

Is the use of human chorionic gonadotropin effective as a weight loss regimen?

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Megan Marie Mosier

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2011

Dedication

I want to dedicate my scholarly project to my family who supported me throughout my undergraduate and especially graduate education. Their continuous love, support, and motivation allowed me to be successful and kept me determined. I am very blessed and grateful for all of you.

I want to especially dedicate my scholarly project to my mom, who has been an editor throughout this entire project. Her endless nights of reading a project she knew nothing about are very much appreciated. She is my backbone that allowed me to complete this project.

Acknowledgements

A special acknowledgement and thank you is needed for my advisor Dr. Susan Batten. With her support, motivation, and pep talks she helped transform my project into one at a graduate level. Her careful proofreading and editing is truly admired and appreciated. Not only did she transform my project, but also me. In the beginning of this project, I was a student always concerned about grades and being wrong, but she taught me that being wrong is part of the learning process and helps us learn from our mistakes. She has helped me grow into a professional and I will forever be grateful. Thank you.

“A teacher's purpose is not to create students in his/her own image, but to develop students who can create their own image.” ~Author Unknown

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I. Introduction

The United States is currently being taken over by an epidemic of obesity. Our current culture consists of increased food intake, unhealthy food choices, and decreased amount of physical activity (Centers for Disease Control and Prevention, 2011). Simply put, this is when an individual takes in more calories than the number of calories expended (Picot et al., 2009). There are many factors that have been linked to being obese and overweight such as genetic, biological, environmental, psychological, social and even economical (Picot, et al., 2009). Obesity and overweight are terms that are used when an individual is over the general weight allotted for a certain height, known as body mass index (BMI). An individual is considered overweight if the measured BMI is 25 to 29. An individual is considered obese when the measured BMI is over 30. Obesity increases risks for disease or health problems leading to diseases such as coronary artery disease, Type II diabetes, gynecologic problems such as polycystic ovarian syndrome or infertility, certain cancers, liver and gallbladder disease, sleep apnea or other respiratory diseases (National Institute of Health, 1998; Picot, et al., 2009).

The rates of overweight and obese individuals are not going down, however. The current estimated rate of obesity in the United States is 33.8% overall, with 32.2% of men and 35.5% of women (Flegal, Carroll, Ogden, & Curtin, 2010). The estimated rate of both obesity and overweight individuals is as high as 68% (Flegal, et al., 2010). The prevalence of obesity in individuals aged 20 to 74 increased 7-8% between 1988 and 2000 with an expected linear increase in the subsequent years (Flegal, et al., 2010). One study approximated that by 2030 approximately 90% of adult Americans

will be overweight or obese with 51% of adults being obese (Wang, Beydoun, Liang, Caballero, & Kumanyika, 2008). The rates of obesity are increasing among children and adolescents as well, which is even more disturbing (Ogden, Carroll, Curtin, Lamb, & Flegal, 2010). The percentage of children in 2007-2008 with a BMI greater than the 95th percentile was 16.9% (Ogden, et al., 2010).

The rising rates of overweight and obese individuals are increasing the cost of health care (Finkelstein, Fiebelkorn, & Wang, 2003). With greater prevalence of diseases associated with obesity, the number of visits to health care professionals, diagnostic testing, and treatment are all increased (Finkelstein, et al., 2003). Overweight and obese individuals accounted for 9.1% of the United States health care costs in 1998, reaching nearly \$78.5 billion (Finkelstein, et al., 2003). Obese individuals alone cost the health care system \$47.5 billion. (Finkelstein, et al., 2003). The projection of health care costs due to overweight and obese individuals showed costs will double every decade if this pattern continues (Wang, et al., 2008). Weight loss is the only way the epidemic can be stopped. However, the nature of human behavior is holding America back from attaining such a goal.

The rising rates of obesity have driven our society to an obsession of thinness and weight loss (Hamilton & Greenway, 2004). Exercise programs, which are the mainstay of weight loss, are on the decline because exercise requires motivation, hard work, dedication, time and money to achieve significant results. Our society, however, has seemingly lost the value of these principles, so individuals turn to the “quick fix” that allows for large amounts of weight loss quickly.

Commercial weight loss programs remain a popular method for weight loss. There are many commercial weight loss programs for an individual to choose from, but the dilemma is how to choose the right plan (Hamilton & Greenway, 2004). There are low carbohydrate diets, such as the Banting and Atkins diets, or high carbohydrate diets like the Pritkin and Ornish diets (Hamilton & Greenway, 2004). There are also very low calorie diets like the Prolinn or Optifast diet (Hamilton & Greenway, 2004). Lifestyle change programs such as Weight Watchers, Jenny Craig, and Nutrisystem are available as well (Hamilton & Greenway, 2004). With so many options, the individual may be left confused and unsatisfied with results, thus continuing to search for a more promising diet and outcome. The problem with many commercial weight loss programs is a lack of research and evidence of producing long term weight loss (Hamilton & Greenway, 2004). Too many programs rely on advertising and testimonials for success (Hamilton & Greenway, 2004).

After attaining unsatisfactory results, some individuals resort to more drastic measures, such as bariatric surgery. The two restrictive types of surgeries are: adjustable gastric banding, known as the Lap Band, and gastroplasty known as the Vertical Sleeve. Both methods decrease the size of the stomach to reduce appetite and convince the brain that the stomach is full (Picot, et al., 2009). There are also malabsorptive types of surgeries such as: Roux-En-Y gastric bypass and biliopancreatic diversion, which bypass the small intestine where nutrients are absorbed from the body (Picot, et al., 2009). Food directly enters into the ileum and is quickly passed through the digestive tract (Picot, et al., 2009). Any bariatric surgery comes with risks and should not be taken lightly.

Many individuals seeking the “quick fix” without surgery resort to medications for weight loss. Orlistat, known as Xenical or Alli, is the only medication available for weight loss (Ioannides-Demos, Piccenna, & McNeil, 2011). Orlistat acts as a pancreatic lipase inhibitor, which prevents the breakdown of triglycerides in the diet allowing fat to pass through the digestive system (Ioannides-Demos, et al., 2011). Sibutramine, known as Meridia, was available by prescription, but was taken off the market due to increased cardiovascular risks and strokes (Ioannides-Demos, et al., 2011). Amphetamines were also used in the treatment of obesity by blocking the reuptake of noradrenaline in the hypothalamus, thus inhibiting appetite (Ioannides-Demos, et al., 2011). Sales of amphetamines for weight loss was restricted due to dependency issues and cardiovascular risks (Ioannides-Demos, et al., 2011). New pharmacotherapies currently being reviewed are fluoxetine, bupropion, and naltrexone; use is off-label and not yet analyzed for effectiveness (Ioannides-Demos, et al., 2011). Human chorionic gonadotropin (hCG) has been used for the promotion of weight loss dating back to the 1950’s. The diet plan includes intramuscular injections of hCG and a strict 500 calorie diet. Use of human chorionic gonadotropin declined after the theory was proposed, but is now a “hot topic” with the media and patients for treatment of obesity and weight loss.

Problem statement: Minimal research has been completed in the past fifty years as to whether this regimen is effective; yet patients are willing to adopt this regimen because the diet seems to achieve significant amounts of weight loss quickly.

Purpose statement: The purpose of this review was to examine current research of the human chorionic diet and whether the diet is effective as a weight loss regimen for overweight and obese individuals.

Research question: Is the use of human chorionic gonadotropin effective as a weight loss regimen?

Definition of terms:

1. Obesity

- a. Theoretical: Adult with a BMI of 30 or higher (Centers for Disease Control and Prevention, 2011)
- b. General: Being excessively overweight
- c. Operational: Having a BMI greater than 30

2. Overweight-

- a. Theoretical: An adult with a BMI between 25 and 29.9 (Centers for Disease Control and Prevention, 2011)
- b. General: Being over a desired weight
- c. Operational: Having a BMI between 25 to 29

3. Body Mass Index-

- a. Theoretical: Calculated as weight in kilograms divided by height in meters squared, rounded to the nearest tenth (Flegal, et al., 2010). tenth.
- b. General: A calculation used to determine the amount of fat and predict health
- c. Operational: A calculation used to approximate the amount of adipose tissue in an individual and to categorize a person as underweight, at

weight, overweight, or obese. It is calculated by dividing the weight in kilograms by the height in meters squared.

