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Abstract

Human Chorionic Gonadotropin (hCG) has recently experienced a resurgence in popular media. Late night television commercials and Internet advertisements have suggested that it is an essential, unequivocal means to losing weight fast. Is hCG really a miracle cure to help patients shed unwanted pounds? In 1954, A.T.W. Simeons claimed that hCG impacts weight loss by decreasing hunger, increasing fat redistribution, and increasing overall mood. Knowing that weight loss cannot be directly attributed to hCG use, Simeons developed a very low calorie diet (VLCD) to which the success of the therapy can be attributed. He saw hCG as a means to an end. Following a VLCD is nearly impossible without a little push, and according to Simeons, this push could be hCG. This increase in mood is an essential reagent to following a low calorie, thus low-energy diet, and therefore is necessary for the product of weight loss. Combination therapy of hCG and diet has been studied using multiple dosage forms, but no definitive answer has been found.

Introduction

Human Chorionic Gonadotropin (hCG) is a glycoprotein hormone normally secreted by trophoblastic cells of the placenta during pregnancy. It was first discovered in the urine of pregnant women by Ascheim and Zodek in 1927 and has since been widely studied and used in the treatment of infertility.[1,2] More recently, hCG has received significant media attention regarding its use in weight management in obese patients. Despite the positive attention the diet may be getting, available studies show conflicting results and inconsistencies in administration route, dosing, and methods for measuring weight loss. hCG has also been evaluated for potential use in the treatment of Kaposi sarcoma, asthma, psychoses, osteopenia, and glaucoma.[1]

Simeons' Therapy

The use of hCG in managing body weight is derived from its use as a treatment for Frohlich's syndrome, an endocrine disorder observed in young boys, which is characterized by tumors of the hypothalamus and pituitary as well as excessive fat accumulation.[3,4] In 1954, Dr. A.T.W Simeons theorized that hCG might play a role in fat metabolism and could potentially stimulate similar weight loss effects in obese individuals. He proposed that low doses of hCG combined with a VLCD would be an effective means of losing weight and began testing the theory.[3]

According to Simeons, hCG liberates fat stores from the waist and hips.[1] By putting this fat in motion, hCG makes it more available for metabolism during the period of low caloric intake. With an increased energy source available, patients should be able to follow a highly restrictive diet without experiencing overwhelming feelings of hunger or weakness.[3,5] In this way, hCG does not directly stimulate weight loss, but rather helps combat the negative side effects associated with dieting such as compulsive hunger and lack of energy, which likely improves patient compliance with the VLCD. On average, it was observed that between 250 and 600 g of weight were lost daily without a negative impact on energy. In fact, when patients were blindly administered saline in place of the hCG injection, weight loss continued, but patients complained of weakness, dizziness, and hunger before eventually straying from the strict diet and regaining weight.[3,6]

In 1974, Simeons compiled a comprehensive diet plan in his book, *Pounds and Inches: A New Approach to Obesity*. His diet calls for daily 125 IU injections of hCG combined with a 500 Kcal/day diet consisting of lean meat, leafy vegetables, and fruit.[7] Injections begin three days prior to dieting and cease three days before the last scheduled day of the diet. Additionally, throughout the two days preceding the third injection, patients must consume as much high-fat food as possible. The low 500 Kcal/day diet begins after the third injection.[7] Simeons argues that this initial binge period is necessary to build up the body's fat reserves, which will provide an energy source throughout the diet. Any gain in weight during this period should be temporary and will be lost quickly when the low calorie diet begins. Furthermore, patients must adhere strictly to the 500 calorie allowance during the diet and up to three days after the final hCG injection.[6,7] If hCG is present in the body, Simeons warns that even a small increase in caloric intake is predicted to produce a disproportionately large gain in weight.[6,7] The duration of the diet is dependent upon the individual weight loss goals of the patient. For weight loss of 15 pounds or less, Simeons recommends a diet consisting of 26 days (23 injection days plus three days post-injection).[7] For weight loss goals greater than 15 pounds, the diet may be extended to include 40 injections. However, one course of treatment is not to exceed 40 injections or a weight loss greater than 34 pounds, as the body may become adapted to the effects of hCG and normal appetite may return.[3,7] If necessary, the regimen may be repeated several times for further weight loss, but patients must abstain from the diet for a period of at least six weeks before beginning an additional course of therapy. After completion of the second course, the interval should then become progressively longer between each repetition. Through multiple courses of treatment, Simeons argues that a morbidly obese patient could lose 100 pounds or more.[7]

