IS THE HUMAN CHORIONIC GONADOTROPIN DIET THE MIRACLE SOLUTION TO THE OBESITY MENACE?

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OBJECTIVES

1. Summarize the epidemiology of obesity and impact on society
2. Review the HCG drug profile and explain the HCG diet protocol
3. Evaluate literature on the safety and efficacy of HCG in the treatment of obesity
4. Apply past and current evidence to clinical practice

KEYWORDS & ABBREVIATIONS

Human chorionic gonadotropin (HCG), Simeons, obesity, body mass index (BMI), very low calorie diet (VLCD), Food and Drug Administration (FDA), Federal Trade Commission (FTC)
THE OBESITY EPIDEMIC: EPIDEMIOLOGY AND IMPACT

I. The World Health Organization considers obesity to be a global epidemic that has become a serious public health challenge. Between 1980 and 2008, worldwide obesity has more than doubled. In 2008, over 1.4 billion adults worldwide are overweight or obese.¹,²,³

II. Currently, over 72.5 million adults are considered obese in the United States with greatest prevalence in those who are ⁴
   a. Adults age 50-69 years
   b. Non-Hispanic blacks
   c. Hispanics
   d. Residents of the Midwest and South

III. In the United States, the prevalence of obesity continues to rise. From 2000 to 2009, the prevalence of obesity in the majority of states has increased drastically.⁴
IV. In 2001, after realizing severity of the obesity epidemic, the Surgeon General issued the *Call to Action to Prevent and Decrease Overweight and Obesity*.

V. Based on the World Health Organization and National Institute of Health’s Clinical Guidelines, obesity is defined based on Body Mass Index (BMI) which is calculated based on height and weight.\(^\text{1,5}\)

\[
\text{BMI} = \frac{\text{weight (kg)}}{\text{height (m}^2\text{)}} \quad \text{or} \quad \frac{\text{weight (lbs)}}{\text{height (in}^2\text{)}} \times 703
\]

<table>
<thead>
<tr>
<th>Weight Classification</th>
<th>Body Mass Index (kg/m(^2))</th>
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<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
</tr>
<tr>
<td>Normal</td>
<td>18.5 – 24.9</td>
</tr>
<tr>
<td>Overweight</td>
<td>25.0 – 29.9</td>
</tr>
<tr>
<td>Obesity Class I</td>
<td>30.0 – 34.9</td>
</tr>
<tr>
<td>Obesity Class II</td>
<td>35.0 – 39.9</td>
</tr>
<tr>
<td>Extreme Obesity Class III</td>
<td>≥ 40</td>
</tr>
</tbody>
</table>

VI. Obesity is a contributing factor to coronary heart disease, hypertension, hyperlipidemia, stroke, diabetes mellitus, osteoarthritis, sleep apnea and premature death. It can also affect quality of life and lead to social stigmatization and discrimination.\(^4\)

VII. Obesity is a costly and a serious health burden. Obesity-associated diseases accounted for \(^\text{4,5}\)

a. 27% of increases in medical costs from 1987 to 2001
b. Over $147 billion in medical costs in 2006
   i. Medical costs of obese persons $1,429 higher than persons of normal weight
HUMAN CHORIONIC GONADOTROPIN: DRUG PROFILE AND DIET PROTOCOL

I. The human chorionic gonadotropin (HCG) is a hormone produced in large quantities during pregnancy and secreted by trophoblastic cells in the placenta. It was discovered by a couple scientists in 1927 in the urine of pregnant women. HCG has been used in the treatment of infertility problems since its discovery.\(^6,7,8\)

II. HCG was first proposed as an aid for weight loss in 1954 by British physician Dr. Albert T.W. Simeons. Dr. Simeon developed this theory based on his experience and observation of using HCG to treat young boys with adiposogenital dystrophy. Adiposogenital dystrophy occurs due to decreased levels of gonadotropin-releasing hormone from secondary hypogonadism. Low levels of gonadotropin-releasing hormone are also associated with defects in the feeding centers of the brain leading to an increase in appetite, caloric intake and weight gain. When the young boys with adiposogenital dystrophy were treated with HCG, they experienced a decrease in appetite and no weight gain or weight loss, and a reduction in hip circumference. Dr. Simeons’ theory and results of the initial studies on HCG in weight loss were published in *The Lancet*. Dr. Simeons also published a book called *Pounds and Inches: A New Approach to Obesity* on the HCG diet. The HCG diet was advocated for years. However, the conclusions of Dr. Simeons’ studies have been challenged multiple times revealing no benefit of HCG therapy in weight loss and leading to discontinuation of its use in weight loss.\(^6,7,9,10\)