4. Human Chorionic Gonadotropin-

- a. Theoretical: Hormone produced by the placenta that supports the corpus luteum after fertilization of the ovum (Molina, 2010).
- b. General: Hormone produced in pregnancy.
- c. Operational: Hormone produced by the placenta and embryo in pregnancy to sustain the production of progesterone throughout the pregnancy.

5. Weight Loss -

- a. Theoretical: Decrease of body weight due to the loss of either adipose tissue, water volume, or protein depletion
- b. General: Having a lower weight than a previous measurement
- c. Operational: The loss of body weight

6. Intramuscular injection-

- a. Theoretical: An injection given directly into the central area of a specific muscle (Encyclopedia of Nursing and Allied Health, 2011).
- b. General: An injection in the muscle.
- c. Operational: The injection of a medication in the muscle layers.

7. Subcutaneous injection-

- a. Theoretical: Administration of a medication directly beneath the skin. Can be placed in the adipose tissue of the abdomen, upper arm, or upper thigh (Encyclopedia of Nursing and Allied Health, 2011).
- b. General: An injection given under the top layers of skin

- c. Operational: The injection of a medication into the adipose tissue below the skin

Assumptions:

1. There is abundant research on the topic.
2. There is current research on the topic.
3. There is a current understanding about the topic.

Limitations:

1. There is no limit to the time of publication of the periodicals since most of the research and writing on this topic span 50 years ago.
2. There is no restriction on the country of origin of publication; however, there will be a restriction to English language publications only.
3. There is no restriction to the type of periodical since public information will be reviewed.
4. There is no restriction placed upon gender, race, culture, or body type.

Hypothesis: The human chorionic gonadotropin hormone has no effect on the weight loss of the individual.

Significance of Study: The significance of this study was to investigate the effects of the human chorionic diet and to inform both consumers and healthcare professionals of the effectiveness and side effects of the weight loss regimen.

II. Literature Review

Human chorionic gonadotropin

The placenta plays a vital role for the fetus during pregnancy by providing supportive function, allowing for exchange of nutrients and gas between mother and fetus (Molina, 2010). The placenta also provides protection from the mother's immune system by serving as a barrier, and synthesizes a number of hormones that promote fetal growth and survival. The placenta produces both steroid and peptide hormones, including human placental lactogen, adrenocorticotropin, growth hormone variant, parathyroid hormone, calcitonin, relaxin, inhibins, activins, and atrial natriuretic peptide (Cunningham et al., 2010a). Human chorionic gonadotropin (hCG), synthesized by the syncytiotrophoblast cells of the placenta and fetal kidneys, is among these hormones (Molina, 2010).

hCG is comprised of two subunits, α and β . The α subunit is common among a group of glycoproteins known as gonadotropins that includes luteinizing hormone (LH), follicle stimulating hormone (FSH), and hCG (Masters, 2009). The β subunit is unique to each glycoprotein and bestows the specificity of the hormone (Cunningham, et al., 2010a; Knuppel, 2007). Each α and β subunit must be covalently bonded to allow G protein coupled receptor activation and thus biological activity (Masters, 2009). The production of LH and FSH is not performed by the placenta, but rather by the pituitary gland under the regulation of gonadotropin regulating hormone (GnRH) is produced by the hypothalamus.

Gonadotropins serve to regulate the functions of the ovaries and testes. Since the gonadotropins share a common α subunit, this lends to similar functions. Of the 97

amino acids that comprise the β subunit of hCG, 67% of amino acids are shared with LH therefore lending common functions (Taylor & Lebovic, 2007). hCG has a longer half life due to its high carbohydrate content, preventing catabolism and allowing for a half life of 36 hours compared to the two hour half life of LH (Cunningham, et al., 2010a). The primary function of FSH is stimulate follicle development in the ovary and to stimulate estrogen production from granulosa cells (Masters, 2009). LH occurs as a surge from the pituitary gland causing ovulation to occur. LH also functions to maintain estrogen and progesterone production from the theca cells of the follicle during the menstrual cycle.

If pregnancy occurs, hCG binds to LH/CG receptors to sustain pregnancy through term by preserving the corpus luteum. The corpus luteum is the major source of progesterone during early pregnancy (Molina, 2010; Schorge et al., 2008). Progesterone allows for uterine quiescence by inhibiting the production of prostaglandins, which stimulates uterine contractions and expulsion of the fetus (Molina, 2010). The placenta eventually attains the capability of producing estrogen and progesterone marking a period known as the "luteal-placental" shift (Schorge, et al., 2008). hCG can also mimic the function of LH in the male fetus to stimulate the production of testosterone in the Leydig cells of the testes which is responsible for male sexual differentiation (Cunningham, et al., 2010a). hCG can also be beneficial for diagnosis, prognosis, response to treatment, as well as relapse in both seminoma and nonseminoma testicular cancers (Presti, 2008). Ectopic production of hCG may be produced by ovarian, prostate, gastrointestinal, lung, breast, and bladder cancers (Shoback & Funk, 2007).

Detection of human chorionic gonadotropin

The most sensitive and specific test performed to diagnose pregnancy is analysis of hCG in plasma. hCG can be detected in pregnant women nine days after the LH surge and can be confirmed in all patients 11 days after fertilization (Knuppel, 2007). The plasma levels of hCG continues to double every two days until it reaches maximum levels of 100,000 mIU/mL around nine to ten weeks gestation (Knuppel, 2007; Schorge, et al., 2008). After maximum concentration has been reached, the levels of hCG decline rapidly in the second trimester and remain at steady state of 10,000 mIU/mL for the remainder of pregnancy (Knuppel, 2007; Schorge, et al., 2008; Taylor & Lebovic, 2007). If levels fail to decline, this may indicate a disease processes of the fetus and/or placenta (Cunningham, et al., 2010a; Molina, 2010). Higher maternal hCG serum levels can signal multiple fetuses, erythroblastosis fetalis, or possible trophoblastic disease such as hytidaform mole. Hytidaform mole may lead to metastasis known as choriocarcinoma (Cunningham, et al., 2010a). Low maternal hCG serum levels can be serious and signify a possible ectopic pregnancy. hCG is also present in fetal blood, but at much lower concentrations. Analysis of the amniotic fluid shows levels similar to the maternal serum and can be used to detect genetic abnormalities such as Down Syndrome. The concentration of hCG in fetal blood and the amniotic fluid will mimic the fluctuation of the maternal hCG concentrations as gestation progresses. Fetal blood contains around 3% and amniotic fluid around 20% of maternal hCG serum levels.

Detection of hCG is performed through both serum and urine testing. Commercial pregnancy tests and serum immunoassays react antibodies with the β subunit of both intact and fragmented hCG known as “sandwich-type” immunoassay

(Cunningham, et al., 2010a; Cunningham et al., 2010b). hCG is tagged with an IgG monoclonal antibody linked to a second polyclonal antibody containing an luminescent agent that causes fluorescence or color change on pregnancy test strips (Cunningham, et al., 2010b). The detection of hCG in urine is made possible through the metabolism and excretion of the hormone. The majority of hCG is processed by the liver and broken down into its respective subunits (Cunningham, et al., 2010a). The kidneys clear approximately 30% of hCG with a higher percentage of fragmented hCG. Commercial pregnancy tests can detect hCG in urine as low as 10 to 20 mIU/mL. Analysis must be performed with concentrated urine as a false negative result may occur when levels are less than 50 mIU/mL (Bardsley, 2011). These tests can detect pregnancy as early as one week after conception if performed correctly, and have a false negative rate of 1%.