Literature Review

A meta-analyses performed by Lijesen, et al. in 1995, concluded that there are more studies reporting that hCG is not effective for weight loss compared to those supporting hCG's efficacy in weight loss. In fact, of 24 trials that were analyzed via computer software, only 12 controlled trials scored above 50 points on a 100-point system measuring the quality of methodolgy.[2] Of these 12 studies, only one, the W.L. Asher study performed in 1973, found hCG to be an effective adjunct in weight loss therapy.[2,8]

In a double-blind, placebo-controlled study by Asher, 40 female patients were divided into two groups to assess the effects of Simeons' original diet plan with hCG injections versus his diet plan with adjunct placebo injections in regard to amount of weight lost, as well as hunger and mood of the study participants. The women were directed to strictly follow the diet plan, starting with three binge days, followed by restricted intake of 500-550 kcal/day divided into two meals of specific foods, with an emphasis on little to no fat intake for the remainder of the study period (>32 days). Patients kept daily food journals and met with nurses six days each week to receive the injections and to assess mood, hunger, and weight loss. Strict preparations and administration of the hCG injections were also followed. At the end of the trial period, the hCG group lost significantly more weight, had a significantly greater mean weight loss per injection, and lost a significantly greater mean percentage of their starting weight, as compared to the placebo group. Additionally, the percentage of responses indicating "little or no hunger" and "feeling good or excellent" was significantly greater in the hCG group versus placebo. The stringent diet, daily meetings, and strict preparation and administration of the injectable drug differentiate this study from most other studies performed on hCG and weight loss, possibly lending to its positive results. To further support Simeons' theory, the study also analyzed four physicians who administered hCG for weight loss. Their patients were not required to follow strict diet plans, received injections anywhere from three to five days each week, and in some cases were even permitted to self-administer injections at home. These patients did not benefit from casual hCG use verses placebo. Additionally, Asher's placebo study group following a strict diet lost significantly more weight than the casual hCG users of the other four physicians. This finding shows that benefits of hCG may only be realized when used appropriately. It may also explain the negative findings against the use of hCG and weight loss conducted by studies with less attention given to Simeons' original protocol.[8]

A double-blind, placebo-controlled study was performed by M.R. Stein and others in 1976 to assess the efficacy of hCG in weight loss. Patients were randomized into two groups and received either 125 units of hCG or normal saline daily via intramuscular injection. In addition to following the VLCD outlined above, participants received these injections six days a week over a period of 32 days. Although those participants on hCG experienced a slightly larger decline in weight, it was of no statistical significance, nor was the reduction in circumference between the two treatment arms. The authors concluded that hCG is no more effective than placebo for weight reduction, fat redistribution, or hunger declines. Both patients on hCG and those on placebo reported headaches, constipation, and fatigue, while one patient receiving hCG treatment became pregnant following years of infertility problems. While this study was well designed, it differs from Simeons' original protocol in significant ways. In this study, patients began the 500-calorie diet on the same day they began receiving injections. They also only received injections for 32 days, skipping injections every Sunday. These differences from Simeons' could have led to the differing results. This study also centered on mainly Caucasian women, leading to poor external validity.[9] Additional studies in the 1970s also found no use for hCG in weight loss therapy and recommended that treatment of obesity with hCG should come to an end.[10] A resurgence of the issue emerged in another double-blind, placebo-controlled trial published by B. Bosch and others in 1990, which also studied only female participants.[11]