III. The HCG diet resurfaced in 2009 and has become very popular with widespread use in the United States. It is unclear what the driving force was that led to the resurfacing of the diet and its popularity today. Claims that have been made for HCG in weight loss include that it decreases hunger, increases weight loss around hips and legs, as well as reduces emotional difficulty and depression.\(^7,9,11\)

IV. HCG Drug Profile\(^12,13,14,15,16\)
   a. Brand Names: Novarel®, Pregnyl®
   b. Current FDA approved indications:
      i. Induction of ovulation in infertile females
      ii. Spermatogenesis induction in men
      iii. Hypogonadotropic hypogonadism in males
      iv. Prepubertal cryptorchidism
   c. Not FDA approved for use in weight loss
   d. Doses for approved indications considerably higher than doses used for weight loss
   e. Mechanism of action
      i. Activates production of gonadal steroid hormones
      ii. Influences development of male secondary sex characteristics
      iii. Influences normal menstrual cycle
      iv. Sustains the corpus luteum during pregnancy
      v. In terms of weight loss, thought to
         ➢ Help the body redistribute and burn fat
         ➢ Provide anorectic effect
         ➢ Cause euphoria/mood-elevating effects
   f. The weight loss mechanisms have never been proven and are based only on the testimonial of Dr. Simeons.
g. Common adverse effects based on doses used for approved indications
   i. Injection site pain
   ii. Headache
   iii. Depression
   iv. Irritability
   v. Restlessness
   vi. Gynecomastia

h. Serious adverse effects based on doses used for approved indications
   i. Thromboembolism
   ii. Pleural effusion, ascites
   iii. Ovarian hyperstimulation syndrome

i. Precautions
   i. Asthma
   ii. Cardiac disease
   iii. Epileptic disorder
   iv. Renal impairment

j. Contraindications
   i. Previous allergic reaction to HCG
   ii. Pregnancy
   iii. Precocious puberty
   iv. Androgen-dependent neoplasm (prostate cancer)

V. Dr. Simeons Diet Protocol
   a. Day 1 and 2
      i. Patient is to begin intramuscular injections of HCG 125 units per day. HCG of 125 units per day is enough to reduce weight at a rate of about 1 pound per day when is with a 500-calorie diet.

   b. Day 3
      i. Patient is to begin very-low-calorie-diet (VLCD) of 500 calories per day and continue intramuscular injections of HCG 125 units per day.

   c. The duration of therapy varies based on amount of weight loss needed. At the end of HCG treatment, the patient is to continue the VLCD for 3 days after the last HCG injection. The patient is free to eat anything except sugar and starches for 3 weeks.

<table>
<thead>
<tr>
<th>BREAKFAST</th>
<th>Tea or coffee in any quantity without sugar. Only one tablespoonful of milk allowed in 24 hours. Saccharin or Stevia may be used.</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUNCH</td>
<td>1. 100 grams of veal, beef, chicken breast, fresh white fish, lobster, crab, or shrimp. All visible fat must be carefully removed before cooking, and the meat must be weighed raw. It must be boiled or grilled without additional fat. Salmon, eel, tuna, herring, dried or pickled fish are not allowed. The chicken breast must be removed from the bird.</td>
</tr>
<tr>
<td></td>
<td>2. One type of vegetable only to be chosen from the following: spinach, chard, chicory, beet-greens, green salad, tomatoes, celery, fennel, onions, red radishes, cucumbers, asparagus, cabbage.</td>
</tr>
<tr>
<td></td>
<td>3. One breadstick (grissini) or one Melba toast.</td>
</tr>
<tr>
<td></td>
<td>4. An apple or a handful of strawberries or one-half grapefruit or orange.</td>
</tr>
<tr>
<td>DINNER</td>
<td>The same four choices as lunch.</td>
</tr>
</tbody>
</table>
Chorionic Gonadotropin in Weight Control: A Double-Blind Crossover Study

I. Objective and Study Design
   a. The purpose of this study was to assess the effectiveness of HCG in a weight reduction program. This was a double-blind, placebo-controlled, cross-over study conducted at Wilford Hall United States Air Force Medical Center in San Antonio, Texas. This was a four 6-week treatment/maintenance cross-over with a population size of 202 patients.