Current uses of human chorionic gonadotropin

hCG is therapeutically available for clinical use by males and females. Current formulations of hCG are isolated from the urine of pregnant women (Parker & Schimmer, 2011). However, new advances in recombinant hCG are proving to be successful and will soon replace urinary hCG providing it is cost effective. Synthetic hCG may lead to increased half life and efficacy of the hormone as well.

hCG is currently being used for the treatment of infertility in males and females and cryptorchidism in infant males. In females, hCG is used as an adjunct for ovarian stimulation in anovulatory women with hypogonadotropic hypogonadism. The process begins with a FSH injection and transvaginal ultrasound, and then the administration of hCG can further stimulate follicles for ovulation. The purpose of a transvaginal ultrasound is to determine if more than three follicles, greater than 16 mm in diameter

are present. The presence of multiple follicles increases the likelihood of multiple pregnancies and ovarian hyperstimulation syndrome (OHSS). The rate of multiple births with use of hCG is as high as 10 to 20%. Multiple births present risks to the mother and fetuses such as gestational diabetes, preeclampsia, and preterm labor (Masters, 2009). OHSS is a major side effect associated with use of hCG due to the longer half life, creating elevated ovarian secretions that increase permeability of vasculature (Parker & Schimmer, 2011). The increase in permeability can lead to rapid accumulation of fluid in the peritoneum, thorax, and even pericardium. Signs and symptoms of OHSS include abdominal pain, ascites, nausea, vomiting, diarrhea, dyspnea, and oliguria. In severe cases of OHSS, hypovolemia, electrolyte imbalances, acute respiratory distress syndrome, hepatic dysfunction, and thrombosis may occur. For this reason, administration of hCG should be given under the supervision of a healthcare provider. Minor side effects include headache, depression, edema, and possible production of antibodies to the hormone (Masters, 2009). Current research hopes to determine if use of hCG for the treatment of infertility raises the risk of ovarian cancer (Parker & Schimmer, 2011). Other treatments currently being investigated are increasing pregnancy rates, prevention of spontaneous abortion, breast cancer, prostate cancer, as well as human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) and Alzheimer's dementia (Rao & Lei, 2007).

hCG is also utilized as a treatment for male infertility. However, this treatment is seldom used due to the expense and possible resistance to the hormone (Parker & Schimmer, 2011). Historically, hCG was used to treat adolescents for hypogonadotropic hypogonadism to mature the testes and stimulate spermatogenesis.

hCG stimulates the Leydig cells of the testes by binding to the LH/CG receptors producing testosterone and triggering sperm production. Undescended testicles in infants can also be treated with hCG to aid the testes in descension if anatomical blockage is not present. Administration of hCG may be considered prior to orchidopexy; if descent of the testicle does not occur, then surgery is performed. In prolonged treatments of hCG, gynecomastia occurs in approximately one-third of patients due to the production of estrogen.

For the past twenty years androgens or anabolic steroids have been used by men and women for enhancement of athletic performance (Snyder, 2011). The injection of anabolic steroids increase muscle strength and bulk and diminish spermatogenesis due to decreased testosterone production and cause testicular atrophy with prolonged use. The presence of anabolic steroids is thoroughly assessed in athletes by organizations that govern sports. Athletes are vulnerable to new treatments that provide the same effects but are undetectable in urine. This led athletes to use hCG to evade detection of performance enhancing drugs. The hormone stimulates testosterone production in Leydig cells and achieve similar effects. Athletes also used intermittent injections of hCG between anabolic steroid doses to increase testosterone levels and prevent testicular atrophy. In actuality, the increase in testosterone inhibits the feedback loop, thus making the situation worse (Handelsman, 2006). hCG use for performance enhancement is currently prohibited in athletics and governing bodies screen for use of hCG along with anabolic steroids.

hCG or Simeons diet

The off-label use of hCG for weight loss has heightened interest in easy weight loss due to the media. The utilization of hCG is not a new concept. Dr. Simeons developed the hCG regimen in the 1950's, based on Frolich's approach to modify the approach of weight loss in obese patients (Birmingham & Smith, 1983; Lijesen, Theeuwen, Assendelft, & Van Der Wal, 1995; Simeons, 1963, 1964). Frolich observed a redistribution of fat from the hips, thighs, and waist when treated with hCG. These areas are the hardest place to lose fat during normal dieting (Birmingham & Smith, 1983). Simeons believed hCG was mobilizing "abnormal" fat from adipose tissue for metabolic use, which prevents the patient from feeling weak or hungry (Craig, Ray, Waxler, & Madigan, 1963; Lijesen, et al., 1995; Simeons, 1963, 1964). Simeons believed the metabolism of fat cells allowed the patient to comply with the diet (Simeons, 1963, 1964). Simeons projected patients would lose 250-600g daily, which is approximately 0.5 to 1.3 pounds a day for a total weight loss of 20 to 30 pounds throughout the regimen.

125 IU of hCG, for a total of 40 injections, and a 500 calorie diet over a period of four to six weeks comprise the plan. The 500 calorie diet consists of low carbohydrates, low fat, and an estimated 45 grams of protein. In the first three days of the diet, patients received injections of hCG with no diet restrictions. The remainder of the four to six weeks included daily injections with a dietary restriction of two meals a day. The diet consisted of 100 grams of lean meat including chicken and fish, one serving of vegetables, an apple, a lemon or 60 grams of a fruit containing less than 15% carbohydrates, ten grams of unsweetened rusk, and salt and fluids as needed (Ballin &

White, 1974; Simeons, 1963, 1964). Patients were required to consult with Simeons daily to record weight and review dietary intake.

As a control, Simeons substituted normal saline for hCG to observe differences in outcome between the two groups (Simeons, 1963, 1964). An increase in appetite, dizziness, weakness, and non-compliance with the diet was noted with normal saline injections; once hCG was resumed, the side effects disappeared.

Simeons stated patients continued the diet for 40 days until “immunity” to hCG developed and started regaining appetite. If desired the patient could receive another course of hCG injections after a six week hiatus resulting in the same effectiveness as the first. Simeons stated 70% of patients maintained weight loss after the last injection and accomplished maintenance by compensating with fasting. Patients were instructed to weigh daily when resuming an unrestricted diet and to observe changes in weight.

Besides weight loss, Simeons claimed there were other useful effects of hCG. Simeons stated patients experienced decreases in depression and anxiety, as well as increases in libido, pregnancy, and relief from oligomenorrhea. Decreases in cholesterol, hair loss, brittle nails, peptic ulcers, psoriasis, arthritis, and lethargy were also observed. Diabetics were able to lose weight with gradual reductions in calories without hypoglycemic effects. Uric acid in gout patients were reduced or remained normal.

Replication and analysis of Simeons theory

After Simeons proposed the use of hCG for weight loss, numerous researchers replicated Simeons research design. The results from the randomized control trials of Stein, Asher, Craig, Greenway, Frank, Bosch, Shetty, Young, Miller, and Lebon will be

analyzed against Simeons results. Researchers tested different aspects of Simeon's theory such as the effect of hCG on mood, well being, compliance with diet, weight loss, and redistribution of fat. Four researchers included the study of changes within the body during the diet by obtaining blood samples from the patients. Blood work studies focused on the changes in glucose, uric acid, blood count, triglycerides, and cholesterol and other components. Blood pressure measurements were included in Asher's study. The majority of the research designs were randomized control trials; two studies included a crossover design which switched the treatments after a certain period of time.

Obese women were subjects in all of the studies; men were included in the studies by Frank, Young, and Miller. Ethnicity was not a parameter of any research study. Five research designs followed the original diet set forth by Simeons; however, Asher, Stein, Greenway, Frank, and Bosh did not follow Simeon's diet. Asher started the diet on the first day and fasted on the second and third day (Asher & Harper, 1973). After the third day, the diet from the first day resumed. In Asher's study, foods the subjects were permitted to eat were specifically outlined by food groups. Stein and Greenway followed Asher's diet (Greenway & Bray, 1977; Stein et al., 1976). Frank utilized a different diet where subjects consumed 85 grams of protein, 31 grams of fat, and 133 grams of carbohydrate totaling 1,030 calories daily (Frank, 1964). Bosch proposed yet another diet, in which subjects consumed 5000 kJ as compared to 2100 kJ in Simeon's regimen; a food diary helped to ensure compliance (Bosch, Venter, Stewart, & Bertram, 1990).