In 2009, shortly after the release of the Lijesen meta-analysis, D.O. Belluscio conducted a study to determine the efficacy of an entirely new dosage form of hCG. Instead of administering intramuscular injections daily, researchers administered hCG via a sublingual-enteral route. Researchers expected the sublingual route to allow quick absorption through the venous plexus under the tongue, thus bypassing first pass metabolism in the liver. Participants were separated into three groups, receiving either placebo, 125 units of hCG twice daily, or 250 units of hCG twice daily, while being maintained on a VLCD. This study reported results similar to those of Simeons'. They found that although all treatment arms lost the same amount of weight, those patients receiving hCG experienced a larger decrease in waistline circumference. Researchers also found hCG to improve mood during the diet just as Simeons' had initially claimed. However, further testing should be done with this new dosage form to assess its overall safety and efficacy versus the injectable drug and placebo.[1]

hCG Disclaimers and Concerns

As with all dietary supplements, hCG is not regulated by the FDA. Efficacy of dietary supplements is not required to be proven upon their addition to the market. Due to this limited regulation, there is little initiative to perform trials. Very few trials have been performed since Simeons' initial discovery of hCG's role in weight loss. There has been some speculation as to why hCG proved effective in 1954, but not in more modern trials. Celeste Robb-Nicholson, editor-in-chief of the *Harvard Women's Health Watch*, stated that the FDA has suggested that there is no benefit to hCG therapy for weight loss.[12] Roger C. Toffle, of the Department of Obstetrics and Gynecology at West Virginia University, supported this FDA claim in the *West Virginia Medical Journal*, saying hCG is closely related to Luteinizing Hormone (LH). In fact, it could be this similarity that made hCG therapy effective in treating males with Frolich's Syndrome. In this special class of patients, hCG may have stimulated LH receptors in the testicles, thus increasing testosterone production. This increase in testosterone could have led to an indirect effect on obesity and fat distribution. Toffle went on to say that the changes in fat me-

tabolism during pregnancy may be attributed to placental growth hormone, not hCG.[4]

If hCG does indeed provide no benefit in weight loss, what could be responsible for the elevated mood in those individuals receiving treatment in the Belluscio trial? This benefit could be attributed to the presence of β-endorphin in some commercial preparations of hCG. It could be this addition that provides the pharmacological activity, not the hCG itself.[1] These are only a few perspectives and possible theories to discredit the efficacy of hCG; more studies need to be performed to assess the validity of these alternate theories.

hCG Counseling Points

Pharmacists should be informed about hCG use including available dosage forms, which patients to consider for therapy, and potential side effects in order to provide appropriate counseling to patients. Originally, hCG was available only as an injection, but the new sublingual dosage form and its appeal for those seeking to lose larger amounts of weight rapidly has brought hCG therapy back into public attention. Many consumers may not be well informed about the therapy and may see it as an easy way to lose weight. Therefore, it is important for the pharmacist to remind patients that hCG does not necessarily stimulate weight loss, but possibly makes dieting more tolerable. Additionally, though hCG is a female hormone, it may also be used safely by men without compromising their masculinity.[7]

Possible side effects associated with its use include increased chance of fertility, hypoglycemia, increased uric acid levels or gout, and increased libido. Interference with pregnancy test results may also result due to the use of hCG.[9,11] Although hCG in itself appears to have minimal risks and adverse effects, following a strict VLCD, as seen in Simeons' therapy, without proper supervision by a health care professional can be dangerous. Therefore, patients should be encouraged to consult a doctor before beginning the hCG diet.

Conclusion

There has been a lot of hype in the media about the safety and efficacy of hCG in weight management. With respect to using hCG for obesity, it would be great to give a definite "yes" or a definite "no" in regards to its efficacy. However, based upon a review of the available literature, a definitive conclusion cannot be reached at this time. Available studies show conflicting results and inconsistencies in administration route, dosing, and methods for measuring weight loss. It seems that hCG may be considered safe in conjunction with diet, as current literature contains no reports of serious risks or adverse events associated with the regimen. However, controlled, clinical trials are scant. Upon its initial discovery, hCG was found to be beneficial in weight loss only when used in combination with a VLCD. Patients on a VLCD as seen in Simeons' therapy will likely lose weight if they can overcome the overwhelming urge to eat. In this sense, hCG may be beneficial. More controlled, clinical studies should be conducted to assess the place of the hCG diet in weight management.

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