals, other professionals who work with them may assist or act on their behalf. I understand that at all times during the research, I will be under the supervision of the principal investigator, Dr. Ransone.

I understand that the purpose of this study is to investigate the effects of ingesting β -hydroxy β -methylbutyrate (HMB) daily for four weeks on body composition, muscle strength and speed in collegiate football players. Those who join the study will be asked to ingest either 750mg capsules of HMB or placebo capsules containing an inert substance (methylcellulose) amounting to 3g dosage per day throughout the prescribed testing period. Each person will receive both HMB and placebo capsules during the investigation.

PROCEDURES

The procedures that I voluntarily agree to take part include:

1. A preliminary screening will be performed with a complete health-history questionnaire, a release of pertinent demographic information and complete medical examination performed by a licensed medical physician.
2. A battery of tests including muscular strength, muscular speed and body composition will be performed on each subject. Strength tests, such as bench press, squats and power cleans will be performed. In addition, horizontal and vertical jump will be assessed. Muscular speed will be determined by running a 40yd shuttle run. Body composition will be assessed with skinfold analysis.
3. The battery of tests will be performed under the supervision of a certified strength and conditioning instructor:
 - a. with the induction of a placebo capsule;
 - b. with the induction of a HMB capsule (double-blind).These treatment orders will be performed at random and will last maximally for 28 days.

CONFIDENTIALITY

I understand that complete confidentiality of records identifying the subject will be maintained throughout this investigation. Subject will be identified by number only and these assigned numbers will be kept confidential and secure. Materials relating myself to my identification number will be kept in a locked cabinet and will be destroyed

immediately after the study is completed. I am aware that the results of this study may be published but my confidentiality will not be compromised.

RISKS

I understand that some risks to my health and well-being may be associated with my participation in this research. In any experimental study, it is possible that I will have side effects which have not been recognized before. If such side effects should become severe, I may be removed from the study. As HMB is a food product recognized for human consumption, we expect no side effects. If there is any new significant information which might change my decision to remain in the study, I will be made aware of these changes.

BENEFITS OF PARTICIPATION

The benefits to the subject in this research are: complete medical physical and health history appraisal by a licensed medical physician, determination of muscular strength, muscle speed performance and body composition. This information will be discussed with the subject, if requested, to aid in designing an individual training program for the athletes.

For no charge, I will receive either the HMB capsules or the capsule without HMB to be taken daily. It has been made clear to me that neither I, nor the investigators, can decide what type of capsule I will be consuming during the testing period. Medical records from this study will be available to me at the end of the study and to my primary physician at my request.

SUBJECT ASSURANCES

I understand that: 1) my participation in this study is voluntary; 2) I may withdraw from this study at any time without penalty or loss of benefits to which I am otherwise entitled; 3) I may be removed from the study for medical reasons or non-compliance to study protocol; 4) my treatment by and relations with the physicians and organizations involved in this research study will not be affected now or in the future if I decide not to participate, or if I start the study and decide later to withdraw; and 5) I have not given up any of my legal rights or released any individual or institution from liability for negligence. Also, if at any time the investigator discovers any problem or an unforeseen situation arises that endangers any subject, I understand that my participation may be terminated by the investigator without regard to my consent.

I understand that I (or my legally authorized representative) may ask questions and request information about this research project at any time. By signing this consent I acknowledge that I have been afforded the necessary opportunities to pose any questions which I may have and that they have been answered to my satisfaction. The medical terms used have been explained to me and I understand them. Dr. Ransone and Kerri Neighbors will be available to answer questions. Dr. Ransone may be reached in his office by calling 405-744-9439, and Kerri Neighbors at 405-744-7469.

I understand that no guarantees are given with regard to my participation in this project. Specifically, I understand that there is a possibility of injury or adverse reactions, as set forth above. I agree that in the event of injury or an adverse reaction, that I hereby consent that any and all appropriate emergency medical care can be given to me in response to my condition. I understand that participation is voluntary, that there is no penalty for refusal to participate, and that I am free to withdraw my consent and participation in this project at any time without penalty after notifying the project director. I may contact Dr. Jack Ransone at 405-744-9439. I may also contact Sharon Bacher, IRB Executive Secretary, 305 Whitehurst, Oklahoma State University, Stillwater, OK 74078; telephone (405) 744-5700.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given to me.