Analysis of weight loss and fat redistribution

Simeons primary claim regarding the hCG regimen was individuals would lose approximately 20 to 30 pounds due to redistribution and metabolism of “abnormal” fat (Simeons, 1963, 1964). All of the researchers except for Miller evaluated the differences in weight among subjects and are recorded in Table 1. Miller represented weight loss in a table form and interpreted the results.

Table 1. Average weight loss of treatment with hCG and control subjects

Researcher	Treatment Wt Loss (mean in pounds)	Control Wt Loss (mean in pounds)
Stein	15.8	15.5
Craig	6.5	8.8
Greenway	19.4	17.8
Frank	11.5	12.3
Bosch	7.5	4.9
Shetty	26.4	26.4
Young	1) 18.7	1) 19.8
	2) 10.0	2) 9.2
Asher	19.96	11.05
Lebon	25	

Stein, Asher, Shetty and Young performed daily weight measurements, whereas Craig, Greenway, and Bosch weighed subjects on a weekly basis. Craig also weighed the subjects six months prior to and after the study to observe weight trends among the subjects. Frank weighed subjects three times a week and performed weight checks at the sixth, eighteenth, and last visit. Lebon weighed subjects before and after the scheduled operation, since the focus of Lebon’s study was weight reduction before surgery. Lebon did not include a control group.

Seven of the nine researchers evaluated changes in fat redistribution by measuring the circumference of certain areas. Of the seven researchers, all evaluated changes in circumference at the waist and hips by measuring at the umbilicus and iliac crest. Craig, Greenway, Shetty, Young, and Frank also measured chest circumference. Craig assessed changes at the axilla whereas Shetty, Greenway, and Young evaluated changes at the areola. Greenway, Shetty, and Young evaluated the circumference of the upper arm by measuring at midpoint of the arm. Bosch, Shetty and Young also measured the circumference of the thigh at midpoint between the iliac crest and knee. Bosch included the circumference of the calf at midpoint between the knee and ankle.

Other than the average weight loss, Stein also evaluated the mean percent body weight loss and pounds lost per injection in the treatment and control group (Stein, et al., 1976). The mean percent body weight loss of hCG treated subjects was 9.5% and 9.3% in control subjects. Pounds of weight loss per injection were 0.61 pounds per injection for the treatment group and 0.59 pounds for the control group. Stein concluded there was no statically significant difference between the two, even though the mean weight loss favored the hCG group. The mean percent change in waist circumference in the treatment group was 7.21% and 6.68% in the control group. The mean percent change in hip circumference was opposite from the waist circumference changes. The control group showed a mean hip circumference percent change of 5.53% and the treatment group 5.32%. Both groups experienced changes in circumference at the hip and waist, but no statistically significant difference between the treatment and control groups was observed.

Craig evaluated weight loss that occurred six months before treatment to six months after treatment (Craig, et al., 1963). The average weight loss, measured six months before to six months after treatment, was 14.2 pounds in the treatment group and 5.3 pounds in the control group. From the commencement of the treatment until six months after completion of the study, the average weight loss was 10.7 pounds in the treatment group and 10 pounds in the control. The results show no statistically significant differences between the groups comparing the amount of weight loss, whereas weight gain six months following completion of the study appeared more common in the control group. Values for the changes in body circumference were not reported in the study, but Craig interpreted no statistically significant difference in changes of circumference at the waist, hips, or chest between the groups.

Greenway and Bray evaluated changes in mean weight loss and no other variables (Greenway & Bray, 1977). Greenway and Bray evaluated the changes in circumference as well. The change in arm circumference for the treatment group was 3.5 cm and 3.3 cm for the control group. The changes in chest circumference were 3.1 cm in the treatment group and 4.6 cm in the control group. Hip circumference was 8.9 cm in the treatment group and 8.1 cm in the control group. Thigh circumference differed with a 4.1 cm reduction in the treatment group and 3.8 cm reduction in the control group. Comparing the results, there was no more than two cm of a difference between any of the circumferences, leaving the results not statistically significant.

Frank evaluated minimum and maximum weight loss for the treatment and control group (Frank, 1964). The treatment group observed a minimum weight loss of 2 pounds and maximum weight loss of 26.4 pounds. The control group experienced a

minimum weight loss of 0.3 pounds and a maximum of 30 pounds. These results contradict Simeons theory since individuals within the control group were able to lose more weight than the treatment group. Frank did not report numerical values for circumference changes, but concluded no statistically significant difference between the control and treatment group during or after the study.

Bosch reported differences in BMI and body fat using a method by Katch and McArdle (Bosch, et al., 1990; Katch & McArdle, 1983). BMI changes experienced for the control group averaged 4.9 and 3.4 for the treatment group. The mean percent of body fat lost for the control group was 8.4% and 7.5% for the treatment group. Bosch did not chart any statistically significant differences between the two groups, but did discover a statistical difference in the values for mean weight loss, mean BMI change, and mean percent of body fat lost from commencement of the study to end for both groups. Bosch examined numerous body sites for changes in circumference, but did not report the values. The same phenomenon was reported in changes of circumference; there was a statistically significant difference from beginning to end of the treatment, but not between the two groups. Bosch reported the greatest reduction in circumference at chest and thigh area, but not in the abdomen or hips as Simeons had proposed.

Shetty did not report numerical differences between the two groups, but rather recorded differences using a linear graph (Shetty & Kalkhoff, 1977). The graph showed a decrease in the cohorts and also allowed for the differences to be compared within the same graph. Changes in weight loss and percentages of total weight loss closely paralleled between the groups. Changes in circumference at the hip and waist showed no statistically significant difference and revealed contraindicative results to Simeons

theory. Both groups lost approximately 6 cm from the hip area and 8 cm from the waist. Each group had estimated reductions of 4 cm from the thighs, 2 cm from the triceps, and 3 cm in the chest area.

Young used a different approach in the research design, by having two treatment periods (Young, Fuchs, & Woltjen, 1976). The subjects completed a four week treatment period with either saline or hCG, then changed of treatment to the other type. The injections were reversed after four weeks to observe differences in results not only between the groups, but also among the reason for weight loss in the individual's trials. A maintenance period was included between the treatment changes. This observation allowed differences in weight and amount of weight subjects gained between treatments to be recorded. Young revealed no statistically significant difference for weight changes during the treatment including the maintenance period. The mean percent of body fat lost in the first weight loss period was 4.2% for the treatment group and 4.0% for the control group. During the maintenance period, both groups gained approximately 4.0 pounds. Changes in body fat percentages occurred more with the treatment group, 0.4% compared to 0.2% for the control group. During the second weight loss period, mean body fat percent lost for the treatment group was 2.3% and 2.6% for the control group. During the second maintenance period, subjects in the treatment group regained 4.4 pounds and in the control group regaining 3.7 pounds. Changes in body fat percent were 0.4% for the treatment group and 0.6% for the control group. Total weight lost for the first treatment group with hCG was 20.2 pounds and 21.3 pounds for the first control group. Findings revealed timing of the administration of hCG does not matter since weight loss was the similar for both groups.

Miller utilized a research design similar to Young's in which groups were switched after four weeks of treatment (Miller & Schneiderman, 1977). Miller presented the results in graphs, but did not include total amounts of weight lost. Miller reported similar results with the first group, who received hCG injections, but losing no more weight than the first group taking the placebo. Subjects also lost less weight during the second four week period of treatment compared to the first four weeks of treatment.

Asher and Lebon were the only researchers reporting a statistically significant difference in studies concerning weight loss (Asher & Harper, 1973; Lebon, 1961). Asher also evaluated mean weight loss per injection; the treatment group lost 0.585 pounds per injection and the control group 0.403 pounds per injection. Asher concluded weight loss in the treatment group was due to higher compliance among treatment group members and the method of preparation of hCG. Asher claimed other research designs did not prepare the injections in the same manner. Lebon's study focused on weight loss with the hCG regimen for surgical patients. Lebon reported a decrease in symptoms of obesity such as "rheumatic" aches and pains, shortness of breath on exertion, and headaches within days due to weight loss. The validity of Lebon's study has been questioned due to lack of a control group being tested.

