HCG DIET – Is it a fad?

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Objectives

- To define the role and nature of HCG (Human chorionic gonadotropin) hormone in the human body
- To describe the general structure and proposed rationale of the HCG diet protocol
- To evaluate the efficacy of HCG diet based on a meta-analysis

Outline

- Obesity Overview
- Human Chorionic Gonadotropin (HcG)
  - Mechanism of action
  - FDA-approved indications
  - Adverse effects
  - Contraindications & Precautions
- HcG diet
  - History
  - Proposed theory & claims
  - Meta-analysis
  - Conclusion

Obesity Trend in U.S.

Obesity

- Prevalence of obesity and overweight has been increasing remarkably in the United States since the 1980s
- Multifactorial – contributory to genetics, environmental, and physiologic factors
**Obesity - Classification**

\[
\text{BMI} = \frac{\text{Weight(kg)}}{\text{Height (m)}^2}
\]

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Weight status</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18.5</td>
<td>Underweight</td>
</tr>
<tr>
<td>18.5 – 24.9</td>
<td>Normal</td>
</tr>
<tr>
<td>25.0 – 29.9</td>
<td>Overweight</td>
</tr>
<tr>
<td>30.0 – 34.9</td>
<td>Class I Obesity</td>
</tr>
<tr>
<td>35.0 – 39.9</td>
<td>Class II Obesity</td>
</tr>
<tr>
<td>≥ 40.0</td>
<td>Class III Obesity</td>
</tr>
</tbody>
</table>

**Obesity - Risk factors**

- Hypothyroidism
- Medication-induced weight gain
- Smoking cessation
- Stress, anxiety, depression
- Menopause

**Obesity - Complications**

Associated with number of serious health risks, disease states, and increased mortality:

- **Cardiovascular**
  - HTN, LV hypertrophy, CHF, CAD, Stroke

- **Metabolic**
  - Hypercholesterolemia, ↑ TG, ↓ HDL, diabetes

- **Pulmonary**
  - Sleep apnea, obstructive airway disease, Pulm HTN

- **Gastrointestinal**
  - GERD, Hiatal hernia, cholelithiasis

- **Psychological**
  - Depression, affective disorders, eating disorders

- **Neoplasm**
  - Breast cancer, colon cancer

**HCG Hormone**

- Human Chorionic Gonadotropin
  - FDA-approved Indications
    - Ovulation & pregnancy induction in anovulatory, infertile females
    - Treatment of hypogonadotropic hypogonadism
    - Treatment of pre-pubertal cryptorchidism
    - Spermatogenesis induction with follictropin alfa

**Human Chorionic Gonadotropin**

- Brands: Novarel®, Pregnyl®
- Pharmacologic class: Ovulation Stimulator
- Mechanism of action:
  - Stimulation of androgen production in testes, thereby enhancing gonadal steroid hormones production
  - Acts as a substitute for luteinizing hormone (LH)
HCG – Dosing

- Ovulation induction
  - 5000-10,000 units IM 1 day after last menotropin dose

- Spermatogenesis induction
  - 1000-2000 units IM 2-3 times weekly
  - May require 2 – 3 months in duration

HCG – Adverse Effects

- Edema
- Depression, fatigue, headache, restlessness
- Gynecomastia, precocious puberty
- Local injection site reaction, pain
- Hypersensitivity reaction
- Arterial thrombus, ovarian hyperstimulation syndrome, ovarian cyst rupture (<1% frequency but significant or life-threatening)

Human Chorionic Gonadotropin

- Contraindications
  - Hypersensitivity to medication
  - Prostatic carcinoma
  - Precocious puberty
  - Pregnancy

- Precautions
  - Asthma
  - Cardiovascular disease
  - Migraine
  - Renal impairment
  - Seizure disorder

The HCG DIET

- Fastest way to lose weight and keep it off
- Lose at least 15 – 30 pounds in a month
- HCG Diet is “FREE”!

- No feelings of hunger through process
- HCG helps reset hypothalamus
  - Redistribute fats
  - Make permanent changes to eating habits
**HCG Diet – History**

Dr. Simeons 1954
- Obesity: a disorder due to abnormal functioning of body
- Three types of stored fat
  - Structural fat
  - Normal fat
  - Abnormal fat
- Exercise & starvation results in exhaustion of “normal fat” and “structural fat”

**HCG Diet – Proposed theory**
- HCG hormone is released in large quantities during pregnancy
- Dr. Simeons calls it a “diencephalic change” – and claims it a phase brought about by HCG production
- In the human body, fixed “abnormal fat” deposits can be transferred back into the “normal fat” current only during pregnancy