Date: _____ Time: _____ (a.m./p.m.)

Signed: _____
(Signature of Subject)

I certify that I have personally explained all elements of this form to the subject or his/her representative before requesting the subject or his/her representative to sign it.

Signed: _____
(project director or his/her authorized representative)

17 APR 1998 11:47:11 AM

Appendix B

Physical Evaluation and Medical History Questionnaire

Physical Record

Name: _____ Age: _____ Birth Date: _____
Height: _____ Weight: _____
Blood Pressure _____ / _____
Urinalysis: Alb. _____ Sugar: _____
Family History: _____

Medical Examination

	OK _____	Problem _____	Comment _____
Dental	_____	_____	_____
Ear, Nose & Throat	_____	_____	_____
Head & Neck	_____	_____	_____
Skin & Scalp	_____	_____	_____
Lymphatics	_____	_____	_____
Thorax	_____	_____	_____
Lungs	_____	_____	_____
Heart	_____	_____	_____
Abdomen	_____	_____	_____
Hernia	_____	_____	_____
Genitalia	_____	_____	_____
Neurologic	_____	_____	_____

Orthopedic Examination

	OK _____	Problem _____	Comment _____
Dental	_____	_____	_____
Neck & Shoulders	_____	_____	_____
Elbow, Hand & Wrist	_____	_____	_____
Back	_____	_____	_____
Knees	_____	_____	_____
Ankles	_____	_____	_____
Feet	_____	_____	_____
Other _____	_____	_____	_____

Recommendations: _____

Physician's Signature _____ Date: _____

History Record

Name: _____ Phone Number: _____

Do you have, or have you ever had, any of the following conditions? If so, state when and if surgery was necessary.

Concussion(s) (number) _____

Neck injuries(number) _____

Shoulder injuries _____

Rib cage injuries _____

Back injuries _____

Hip injuries _____

Thigh injuries _____

Knee injuries _____

Lower leg injuries/"shin splints" _____

Ankle injuries _____

Foot injuries _____

Muscle injuries _____

Past Illness or Medical Problems: _____

Do you now have, or have you ever had, any of the following conditions? If so, state when and if you have had surgery for the condition.

Frequent headaches _____

Fainting spells, dizziness or weakness _____

Weakness or illness when exposed to high temperatures _____

Epilepsy or convulsions _____

Nosebleeds _____

Difficulty hearing _____

Frequent colds _____

Heart murmur _____

High blood pressure _____

Arthritis _____

Diabetes _____

Abnormal bleeding tendencies _____

Anemia _____

Thyroid disorders _____

Skin disorders _____

Allergies- Drugs/medication _____

- skin _____

- asthma _____

- hayfever _____

Loss of, or serious impairment of, a paired organ, (e.g. kidney, eye, etc.)

Hepatitis or jaundice _____

Infectious mononucleosis (mono) _____

Abdominal (stomach/intestines) _____

Kidney/bladder problems _____

Are you currently taking prescription medications? (list, and why)

Appendix C

Exclusion Criteria

Absolute

1. Absence of one apparent organ
2. Blood disease or blood deficiency (sickle cell, HIV)
3. Heart disease - marfan syndrome heart murmurs are common in adolescence, may participate if monitored
4. Unrepaired hernia
5. Physical immaturity
6. History of concussions or frequent epileptic seizures
7. Congenital cervical or lumbar defect
8. More than four (4) missed practice sessions, regardless of reason (injury, illness, etc.) throughout supplementation period
9. Noncompliance with exercise program
10. Noncompliance in taking the supplement as prescribed
11. Taking medication or supplementation that may interfere with HMB kinetics

Temporary

1. acute infections - contagious
 - A. Impetigo
 - B. Acne adolescence
 - C. Cold sores and fever blisters
 - D. bores - treated by covering up and send to physicians
2. asthma
3. untreated tuberculosis
4. uncontrolled diabetes
5. high blood pressure
6. previous injuries or surgery that hasn't recovered

Appendix D

Exercise Program

Note: Not all drills/lifts performed at each exercise session.