Seven of the nine researchers reported no statistically significant difference between the treatment and control group for weight loss and changes in circumference. Asher and Lebon were the only researchers who reported a significant difference in weight loss between the treatment and control group. Six of the nine researchers did not observe the 20 to 30 pound weight loss as Simeons proposed.

The different variables within each study limits comparison of results for weight loss and circumference. The only values comparable among the researchers are mean weight loss and statistical differences reported.

Analysis of mood and appetite

Simeons claimed hCG injections allowed subjects to comply with the diet longer than the placebo group. This statement was based upon the loss of appetite and increase in mood after injection. Stein, Asher, Greenway, Frank, Bosch, Shetty, Miller, Young and Lebon assessed changes in mood and appetites by using scales, which varied among the different research designs. Stein, Frank, Lebon, and Young did not evaluate mood changes. Young did not evaluate appetite changes. Young and Miller were the only researchers to evaluate compliance with diet. The scales for hunger used responses of “little” to “no hunger” to “extreme hunger” and each response was given a designated number one through five. Mood was measured among the subjects using responses such as “excellent”, “good”, “fair”, and “poor”.

In Stein’s study there was no statistically significant difference between the placebo and treatment groups regarding appetite (Stein, et al., 1976). The majority of subjects responded to the appetite scale as having little to some hunger, but there was no difference between groups, as Simeon’s had suggested. Only a few individuals experienced more or uncontrollable hunger.

Asher compared appetite and mood and reported a statistically significant difference between the groups (Asher & Harper, 1973). 76.6% of the hCG group had little or no hunger, whereas 48.7% in the placebo group experienced little or no hunger.

Feeling “good” to “excellent”, was reported by 86.5% of the hCG and only 70.0% of the placebo group.

Greenway studied the treatment and control group for mood and appetite as well. However, the scales were different than other research trials (Greenway & Bray, 1977). Greenway’s scale ranged from one to nine, with one being “not hungry” and nine representing “maximum hunger”. Mood was gauged using the Multiple Affect Adjective Check List from Zuckerman; this method analyzes anxiety, hostility, and depression before and during the study. Greenway observed no statistically significant difference for mood or appetite within groups. The average score of hunger for the treatment group was 3.3 and 2.9 for the control group before the study and 4.4 and 4.2 during the study respectively. The only statistically significant difference, determined by the Multiple Affect Adjective Check List by Zuckerman was an increase in anxiety for the treatment group prior to the study. Anxiety for the treatment group was 85.1 prior to the study and 64.5 during the study; the control group scores were 67.1 before and 65.4 during the study. Hostility score for the treatment group was 66.9 prior to the study and 66.4 during the study; the control group score was 72.6 before and 60.9 during the study. Depression score for the treatment group was 72.1 before and 67.9 during the study; the control group was 67.7 before and 62.4 during testing.

Frank analyzed the difference in appetite between the groups and reported no statistical difference (Frank, 1964). Eleven subjects in the control group stated appetite was “decreased” and thirteen subjects noticed “no change” in appetite. Ten subjects in the treatment group stated appetite was “decreased” and eleven subjects noticed “no difference” in appetite.

Bosch not only measured mood and appetite, but self-image as well before and after treatment (Bosch, et al., 1990). Bosch noted mood of the treatment group was higher from beginning and end of the study (19.4 vs. 17.9), whereas the control group was lower (18.6 vs. 17.2). An improvement percentage of 9.6% was noted in the treatment group and 4.8% in the control group resulting in no significant difference. Bosch observed a significant and equal reduction in hunger in both groups, but no statistically significant difference between the groups.

Shetty interpreted mood and appetite based on the attitude of the subjects by observing subjects (Shetty & Kalkhoff, 1977). Shetty concluded the groups showed no difference in regards to appetite and mood because neither group complained of excessive hunger or stated changes in mood.

Miller asked subjects to circle and quantify feelings and appetite; no values were assigned to these variables, however. Miller noted no statistically significant difference in mood or appetite between the groups or trials.

Young did not measure mood and appetite, but rather analyzed the compliance rate of patients when subjects were asked to perform a second round of injections (Young, et al., 1976). Miller also analyzed compliance rates during second round of injections (Miller & Schneiderman, 1977). Both researchers reported an increase in subjects dropping from the second trial of injections. In Young's study, the more time the trial continued, the more subjects discontinued treatment. Numerous subjects also left during maintenance periods and chose not to be followed. Young lost over a third of subjects from the beginning to end of the study. Miller reported the same trend and lost almost half of the subjects from the first to the second trial.

Lebon's research was not a randomized control trial and only assessed appetite of the hCG treatment group (Lebon, 1961). The subjects did not report feeling weak or hungry when treated with hCG; assessment was based on observations with no scale.

Of the eight studies that evaluated appetite, only Asher reported a significant difference between the treatment and control group. Lebon reported a decrease in appetite, but the study lacked a control group to compare the results. Asher was the only researcher to reveal a statistically significant difference for mood. Miller and Young evaluated compliance and noted subjects were more inclined to withdraw from treatments as the treatment continued.

The same methodological issues exist in analyzing appetite and mood changes as was in weight loss and circumference changes. There was no consistency in variables studied among the researchers, leaving one to question validity and correlation among studies.

Analysis of blood samples and blood pressure changes

Stein, Craig, Shetty, and Bosch measured changes in the blood between the treatment and control group to identify if hCG actually had an effect on the body. Comparison of different tests performed is summarized in Table 2. If Simeon's theory was correct there would be mobilization and utilization of "abnormal" fat in the body.

Stein reported a significant decrease in blood pressure in the groups, but not a significant decrease between the groups (Stein, et al., 1976). Asher also reported no statistically significant difference between the groups as well (Asher & Harper, 1973).

Table 2. Comparison of variables within the blood

	Stein	Craig	Shetty	Bosch
Hematocrit	↓ both groups			
White Blood Cells	↓ both groups			
Blood Urea Nitrogen	↓ both groups			
Triglycerides	↓ both groups	Unchanged in both groups		↓ both groups
Cholesterol	↓ both groups			↓ both groups
Total Protein	↓ both groups			
Serum Uric Acid	↓ both groups		↑ both groups	
Urine Uric Acid			↑ both groups	
Sodium			Unchanged in both groups	
Urine Sodium			↑ early in both groups; later returned to normal	
Potassium			Unchanged in both groups	
Urine Potassium			Unchanged in both groups	
Urine Ketones			↑ throughout study in both groups	
Glucagon			↑ both but ↓ later in both groups	
Insulin			↓ both groups	
Glucose	↑ in treatment	Unchanged in both groups	↓ both groups	
Basal Metabolic Rate		↓ both groups		

The treatment and control groups in Stein's study demonstrated a significant decrease in Hct, WBC, BUN, cholesterol, triglycerides, and total protein, but there was no significant difference between the control group and treatment group (Stein, et al., 1976). The only statistically significant difference was the control group showed a significant increase in fasting glucose compared to the treatment group.

Even though a small increase in basal metabolic rate was reported in both treatment and control subjects of Craig's study, one treatment subject experienced a decrease in basal metabolic rate rendering the results inconclusive and insignificant (Craig, et al., 1963). Fasting blood sugar levels were unchanged even in diabetic patients. The serum level of lipids remained normal in most subjects, except for one subject in the control group who experienced elevated lipids.

Bosch reported high triglycerides and cholesterol among both groups before the study began and levels at the upper limits of cholesterol and triglycerides at the end of the study, but overall subjects experienced a decrease (Bosch, et al., 1990). Comparison of results between the groups from the beginning to end of the study was not significant. The high density lipoprotein (HDL)/ total cholesterol ratio levels in the treatment group were increased and significantly different than the control group, but the HDL/low density lipoprotein to cholesterol ratio was not significant between the groups. The ratio for HDL/total cholesterol remained unchanged among the women in both the treatment and control group.