II. Inclusion Criteria
   a. Age ≥ 18 years
   b. Calculated excess fat of 18.2 kg or more
      i. Assume normal percent fat of 17% in men and 23% in women
      ii. For example, a woman who weighed 91 kg and had a calculated percent fat of 43% would have exactly 18.2 kg of excess fat.
   c. General healthy condition

III. Exclusion Criteria
   a. Age < 18 years
   b. Major medical illness requiring therapy other than diet

IV. Intervention
   a. Treatment phase x 6 weeks
      i. HCG 125 units intramuscular injections 6 days per week
      ii. Placebo intramuscular injections 6 days per week
   b. Maintenance phase x 6 weeks
      i. Gradual increase in calories to maintain weight
   c. All patients began 500-calorie diet on third day of treatment phase
      i. Options from Simeons diet protocol
   d. Diet and behavior modification lectures were given twice weekly

V. Treatment and Maintenance Phases

<table>
<thead>
<tr>
<th>Designation of Groups and Time Periods for HCG vs. Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1 (n = 100)</strong></td>
</tr>
<tr>
<td><strong>Group 2 (n = 102)</strong></td>
</tr>
<tr>
<td>Treatment period 1</td>
</tr>
<tr>
<td>HCG 6 days per week for 6 weeks</td>
</tr>
<tr>
<td>Placebo 6 days per week for 6 weeks</td>
</tr>
<tr>
<td>Maintenance period 1</td>
</tr>
<tr>
<td>No therapy; keep weight stable for 6 weeks</td>
</tr>
<tr>
<td>No therapy; keep weight stable for 6 weeks</td>
</tr>
<tr>
<td>Treatment period 2</td>
</tr>
<tr>
<td>Placebo 6 days per week for 6 weeks</td>
</tr>
<tr>
<td>HCG 6 days per week for 6 weeks</td>
</tr>
<tr>
<td>Maintenance period 2</td>
</tr>
<tr>
<td>No therapy; keep weight stable for 6 weeks</td>
</tr>
<tr>
<td>No therapy; keep weight stable for 6 weeks</td>
</tr>
</tbody>
</table>
VI. Outcomes
   a. Primary
      i. Reduction in weight
         ➢ Patients weighed daily
   b. Secondary
      i. Reduction in percent body fat
      ii. Reduction in skinfold thicknesses
         ➢ Triceps, biceps, subscapular and suprailiac areas
      iii. Reduction in circumference measurements
         ➢ Upper arm, chest, waist, hop and thigh
      iv. Subjective responses to questionnaires

VII. Statistical Analysis
   a. One-way analysis of variance for continuous data
   b. Statistical significance defined as $p < 0.1$

VIII. Baseline Data

<table>
<thead>
<tr>
<th>Baseline Data in Patients Entered into HCG vs. Placebo Study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>Duration of obesity (years)</td>
</tr>
<tr>
<td>Change in weight over last 6 months (kg)</td>
</tr>
<tr>
<td>Weight (kg)</td>
</tr>
<tr>
<td>Height (cm)</td>
</tr>
<tr>
<td>Body fat (%)</td>
</tr>
<tr>
<td>Triceps skinfold (mm)</td>
</tr>
<tr>
<td>Subscapular skinfold (mm)</td>
</tr>
</tbody>
</table>

IX. Results
   a. No statistically significant differences in baseline data
   b. Mean of more than 27.3 kg over standard weight for both groups
   c. No difference between the groups in treatment and maintenance phases in terms of
      i. Weight loss
      ii. Change in percent body fat
      iii. Change in skinfold thickness
      iv. Reduction in body circumference
   d. First treatment phase vs. second treatment phase within groups
      i. Statistically significant weight and percent body fat loss in both groups
e. Mean changes in weight

<table>
<thead>
<tr>
<th></th>
<th>Number of Patients</th>
<th>Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment period 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCG</td>
<td>80</td>
<td>- 8.5</td>
</tr>
<tr>
<td>Placebo</td>
<td>92</td>
<td>- 9.0</td>
</tr>
<tr>
<td><strong>Maintenance period 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCG</td>
<td>73</td>
<td>+ 1.8</td>
</tr>
<tr>
<td>Placebo</td>
<td>83</td>
<td>+ 1.8</td>
</tr>
<tr>
<td><strong>Treatment period 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCG</td>
<td>62</td>
<td>- 4.5</td>
</tr>
<tr>
<td>Placebo</td>
<td>49</td>
<td>- 4.2</td>
</tr>
<tr>
<td><strong>Maintenance period 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCG</td>
<td>53</td>
<td>+ 2.0</td>
</tr>
<tr>
<td>Placebo</td>
<td>43</td>
<td>+ 1.7</td>
</tr>
</tbody>
</table>