Warmup

10 minutes jogging
10 minutes stretching

Endurance

Speed 2x/week

<u>Drill</u>	<u>Distance</u>	<u>Recovery</u>
Parachute	4 x 40 yards	Full between sets, 26-30 sec. between reps
Surgical tubing	4 x 50 yards	Full between sets, 26-30 sec. between reps
Stadium steps	4 flights	Full between sets, 26-30 sec. between reps
Box Jumps	2 x 20 sec.	Full between sets, 26-30 sec. between reps
Foot ladder	4 x 20 yards	Full between sets, 26-30 sec. between reps
Medicine ball	2 x 10 yards	Full between sets, 26-30 sec. between reps
Metabolic Training (position specific running patterns)	6 x 50 yards	Full between sets, 26-30 sec. between reps

Tempo 2x/week

<u>Drill</u>	<u>Distance</u>	<u>Recovery</u>
50-yard dash	2 x 5	Full between sets, 26-30 sec. between reps
Metabolic Training (position specific running patterns)		

Strength

4 weightlifting sessions/week
Sets: 8-12
Reps: 2-10
% Max: 70-90
Total at 10 lifts/session

Exercises (lifts):

Snatch pulls	Power pulls	Push press
Split snatches	Incline plyometric push-ups	Step-ups
Jump squats	Seated power pass	Leg curls
Squats	Bench press	2-way E-Z curls
Front squats	Incline bench	Upright row
Step-ups	Sumo deadlift	Military press
Leg curls	2-way latissimus pulldown	2-way E-Z curls
Triceps pushdown	Close grip	Hang clean
Up-right row	Pullover press	Dumbbell rows

Appendix E

Demographic Information and Testing Data Form

Name _____

Date of Birth _____

Height _____ ft. _____ in.

Weight _____

Years of playing football _____

Years of weight training _____

Normal football position _____

TEST 1

TEST 2

TEST 3

	TEST 1	TEST 2	TEST 3
Body Weight (lbs.)			
Bench Press (lbs.)			
Squats (lbs.)			
Power Cleans (lbs.)			
Thigh skinfold (mm)			
Chest skinfold (mm)			
Abdomen skinfold (mm)			

Appendix F

Dietary Analysis Form

FOOD FREQUENCY QUESTIONNAIRE

Name _____ Date of Birth _____

How many days/week do you eat breakfast? (circle one) 1 2 3 4 5 6 7

How many days/week do you eat lunch? (circle one) 1 2 3 4 5 6 7

How many days/week do you eat dinner? (circle one) 1 2 3 4 5 6 7

How many snacks/day do you eat? (circle one) 1 2 3 4 5 6 7 8 9 10

How often do you eat the following foods?

Food **# Servings/day** **Never**

Meat (one serving is the size of a deck of cards)

Beef, hamburger	_____	_____
Pork, ham	_____	_____
Bacon	_____	_____
Liver	_____	_____
Lamb	_____	_____
Veal	_____	_____
Lunch meat	_____	_____
Poultry, chicken	_____	_____
Fish	_____	_____
Beans	_____	_____
Nuts	_____	_____
Eggs	_____	_____
Peanut butter	_____	_____

Dairy (one serving is 1 slice of cheese or 1 cup of milk)

Cheese	_____	_____
Milk	_____	_____
Yogurt	_____	_____
Ice Cream	_____	_____

Breads & Cereals (one serving is 1 slice of bread, 1/2 bagel, or 1 cup of cereal)

Bread, bagels	_____	_____
Cereal	_____	_____
Pasta	_____	_____
Baked goods, muffins	_____	_____

<u>Food</u>	<u># Servings/day</u>	<u>Never</u>
-------------	-----------------------	--------------

Vegetables (one serving is 1/2 cup of vegetables)

Dark green	_____	_____
Dark yellow	_____	_____
Potatoes	_____	_____
Other	_____	_____

Fruit and Fruit Juice (one serving is 1/2 cup of juice or 1 piece of fruit)

Citrus	_____	_____
Other	_____	_____
Tomatoes	_____	_____
Dried fruit	_____	_____

Fats and Oils (one serving is 1 tablespoon)

Margarine	_____	_____
Butter	_____	_____
Cooking fat/oil	_____	_____
Salad dressing	_____	_____
Cream gravy	_____	_____
Fried foods	_____	_____

Beverages (one serving is 1 cup or 8 oz.)