An increase in free fatty acid levels for the treatment and control groups was noted in Shetty's study, however, these levels reversed when eating resumed (Shetty & Kalkhoff, 1977). Glucagon levels, as expected, increased during the first few days of semi-starvation, but unexpectedly decreased as starvation continued. Ketones in the urine were present on day two of the study and ranged from trace to heavy throughout the study, but no statistically significant difference occurred among the groups.

Overall, the only measurable difference was in Stein's study, but no statistically significant difference took place between the groups. Differences were noted in

triglycerides, serum uric acid, and glucose between the different researchers. For triglycerides, Stein and Bosch noted a decrease, whereas Craig noted triglycerides were in normal range. Craig did not report the exact change that occurred. For serum uric acid, Stein reported a decrease, whereas Shetty reported an increase. In regards to glucose, Stein noted an increase, Craig noted no change, and Shetty reported a decrease. With the discrepancies between the results, one questions the population, timing, and validity of these results.

Analysis of side effects

Stein was the only researcher to report side effects experienced by the treatment and control groups (Stein, et al., 1976). Stein disclosed several subjects from both groups experienced severe headaches, constipation, fatigue, and delayed menses. One subject developed severe gastritis and was hospitalized. Another subject, diagnosed infertile before the study, became pregnant during the study. Minor side effects during Stein's study were upper respiratory infections and sinusitis. Birmingham and Smith (1983) suggested other problems may be experienced such as ovarian hyperstimulation syndrome, multiple pregnancies, ascites, pleural effusion, hypercoagulability and thromboembolism. The amount of hCG, nor the route of administration to cause such side effects has not been determined, but caution should be taken.

Availability of hCG

hCG is available to consumers in many different forms and may be purchased at various retail outlets, nutrition stores, and health clinics. The most popular form of hCG is not the traditional intramuscular injection, but rather pill or sublingual liquid form.

Health clinics offering hCG weight loss provide hCG as a intramuscular injection, which is rather expensive. At GNC and Vitamin Shoppe, popular vitamin and supplement stores across the United States, hCG is available as four different products, three as a liquid and one as a capsule (Vitamin Shoppe and GNC). The products range in cost from \$40.00 to \$80.00 for one ounce of fluid or 120 capsules. Upon researching the ingredients of the different products this author determined, only one product contains the hCG hormone. Other products contain amino acids, B vitamins, caffeine, and various supplements. Most products do not advertise the restrictive diet on the label, only the quick weight loss. Labeling of the retail products also claim extra benefits not part of the original plan proposed by Simeons. The extra benefits advertised are an increase in energy, muscle growth, and blood flow. Retail chain pharmacies, such as CVS, also offer hCG at the same price as the vitamin stores, which eases public access.

The hCG diet offered by health clinics has become popular. Many medical clinics offer the same regimen as Simeons, with daily or weekly visits for injections and assessment of weight loss. Physicians administer injections and provide weight loss advice, which can be perceived as “easy” money, but time consuming. The cost of regimens can range from \$400 to \$600 for a forty day regimen. An internet word search through Google reveals as many as 4.5 million search results to buy hCG products, learn about the diet, or warn consumers about the diet.

Psychology of dieting

Reas, Masheb, and Grillo (1993) assessed rationale for dieting; the study showed 64% of people stated the reason was for better health. If this was the true reasoning for dieting, the amount of chronic diseases and obesity in the United States would be much lower. Brink and Ferguson (1998) also examined reasons for dieting. 44 subjects stated health as the main reason for dieting, with men being greater in number than women. Subjects claimed to diet because of chronic diseases such as coronary artery disease, diabetes, and hypertension. However, research has shown patients do not diet until an acute event occurs that threatens health and increases risk of mortality (Brink & Ferguson, 1998; Visscher & Seidell, 2001). Fear of dying from a chronic disease served as motivation for dieting in six subjects of Brinks' study (Brink & Ferguson, 1998). Brink stated patients do not consider dieting until a medical professional discusses the consequences of increased or unhealthy weight. Patients do not acknowledge being overweight or obese until a health care provider confronts the issue, which is the most influential factor for motivation to lose weight.

The most common motivation for dieting is for personal appearance. The highest rate of dieting occurs among women in their early twenties and adolescent years; these individuals are usually at a healthy weight or slightly overweight (French & Jeffery, 1994; French, Story, Downes, Resnick, & Blum, 1995). In Brink's study, 36 subjects both men and women, stated appearance as the motivation for dieting, with women more likely to be motivated (Brink & Ferguson, 1998). However, Putterman and Linden revealed patients motivated by health reasons (internal motivation) rather than

appearance reasons (external motivation) are less likely to try unhealthy dieting strategies and experience lapses in restraint (Putterman & Linden, 2004).

One's sense of appearance is formed from body image, body dissatisfaction, and perception of attractive traits. Studies indicate both women and men who experience body dissatisfaction are more likely to diet to enhance body image (Grogan, 1999; Wardle & Marsland, 1990). Men are less likely to suffer psychologically from body dissatisfaction and are more accepting of body size than women (Markey & Markey, 2005).

Ziebland et al. asked subjects to state the current perception of body size and the preferred body size (Ziebland, Robertson, Jay, & Neil, 2002). Ziebland provided subjects with pictures of eight different body shapes and asked subjects to indicate current perception of body size and the preferred body size. The study indicated people were more critical of body size and desired to be a smaller body size than concerned with perceived body type. Ziebland reported women depicted body size at ideal or overweight body size, while the majority preferred to be ideal shape. Men were more likely to depict their body size at a larger size and also desired to be at smaller body size.

What causes dissatisfaction with body size and the misperception of body image? The concern relates to one's perception of attractiveness and desire of the opposite sex. Women learn at a young age the desired body shape is slender and thin; whereas men learn the desired body shape is muscular, slender and sculpted (Markey & Markey, 2005; Polivy, 2006). Women tend to believe body size is a reflection of self worth, which affects self esteem. Girls learn early in life that bodies are objects for

others to observe and admire; whereas boys believe bodies are objects of function and admiration is related to function (Fredrickson & Roberts, 1997; Smolak, 2003).

A contradiction exists in public perception that men desire slender and skinny females. Males subconsciously prefer females with wider hip to waist ratio or hourglass figure, which is actually “fatter” than the female ideal (Fallon & Rozin, 1985; Jarry, Polivy, Herman, Pliner, & Arrowood; Singh, 1993). Male perception relates to the requirement of females to attain a certain amount of body fat for reproduction and which is a reflection of a woman’s fertility (Fallon & Rozin, 1985; Singh, 1993).

Even though men desire a different body type than women perceive, the aspiration to attain impractical body images still exists (Markey & Markey, 2005). The desired body size is becoming harder to attain since the overall body size becoming larger, which leads to an increase in body dissatisfaction (Stice, Mazotti, Krebs, & Martin, 1998). Markey revealed the more dissatisfied a person is with body image, the more likely the person is to pursue unhealthy dieting measures in order to achieve radical results (Markey & Markey, 2005). People believe once a slim and slender physique is obtained, they will be more attractive to the opposite sex (Jarry, et al.; Polivy & Herman, 2006).

As previously discussed, self esteem seems to be the underlying factor of self beliefs and dieting practices. An individual’s self esteem is largely shaped by experiences during childhood, adolescence, and what is conveyed by the media. Adolescence is a crucial time in which for identity formation (Harter, 1999). This formation is associated with self consciousness, concern with social acceptance, and preoccupation with image. French and Brownell examined psychosocial factors that

increase prevalence of adolescent dieting. Adolescents are less likely to diet if a close family connectedness exists with low family stress, which may correlate with less criticism from parents regarding body size (Brownell, 1991; French & Jeffery, 1994; French, et al., 1995). Parents, especially mothers, play an integral part in the formation of self esteem and body image (Benedikt, Wertheim, & Love, 1998; Ricca et al., 2010). The parent's view of body image may be translated to the child influencing the child's self esteem, body image, and dieting practices (Moreno & Thelen, 1995).