f. Mean changes in percent body weight

<table>
<thead>
<tr>
<th></th>
<th>Number of Patients</th>
<th>Body Fat (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment period 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCG</td>
<td>80</td>
<td>- 4.2</td>
</tr>
<tr>
<td>Placebo</td>
<td>92</td>
<td>- 4.0</td>
</tr>
<tr>
<td><strong>Maintenance period 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCG</td>
<td>73</td>
<td>+ 0.4</td>
</tr>
<tr>
<td>Placebo</td>
<td>83</td>
<td>+ 0.2</td>
</tr>
<tr>
<td><strong>Treatment period 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCG</td>
<td>62</td>
<td>- 2.3</td>
</tr>
<tr>
<td>Placebo</td>
<td>49</td>
<td>- 2.6</td>
</tr>
<tr>
<td><strong>Maintenance period 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCG</td>
<td>53</td>
<td>+ 0.4</td>
</tr>
<tr>
<td>Placebo</td>
<td>43</td>
<td>+ 0.6</td>
</tr>
</tbody>
</table>

g. Patient who completed all phases of the protocol
   i. Mean weight loss not significantly different between groups
   ii. Overall percent body fat loss not significantly different
h. Dropout rate between groups not significantly different during any time period
i. Number of injections
   i. 1 patient received only 26 shots during placebo phase
   ii. 1 patient received only 28 shots during the HCG phase
   iii. All others received 30 shots or more

j. Patient questionnaire showed no significant clinical differences between groups
   i. Questionnaire had questions on response and symptoms to injections, satisfaction with program and even asked if patient could guess which group they were in.
   ii. Patients could not guess when they received HCG

X. Author’s Conclusions
   a. HCG’s benefit in promoting weight loss was not demonstrated by any objective indicator
   b. No evidence of better weight loss maintenance with HCG
   c. No evidence that those receiving HCG were more satisfied with program

XI. Strengths
    a. Study design
    b. Large sample size

XII. Limitations
    a. High dropout rate which will affect power to detect a difference
       i. 57 patients dropped out during HCG therapy or following maintenance phase
       ii. 49 patients dropped out during placebo therapy or following maintenance phase
       iii. Reasons for dropping out: reasons beyond patient’s control, dissatisfaction with program, inconvenience to continue, unsatisfactory weight loss.
       iv. No significant difference in dropout rates at any time period between groups.
    b. Percent fat calculation underestimates degree of overweight
       i. Assumes all weight loss would be fat loss
    c. 2-3 times more female patients


I. Objective and Study Design
   a. The purpose of this study was to test the claims of HCG aiding in weight reduction by reducing hunger and affecting mood as well as aiding in localized fat reduction. This was a randomized, double-blind, placebo-controlled study conducted at Harbor General Hospital in Torrance, California with a 6 week follow-up and a population size of 40 patients.

II. Inclusion Criteria
   a. General good health
   b. No previous treatment with HCG
   c. Not currently receiving any medications for obesity
III. Exclusion Criteria
   a. Current treatment of obesity with medications
   b. Previous treatment with HCG therapy
   c. Severe and uncontrolled medical conditions

IV. Intervention
   a. Control group
      i. Placebo IM injections of diluents 6 days per week
   b. Treatment
      i. HCG 125 units IM injections 6 days per week
   c. Diet of 500 calories for all patients

V. Outcomes
   a. Primary
      i. Change in weight
         ➢ Weights obtained weekly
   b. Secondary
      i. Effect on hunger
         ➢ Evaluated by marking a line between 1 and 9 based on rating of hunger (1 = not hungry; 9 = maximum hunger)
         ➢ Obtained at beginning and end of treatment
      ii. Localized fat reduction
         ➢ Circumference of mid-thigh, chest, hips at iliac crest and mid-upper arm
         ➢ Measured at beginning and end of treatment
      iii. Change in mood
         ➢ Multiple Affect Adjective Check List which is a valid and reliable scale
         ➢ Rated anxiety, hostility and depression

VI. Statistical Analysis
   a. Analysis of variance for continuous and ordinal data
   b. Chi-square test for nominal data
   c. Statistical significance defined as p < 0.05
II. Baseline Data
   a. The participants of this study were white women between 20 and 40 years of age, and 20 to 60 percent overweight.