Soft drinks	_____	_____
Coffee	_____	_____
Tea	_____	_____
Alcohol	_____	_____
Water	_____	_____

Are there any other foods not listed that you eat regularly? If so, what and how much?

**Thank you for filling this questionnaire out
and participating in the HMB study!!**

Appendix G

IRB Approval Form

OKLAHOMA STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Date: May 5, 1999 IRB #: ED-99-122

Proposal Title: "THE EFFECT OF B-HYDROXY B-METHYLBUTYRATE ON BODY COMPOSITION, STRENGTH AND SPEED IN COLLEGIATE FOOTBALL PLAYERS"

Principal Investigator(s): Jack Ransone
Kerri Neighbors-Buchanan

Reviewed and Processed as: Expedited

Approval Status Recommended by Reviewer(s): Approved

Signature:



Carol Olson, Director of University Research Compliance

May 5, 1999
Date

Approvals are valid for one calendar year, after which time a request for continuation must be submitted. Any modification to the research project approved by the IRB must be submitted for approval. Approved projects are subject to monitoring by the IRB. Expedited and exempt projects may be reviewed by the full Institutional Review Board.

Appendix H

Dietary Intake Results

Subject Code	Meat	Dairy	Bread	Veg	Fruit	Fat
11	6	4	7	2	1	4
12	4	7	6	3	1	3
13	5	2	7	1	2	3
14	8	3	6	4	4	6
15	2	2	9	1	1	4
16	9	7	11	3	4	5
17	8	7	8	2	2	3
18	6	2	9	1	3	3
19	10	6	9	2	2	6
110	5	4	7	4	4	4
111	11	6	8	3	1	3
112	11	12	10	6	5	6
113	4	3	6	2	1	3
114	6	4	6	3	9	3
115	5	4	6	1	1	3
116	4	5	11		2	5
217	7	5	7	4	2	5
218	4	2	6	4	3	3
219	6	4	6	2	1	3
220	7	6	18	3	2	7
221	3	3	6	0	1	3
222	6	4	7	3	2	12
223	7	4	7	6	9	5
224	6	3	6	2	3	4
225	7	4	7	2	2	4
226	8	13	9	2	4	8
227	9	3	8	3	2	5
228	8	3	7	2	3	3
229	3	4	7	0	1	3
230	6	8	20	4	3	4
231	6	4	8	3	1	5
232	8	4	11	4	4	4
233	6	6	7	2	4	6
234	18	9	22	3	2	19
235	6	3	6	3	2	3
Total Exchanges	235	170	301	90	94	170
Average Exchanges	7	5	9	3	3	5