Self esteem is not only influenced by parents, but also by peers. Adolescent girls are greatly influenced by friends (McCabe & Ricciardelli, 2004). Teasing occurring throughout the adolescent period is reflected into the adult's body image (Thompson & Psaltis, 1988). Adolescents having a deeper concern with appearance and peer approval are more likely to diet to obtain an ideal body type (French & Jeffery, 1994; French, et al., 1995; McCabe & Ricciardelli, 2004). In addition, these adolescents are likely to participate in negative behaviors such as extreme dieting, alcohol, sex, and illicit drugs (French, et al., 1995).

The media plays an extremely powerful role in self esteem, promoting a thin ideal which contributes to an increase in body dissatisfaction among men and women (Brownell, 1991; McCabe & Ricciardelli, 2004). Studies indicate a positive correlation between the number of magazines read and television hours viewed to body dissatisfaction (Turner, Hamilton, Jacobs, Angood, & Hovde, 1997). Monro demonstrated exposure to idealized images led to an increase in body shame and appearance anxiety especially with television viewing for adult women (Monro & Huon, 2005). Likewise, there was a positive correlation for both magazine reading and

television viewing with body shame, appearance anxiety, and drive for thinness in children and adolescents (Monro & Huon, 2005).

“Fad” dieting

Commercial weight loss programs are a 33 billion dollar per year industry with \$74 billion in annual sales of weight loss products (Lemaire, 1993). Marketing tends to prey on low self esteem individuals, who are uneducated about proper weight loss with the drive to attain the thin ideal (Roberts, 2001; Wells, 2004). The growth of this market continues because consumers are willing to participate by purchasing products thus continuing the production of new fad diets and weight loss programs by manufacturers (Lemaire, 1993).

The market growth can be attributed to current mentality of American society. Many dieters turn to “fad” diets that promise quick results of large amounts of weight loss. Many Americans seek for a quick fix that will erase years of poor diet, lack of physical activity, and bad habits in a matter of weeks with the least amount of work required (Downs, 2006; Katz, 2003; Lemaire, 1993; Orr, 2010). One study reported approximately one in five individuals have participated in a “fad” diet (Jeffery, Folsom, & Luepker, 1984). Pillitteri et al. (2008) reported the prevalence of “fad” dieting is highest among young women and individuals with higher body dissatisfaction (Pillitteri et al., 2008). Dieters believe the cost of giving up the current lifestyle is too difficult and are more willing to try “fad” diets rather than researching or discussing with their physician methods to successfully lose weight permanently (Downs, 2006; Katz, 2003; Roberts, 2001). Dieters opt for “fad” diets because balanced nutrition can be confusing while “fad” diets take the “guesswork” out of dieting (Downs, 2006). When weight loss fails or

the regimen becomes monotonous, consumers tend to switch to a different regimen or stop dieting altogether. This leads to waste of consumers' money, growth of the diet products market, and increase in frustration.

To lure consumers, many "fad" diets promote the ease of quick weight loss (Jeffery, et al., 1984; Roberts, 2001). These diets employ tactics to "bait" consumers such as having an expert in the field discuss "scientific evidence" supporting the claim for quick weight loss and using anecdotes or testimonials rather than presenting actual statistical studies. Another prominent feature of "fad" diets is ritual and sacrifice. The consumer is told what must be consumed daily (ritual) and what cannot be consumed (sacrifice) as part of the diet. Consumers may be attracted because "fad" diets promise weight loss while allowing consumption of favorite foods, but severely restricting other food groups (Fisher & Lachance, 1985; Roberts, 2001). Many diets are not new nor as cutting edge as advertised but are commonly recycled ideas from previous campaigns with an added twist to the diet while others are simply reintroduced (Downs, 2006).

Consumers do not understand how "fad" diets can endanger health. Commercial weight loss programs typically fall into two categories: restrictive intake and dietary pills. Restrictive diets that promote the consumption of certain food groups may lead to the depletion of essential vitamins, minerals, and fiber which leads to anemia, osteoporosis, constipation, irritable bowel syndrome, amenorrhea or stunting of growth in teenagers (Knight-Ridder, 2004). Restrictive diets may also affect hair, nails, and skin as well as leading to being tired and moody. Dieters remaining on restrictive diets for extended periods of time may endure harmful effects to the kidneys and heart.

Dietary supplements can be just as dangerous as restrictive diets. Dietary supplements are not regulated by the Food and Drug Administration (FDA) due to the Dietary Supplement Health and Education Act (Pillitteri, et al., 2008). The effectiveness, quality, safety, appropriate dosages, and possible drug interactions are not tested; producers add other ingredients and fillers, but still label as the supposed product. The FDA only removes supplements from the market if serious injury or illness has occurred and reported.

Consumers try products because the diets “appear” to work. Some dieters lose weight due to restriction of calories lower than one’s needed daily consumption (Knight-Ridder, 2004). Some diets trick the body into sensing that starvation is occurring, and the body’s natural reaction is to lose water, rather than fat. The body then turns to other means of producing glucose by metabolizing protein and amino acids at a high rate, which decreases muscle mass (Downs, 2006; Johnson, Consolazio, Krzywicki, Isaac, & Witt, 1971). The body can metabolize fat at slower rate through a process called ketosis which causes byproducts of fats and proteins to suppress the appetite (Johnson, et al., 1971). A decrease in weight and suppression of appetite leads the consumer to believe the diet is working.

“Fad” diets do not work for long term maintenance of weight loss, as dieters end up regaining lost weight and possibly gaining more weight than before (Foreyt, Goodrick, Cutter, Brownell, & St. Jeor, 1995; Lowe & Timko, 2004; Polivy, 2006). The weight regain is due to psychological reasons intertwined with evolutionary reasons. Restrictive dieting is not natural, so the body adapts by counteracting perceived starvation with slowed metabolism, maturation and aging, therefore, entering into a

“waking hibernatory state” waiting for food (Polivy, 2006). When food becomes available the individual is more likely to binge, rather than withholding, because the body believes starvation is imminent and self maintenance is imperative.

Another prominent psychological theory is disinhibition, when the individual breaks the regimen and loses self control (Polivy, 1996, 2006). Following the loss of self control, the person either discontinues the diet or tries the diet again until there is another attempt. Dieters have problems restraining when food is plentiful, and this situation is prevalent in the United States. Most individuals in the United States have access of numerous types of foods, especially sweet, fatty, and salty options (Pinel, Assanande, & Lehman, 2000). However, the warfare with dieting does not stop there, because once an individual realizes self indulgence has taken over there is stress, frustration, guilt, and low self esteem, and the vicious cycle continues (Polivy, 1996, 2006). Studies indicate the more an individual performs “yo-yo” dieting with continual weight fluctuation, the more a person’s metabolism slows, making it harder to lose weight over time (Blackburn et al., 1989).

The psychological warfare of dieting is not easy to overcome. Even though dieting may perceive to be highly prevalent, the correct type of dieting is not prevalent; this is a contributing factor of the current obesity epidemic (Foreyt, et al., 1995; Polivy & Herman, 2006). Individuals are not taught how to change dieting lifestyles permanently, so people resort to quick fixes that damage health and limit chances of losing weight (Katz, 2003). Dieters need to address the physicality of dieting as well as the psychological aspects. Dieters need an internal source of motivation rather than external motivation; dieting should be performed to better oneself rather than meet

expectations of others (Putterman & Linden, 2004). Dieting for self improvement is associated with more positive eating patterns and less disinhibition. Behavior modification is required to control impulsive eating. Healthcare providers need to educate patients regarding effective strategies for successful long term weight loss and motivate patients to adhere with goal.

III. Methodology

Search terms for this project were:

- Human chorionic gonadotropin
- Weight loss
- Obesity
- Dieting
- Psychology of dieting
- Fad diets
- Commercial weight loss programs
- Dieting behavior
- Simeon

Databases: Databases that were used to collect articles included PubMed, CINAHL, and Electronic Journal Center.

Inclusion and Exclusion criteria: First tier research studies incorporated were random controlled trials and meta-analyses. Second tier research studies used were non random controlled trials. Non professional literature included books, web sites, and public information. English only articles were reviewed.