| Initial Mean Values for Clinical Measurements in HCG vs. Placebo Group |
|--------------------------|-----------------|-----------------|-----------------|
|                          | HCG (n = 20)    | Placebo (n = 20)| p-value         |
| Body weight (kg)         | 81.4            | 79.4            | NS              |
| Circumferences (cm)      |                 |                 |                 |
| Biceps                  | 33.3            | 33.0            | NS              |
| Chest                   | 91.2            | 94.0            | NS              |
| Iliac crest              | 104.6           | 101.8           | NS              |
| Midthigh                | 58.2            | 57.4            | NS              |
| Hunger score             | 3.3             | 2.8             | NS              |
| Anxiety score            | 83.6            | 63.2            | .017            |
| Hostility score          | 69.1            | 71.6            | NS              |
| Depression score         | 74.1            | 69.4            | NS              |

NS = not significant

III. Results
   a. The initial measurements on the anxiety scale was the only significant difference between the groups
      i. Patients in HCG group were more anxious
   b. No significant differences in terms of
      i. Weight loss
      ii. Circumference measurements
      iii. Psychological variables
   c. Changes in weight

![Graph showing changes in weight over time](image)
d. Initial and final clinical data

<table>
<thead>
<tr>
<th>Initial and Final Mean Values for Clinical Data in HCG vs. Placebo Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td>Body weight (kg)</td>
</tr>
<tr>
<td>Circumferences (cm)</td>
</tr>
<tr>
<td>Arm</td>
</tr>
<tr>
<td>Chest</td>
</tr>
<tr>
<td>Iliac crest</td>
</tr>
<tr>
<td>Midthigh</td>
</tr>
<tr>
<td>Hunger score</td>
</tr>
<tr>
<td>Anxiety score</td>
</tr>
<tr>
<td>Hostility score</td>
</tr>
<tr>
<td>Depression score</td>
</tr>
</tbody>
</table>

NS = not significant

IX. Author’s Conclusions
   a. HCG injections did not enhance the rate of weight loss
   b. HCG also did not significantly reduce hunger
   c. No significant changes in the ratings of anxiety, hostility or depression

X. Strengths
   a. Study design
   b. Conducted by clinical research center
   c. Supported by a grant from National Institutes of Health (NIH)

XI. Limitations
   a. Small population size
   b. All Caucasian females
   c. Lacks external validity

Utility of an Oral Presentation of HCG (Human Choriogonadotropin) for the Measurement of Obesity:
A Double-Blind Study

I. Objectives and Study Design
   a. The purpose of this study was to assess the utility of sublingual HCG for the management of obesity. This was a double-blind, randomized, placebo-controlled study conducted at a gynecology clinic in Buenos Aires, Argentina with a 5 week follow-up and a population size of 70 patients.
II. Inclusion Criteria
   a. Age 18-75 years of age
   b. BMI ≥ 25
   c. Overweight
   d. Not on medications to treat obesity
   e. General healthy condition

III. Exclusion Criteria
   a. Treatment with steroids, diuretics or hormones
   b. Severe and/or uncontrolled diseases
   c. Treatment of obesity with medication within month of study

IV. Intervention
   a. Placebo (N = 26)
      i. Normal saline sublingual twice daily
   b. HCG group 1 (G1) (N = 36)
      i. 125 IU HCG sublingual twice daily
   c. HCG group 2 (G2) (N = 8)
      i. 250 IU HCG sublingual twice daily
   d. Diet plan for all groups
      i. Very-Low-Calorie Diet (VLCD)
   e. First dose of the day administered before breakfast while fasting. The second dose was administered 1 hour before dinner. All patients were to maintain solution sublingually for at least 2 minutes in the oral cavity before swallowing. HCG is destroyed by digestive enzymes and therefore is administered sublingually. Medication had to be maintained under refrigeration at all times.

V. Outcomes
   a. Primary
      i. Reduction in body weight
         ➢ Measured on medical scale
      ii. Reduction in fat weight
         ➢ Measured by bioelectrical impedance
      iii. Reduction in lean weight
         ➢ Measured by bioelectrical impedance
   b. Secondary
      i. Reduction in body circumferences
         ➢ Measured using a flexible, non-elastic metric tape
      ii. Skinfold thickness reduction
         ➢ Measured using a Lange Skinfold Caliper
      iii. Improvement in mood-related parameters
         ➢ Self-administered questionnaire

VI. Statistical Analysis
   a. Multivariate analysis of variance for continuous data
   b. Chi-square test for nominal data
   c. Statistical significance defined as p < 0.05
VII. Results
   a. Reduction in body, fat and lean weight
      i. Similar results across all groups
      ii. Decreasing observed patterns were the consequence of VLCD
      iii. No significant difference between all groups
      iv. Statistically significant differences found within groups
   b. Reduction in body weight
   c. Reduction in fat weight
d. Reduction in lean weight

![Graph showing reduction in lean weight over weeks for Placebo, Group 1, and Group 2.]