Average: 2600 calories/day
 44% Carbohydrate
 22% Protein
 34% Fat

Appendix I

Means of Test Data

Subject Code	Bench Press			Squat			Power Clean			Body Fat			Weight		
11	215	204	200	295	319	285	229	210	222	15.9	16	14.4	178	175	165
12	355	330	337	553	489	523	366	311	344	21.4	21.6	24	277	280	272
13	284	286	255	503	539	482	331	339	309	17.9	13.8	15.4	215	215	218
14	402	394	433	678	595	639	356	331	389	11.7	17.8	11.6	280	289	287
15	247	222	225	409	378	397	239	215	219	7.5	8.1	6.9	190	193	188
16	292	299	309	381	321	323	306	293	298	6.6	8.5	9.9	198	185	201
17	362	340	362	736	764	765	311	313	310	24.5	20	22.1	277	290	293
18	293	286	293	447	464	502	277	286	300	24.5	24.8	22.7	305	295	292
19	276	270	300	299	287	315	286	263	294	4	4.3	4.1	178	181	179
110	337	368	350	469	565	502	321	349	328	11.6	10	10.9	216	218	217
111	282	294	275	442	445	385	300	299	315	6.7	7.9	6.5	192	200	197
112	327	312	349	447	514	482	368	428	410	6.5	7	5	230	229	225
113	327	321	335	520	487	520	286	288	321	22.3	18.6	21.2	250	256	252
114	222	236	225	396	425	409	246	273	255	5.7	5.9	5.1	186	185	183
115	276	267	284	355	424	391	209	246	270	12.3	10	8.4	180	186	180
116	260	254	265	470	424	441	325	267	300	6.5	8.2	5.2	186	189	188
217	337	316	328	520	482	475	325	340	311	28.5	25.5	27.7	288	279	285
218	228	209	204	362	361	379	246	253	234	11.6	12.3	12.8	177	173	172
219	385	373	368	520	520	565	358	361	326	12.1	9.5	13.4	210	213	214
220	355	362	349	482	553	514	349	356	331	13.2	12.8	13	228	232	230
221	305	310	286	441	455	426	333	358	333	6	5.8	6.3	193	189	196
222	194	210	194	344	365	344	234	245	235	11	6.6	10.1	180	173	177
223	315	337	328	450	457	451	295	319	311	7.7	5.5	7.3	205	206	212
224	276	265	263	365	395	400	243	256	245	10.7	9.5	11.4	169	175	174
225	313	320	311	482	435	426	294	287	303	10.3	9.7	12.2	190	186	194
226	325	345	336	520	509	501	400	400	356	16.1	12.8	16.1	230	222	232
227	385	360	332	553	560	489	356	379	313	28.3	24	25	305	304	302
228	325	347	340	545	563	534	275	325	315	6.6	4.2	6.5	235	224	231
229	346	350	331	450	505	506	358	344	331	20.2	19.8	19.6	263	261	262
230	273	293	286	263	283	286	245	228	233	5.7	5.5	6.2	170	168	167
231	225	245	236	450	425	439	286	303	303	8.9	9.5	9	186	178	188
232	237	268	239	435	403	387	267	277	245	3.8	4	5.5	175	179	180
233	196	205	194	251	273	263	165	209	191	10.1	8.9	12.4	163	160	165
234	337	316	311	520	490	488	331	320	306	7.2	5.2	8.5	177	198	192
235	346	339	312	450	507	476	331	341	294	11.8	8.5	9.5	230	233	238
MEAN	299	299	296	452	457	449	298	303	297	12.4	11.5	12.2	215	215	216

Column 1 Pre-test

Column 2 HMB

Column 3 Placebo

VITA

Kerri Lynn Neighbors

Candidate for the Degree of

Master of Science

Thesis: THE EFFECT OF β -HYDROXY β -METHYLBUTYRATE ON MUSCULAR STRENGTH AND BODY COMPOSITION IN COLLEGIATE FOOTBALL PLAYERS

Major Field: Health, Physical Education and Leisure

Biographical:

Personal Data: Born in Oklahoma City, Oklahoma, on May 16, 1973, the daughter of Steve and Linda Neighbors.

Education: Graduated from Edmond Memorial High School, Edmond, Oklahoma in May 1991; received Bachelor of Science degree in Nutritional Sciences with a specialization in dietetics from Oklahoma State University, Stillwater, Oklahoma in May 1997. Completed the requirements for the Master of Science degree with a major in Health and Human Performance at Oklahoma State University in December, 1999.

Experience: A Registered and Licensed Dietitian in the State of Oklahoma, employed by the Oklahoma Dietetic Association 1998-present. Other experiences include acting as Sports Nutritionist for the athletes of Oklahoma State University, teaching undergraduate nutrition classes, fulfilling speaking engagements, presenting at personal trainer and fitness counselor certification workshops, planning eating disorder awareness programs, instructing aerobics classes, and consulting to various individuals and organizations.

Professional Memberships: Oklahoma Dietetic Association, American Dietetic Association, Sports, Cardiovascular and Wellness Nutritionists, Oklahoma Coalition on Folic Acid.

Certifications: American College of Sports Medicine, Exercise Leader; American Council on Exercise, Personal Trainer; Aerobics and Fitness Association of America, Personal Trainer/Fitness Counselor.