IV. Summary of Results

Purpose statement: The purpose of this review was to examine current research of the human chorionic diet and whether the diet is effective as a weight loss regimen for overweight and obese individuals.

Problem statement: Minimal research has been performed over the past fifty years as to whether this regimen is effective; yet patients are willing to utilize this regimen because the diet seems to achieve significant amounts of weight loss quickly.

Significance of Study: The significance of this study was to investigate the effects of the human chorionic diet and to inform both consumers and healthcare professionals of the effectiveness and side effects of the weight loss regimen.

Hypothesis: The human chorionic gonadotropin hormone has no effect on the weight loss of the individual.

Findings

A. Weight loss. Seven of the nine researchers reported no statistically significant difference between the treatment and control group regarding average weight loss. Asher reported a statistically significant difference between the treatment and control group and Lebon did not include a control group in the study. Six of the nine researchers did not note a 20 to 30 pound weight loss as Simeons described.

B. Fat re-distribution and circumference. Of the seven researchers that evaluated circumference differences reported no significant difference between the treatment and control group. Many researchers evaluated different areas for circumference and no standard was set for evaluation.

- C. Appetite.** Seven of the eight researchers that evaluated appetite stated no statistically significant difference between the treatment and control group. Asher noted a statistically significant difference between the two groups. Lebon reported a decrease in appetite for the treatment group, but lacked a control group.
- D. Mood.** Four of the five researchers that evaluated mood reported no statistically significant difference between the treatment and control group. Asher reported a significant difference between the two groups.
- E. Blood levels.** Four researchers evaluated changes taking place in the blood during the diet, but different variables were assessed. No statistically significant differences were reported between the groups. The only consistent values that were evaluated were triglycerides, cholesterol, serum uric acid, and glucose. Stein and Bosch reported a decrease in both groups for triglycerides, whereas Shetty reported no change. Stein and Bosch also reported a decrease in both groups for cholesterol. Stein reported an increase in serum uric acid, whereas Shetty noted a decrease in serum uric acid. For glucose, Stein reported an increase in only the treatment group, Craig reported no change for both groups, and Shetty reported a decrease in both groups.
- F. Side effects-** Stein was the only researcher to report side effects during the study. Several subjects experienced headaches, constipation, fatigue, and delayed menses. One subject developed gastritis and another became pregnant.

Discussion

The interpretation and analysis of the current literature of the hCG diet is difficult to extrapolate since there is limited studies since the first medical report on the hCG diet. The role and function of hCG and related hormones were just being discovered and many researchers did not understand how to properly design studies. The pharmacokinetics or pharmacodynamics of the hormone was unknown and the proper dosage of the hormone was not documented. The majority of the studies within the literature focuses on certain populations such as obese women and did not address the effects on men.

Most of the research performed during these trials was procedurally inadequate, leaving room for error as well as inconsistencies that challenge validity and reliability. Many studies varied from the original experiment by Simeons, even though the claim of research was to test the hypothesis and replicate the original results. Comparison of studies is difficult because there is a lack of a set standard to compare the studies against. Researchers chose to follow different diet regimens from Simeons, ranging from the amount of calories to the amount of days on the diet. Researchers chose to weigh subjects differently and vary how the injections were prepared and given. Circumference measurements were performed differently from researcher to researcher, leaving one to question whether the outcomes are reliable. There are also inconsistencies when comparing lab results, with different values for the same lab test.

Most of the research used small group sizes; many subjects left the study during trials making groups even smaller which increase the risk of type II error or false negative findings. The shortcomings likely skew the results and shows no statistically

significant difference between the groups when there actually was a difference. The researchers also utilized the incorrect statistical analysis on the data, as was evident in the interpretation on appetite and mood. For example, researchers used Likert scales for responses of appetite or mood; however, statistical analysis was performed on ordinal level data, which can hinder the correct interpretation. Asher and Lebon, the only researchers to obtain statistically significant results, also had problems with data analysis. Asher used incorrect statistical technique on most of the data, including weight loss. Lebon did not utilize a control group, leaving the interpretation of the data as questionable.

Conclusion

Based on these factors, comparison and correlation between the studies cannot be made. From these studies, one can conclude that subjects did lose weight while on the diet, but no statistically significant difference is noted between the treatment and control group. Research, with consistent standards and proper statistical analysis, is needed to investigate effectiveness and to correctly determine the effects of the hCG diet.

The hypothesis is rejected because the weight loss achieved during the diet cannot be attributed to the hCG hormone. The hCG diet appears to be effective because individuals participating in the diet do lose weight. However, individuals that merely utilized the restrictive diet without the hormone also lost respectable amounts of weight. Therefore, the weight loss documented for the diet cannot be attributed to hCG and is likely due to the 500 calorie restrictive diet.

Recommendations

A. Recommendations for research

. Current research is warranted to truly evaluate the effects of hCG on the body. Strict procedures with limited well defined variables should be implemented to address validity and reliability and minimize errors. Larger research cohorts are needed to limit the Type II errors occurring in these studies. Research should include variables such as men and non-obese individuals to expand upon the current understanding since the diet regimen is being used by all types of individuals. Studies that may be of interest is the assessment of hormone levels within the body and the activity levels of the hormone at different dosages. The dosage used during Simeon's study had no effect, so the exploration of different dosages could contribute to understanding as to whether the hormone actually has an effect. Another potential for research is the bioavailability of oral forms of hCG, since this formulation is the most popular type on the market. A comparison between the oral and injection form could be investigated so demonstrate if there is a difference.

B. Recommendations to healthcare providers

Media and healthcare providers are the primary sources of information about nutrition for the public (Cohen, 1987). Healthcare providers have a responsibility to be familiar with current dieting trends and associated effectiveness and dangers. Healthcare professionals should educate patients on proper strategies to lose weight and serve as coaches and cheerleaders. As Brink explained, most patients do not start dieting or even recognize being obese until a healthcare provider discusses weight issues. The risks of being overweight or obese should be discussed with patients,

rather than remaining a taboo. Helping patients discover an internal source of motivation for weight loss rather than for an external source of motivation may lead to fewer lapses in restraint and setbacks in dieting (Putterman & Linden, 2004).

A comprehensive weight loss discussion between the provider and patient should include recommendations for nutrition counseling, behavior modification techniques, exercise therapy, and psychological support (Lemaire, 1993). Nutrition counseling should focus on foods high in fiber including fruits and vegetables, complex carbohydrates from unrefined cereal grains, lean meats such as seafood, and low fat dairy foods (Katz, 2003; Lemaire, 1993). Referral to a dietician may also help patients construct a weight loss program specific to lifestyle needs (Knight-Ridder, 2004). Keeping a food journal can help patients detect hidden calories that contribute to weight gain. To achieve long term weight loss, healthcare providers should reinforce that “weight loss occurs when the expenditure exceeds intake.”

C. Recommendations for the public

The responsibility for weight loss and good nutrition involves both the patient and healthcare provider. The patient is responsible for obtaining accurate information on nutrition and exercise, as well as researching diets before committing to a new regimen. Patients need to know the risks and benefits of a diet, and utilizing the expertise of healthcare providers is prudent. Successful self-care should be viewed as a team effort between all disciplines and most importantly, between the healthcare provider and patient.

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VI. Abstract

Objective: The purpose of this review is to determine whether the hCG diet is effective as a weight loss regimen for overweight and obese individuals. **Methods:** A review of the current literature was performed using databases such as PubMed, CINAHL, and Electronic Journal Center. Search terms included “human chorionic gonadotropin,” “weight loss,” “obesity,” “dieting,” “psychology of dieting,” “fad diets,” “commercial weight loss programs,” “dieting behavior,” and “Simeon.” **Results:** Weight loss, circumference changes, appetite, mood, laboratory values, and side effects were reviewed. Seven of the nine researchers reviewed weight loss changes and showed no significant difference between the treatment and control group. **Conclusion:** This review demonstrates weight loss is achieved on the hCG diet, but cannot be attributed to effects of the hormone and is due to the 500 calorie restrictive diet.