**HCG Diet – The Claim**
- People who adhere to HCG diet will:
  - Lose weight quickly
  - Do not feel weak
  - Do not feel hungry
  - Preferentially burn stored fat

**HCG Diet – The DIET**
- Also known as Simeons therapy
- Two components:
  1. HCG hormone use
     - 125 IU - IM injection or oral drops
  2. Very low calorie diet:
     - 500-800 calories/day
- Duration of therapy - varies

**HCG Diet Meal Plan:**
- **Days 1 – 2:** Loading phase
  - No restriction in food intake
- **Beginning on day 3:** Maintenance phase
  - Restricted to 500-calorie-per-day diet
  - Calorie restriction applied through 72 hours after last HCG injection
- **For 3 weeks after last injection:**
  - No sugar & starch

**Meta-analysis**
- The effect of human chorionic gonadotropin (HCG) in the treatment of obesity by means of the Simeons therapy
- Found 8 uncontrolled & 16 controlled trials
- Studies scored for quality of methods
  - Study population
  - Interventions
  - Measurement of effect
  - Data presentation and analysis
- Methodological scores: 16 – 73 (maximum 100 points)
Meta-analysis - Conclusion

- A number of studies using HCG in treatment of obesity have been conducted and published.
- No scientific evidence of HCG hormone efficacy.
- Weight loss resulting from Simeons therapy is attributed to its very-low-calorie diet.
- Weight loss is regarded as an inappropriate indication for HCG use.

True/False

- The HCG diet protocol requires a period of 500-calorie daily intake. **True**
- HCG has FDA-labeled indications for infertility in women and hypergonadism in men. **False (HYPOgonadism)**
- Prescription HCG advertised for weight loss purpose is available in both sublingual and nasal spray formulations. **True**

FDA Consumer Update 12/2011

- HCG not approved for OTC sale.
- HCG is not listed under **Homeopathic Pharmacopoeia of the United States** – thus cannot be sold legally as homeopathic medication.
- 500-calorie-a-day diet increases health risks and may be fatal.
**FDA Consumer Update 12/2011**

- FDA and FTC taking action on illegal HCG products
- Warning letters issued to seven companies
- Fifteen days allotted for companies to notify FDA regarding their plans
- FDA encouraging consumers to report any side effects associated with the use of these products to MedWatch

**Conclusion**

- Prevalence of obesity in U.S. has increased dramatically over the past decades
- Two components to the HCG diet: HCG injection (or alternative forms) in adjunct to a 500-calorie-a-day diet
- A meta-analysis has shown no effect of HCG hormone in the weight loss

**FDA Consumer Update 12/2011**

“These products are marketed with incredible claims and people think that if they’re losing weight, HCG must be working. But the data simply does not support this; any loss is from severe calorie restriction. Not from the HCG.”

*Elizabeth Miller*
Director of FDA’s Division of Non-Prescription Drugs and Health Fraud

**Conclusion**

- The increasing popularity of this diet has encouraged the emergence of OTC products that claim to contain HCG hormone
- HCG hormone is only FDA-approved for infertility and other health conditions
- FDA and FTC taking action on illegal HCG products
- FDA warns public: a very-low-calorie diet poses health risks and may be dangerous

**Case Practice**

A 29 yo female comes into your pharmacy to pick up her prenatal vitamins and would like to talk to you, the pharmacist, regarding the HCG diet that she had recently learned from a TV advertisement. She expresses a very strong interest in this diet but has a fear for needles, and would like to know if there are other routes in which she can 'consume' this HCG hormone. What would you tell her?

**Answer:**

HCG hormone products marketed for weight loss also comes in an oral sublingual formulation.

**Case Practice**

The following information are found in her profile:

- **Height:** 5'5
- **Weight:** 91 kg
- **Allergies:** NKDA

**PMH**

- HTN
- GERD
- DM II
- Dyslipidemia
- Anxiety
- Low back pain
- Allergic rhinitis

**Active medications**

- Acetaminophen 500mg Q6H prn pain
- Diphenhydramine 50mg po Q6H prn allergy
- Folic acid 1mg po daily
- Insulin Glargine 17 units QHS
- Insulin Aspart 8 units TID AC
- Metformin 1g po BID
- Methyldopa 250mg po BID
- Ranitidine 150mg po BID
- Prenatal vitamin tablet 1 tab po daily
Case Practice

Would you recommend the HCG diet for this patient? Why or why not?

**Answer:**

No. HCG products are absolutely contraindicated in pregnancy. Animal studies have revealed evidence of forelimbs and CNS defects in fetuses.

References


Questions?

- FDA Consumer Health Information. “HCG diet products are illegal.” Food and Drug Administration. 12 Dec 2011.