- Significant decrease between groups

e. Waist circumference
   i. Significant decrease between groups

![Graph showing waist circumference changes over weeks for Placebo, Group 1, and Group 2.]

- Significant decrease between groups
f. Abdominal circumference
   i. Significant decrease between groups

![Abdominal Circumference Graph]

g. No statistical difference found in other body circumference measurements
h. Reduction in skinfold thicknesses
   i. Statistically significant between groups for all skinfolds measured
   ii. Higher significances and most affected by pharmacological treatment
   i. Tricipital
   ii. Subscapular
   iii. Iliac
j. Reduction in tricipital skinfold

![Skinfold Thickness Graph]
k. Reduction in subscapular skinfold

![Graph showing reduction in subscapular skinfold across weeks for Placebo, Group 1, and Group 2.]

l. Reduction in iliac skinfold

![Graph showing reduction in iliac skinfold across weeks for Placebo, Group 1, and Group 2.]

m. Mood-related parameters statistical difference only found in four parameters
   i. Mood stability at home
   ii. Irritating episodes
   iii. Escalating discussions
   iv. Nervousness

n. HCG groups
   i. Coped better with daily irritating situations
   ii. Less prone to episodes of extreme nervousness
   iii. Trend towards improvement

o. Placebo group
   i. More adversely affected
   ii. Trend towards impairment
p. No side effects were observed
q. HCG plasma levels
   i. Patients screened on treatment days 0, 15, 30
   ii. Undetectable concentrations in all cases

VIII. Author’s Conclusions
   a. Oral administration of HCG proved to be safe and effective in treatment of obesity
   b. HCG plus VLCD decreased specific body circumferences and skinfold thickness more efficiently
   c. Positive mood changes detected in HCG-treated patients

IX. Strengths
   a. Study design
   b. Assessed several variables

X. Limitations
   a. All female patients
   b. Lacks external validity

APPLICATION TO CLINICAL PRACTICE

I. Presenter’s Conclusions
   a. Obesity is an ongoing health burden and continues to increase dramatically worldwide and in the United States. Current evidence does not support the use of HCG in weight loss. Most of the studies evaluate the injectable form of HCG with only a few small studies supporting the use of HCG in weight loss. Majority of these studies also have a small population size which can affect the power to detect a difference. Currently, there are 2 studies evaluating the sublingual form of HCG with both showing positive results for the use of HCG in weight loss. However, more studies are needed.
   b. In addition, patients can lose weight on a low calorie diet alone but a VLCD diet of only 500 calories per day with a goal weight loss of 1 lb per day may be hazardous to the body. The NIH Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults currently recommends a regular reduced calorie and fat diet and exercise with a goal weight loss of 1 to 2 lbs per week. Pharmacotherapy may be used to aid weight loss in addition to diet and exercise but only FDA approved weight loss drugs are recommended. Pharmacotherapy should only be used in patients with a BMI of ≥ 30 with no concomitant obesity-related diseases and risk factors. Pharmacotherapy may also be used in patients with a BMI ≥ 27 with concomitant obesity-related diseases and risk factors. 

5
II. Updates & Regulation
   a. The use of HCG in weight loss not supported by the American Medical Association or the American Society of Bariatric Physicians.\textsuperscript{17}
   b. In 1995, FDA required labeling and advertisements to state no evidence of efficacy in weight loss.\textsuperscript{18}
      i. "HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or 'normal' distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets."
   c. In December 2011, FDA and FTC issued warning letters to remove illegal over-the-counter homeopathic HCG weight loss products.\textsuperscript{19}
   d. In October 2011, Attorney General of Texas issued statement against off-label marketing.\textsuperscript{20}

III. Serious adverse events associated with the use of HCG injections for weight loss that have been reported to FDA\textsuperscript{18}
   a. Pulmonary embolism
   b. Cerebrovascular issues
   c. Depression
   d. Cardiac arrest
   e. Death

REFERENCES


