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

Obesity Trend in U.S.

- Prevalence of obesity and overweight has been increasing remarkably in the United States since the 1980s
  - **Overweight** 6% (1980) ➔ 19% (2004)
- 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>&gt;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

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

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

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

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

- **Neoplasm**
  - Breast cancer, Colon cancer

HCG Hormone

- **FDA-approved Indications**
  - Ovulation & pregnancy induction in anovulatory, infertile females
  - Treatment of hypogonadotropic hypogonadism
  - Treatment of pre-pubertal cryptorchidism
  - Spermatogenesis induction with follitropin 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**

**HCG Diet – As Advertised**

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

**HCG Diet – As Advertised**

- 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

<table>
<thead>
<tr>
<th>First author</th>
<th>Reference</th>
<th>Review score</th>
<th>Duration of intervention</th>
<th>Follow-up*</th>
<th>HCG: weight loss in pounds (95% CI)</th>
<th>Weight loss resulting from Simeons therapy</th>
<th>Inappropriate indication for HCG use</th>
<th>Authors' conclusion on results of the study</th>
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</thead>
<tbody>
<tr>
<td>Stein (29)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15.5 (15.3-15.7)</td>
<td>Negative</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>Young (30)</td>
<td></td>
<td>75</td>
<td>4 weeks</td>
<td>18 weeks</td>
<td>15.7 (15.2-15.9)</td>
<td>Negative</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>Franz (31)</td>
<td></td>
<td>63</td>
<td>6 weeks</td>
<td>3 months</td>
<td>15.7 (15.3-15.9)</td>
<td>Negative</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>Stepan (32)</td>
<td></td>
<td>63</td>
<td>6 weeks</td>
<td>3 months</td>
<td>15.7 (15.3-15.9)</td>
<td>Negative</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>Rischer (33)</td>
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<td>66</td>
<td>6 weeks</td>
<td>4 months</td>
<td>15.76 (15.3-15.9)</td>
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<td></td>
<td>Negative</td>
</tr>
<tr>
<td>Oster (34)</td>
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<td>62</td>
<td>4 weeks</td>
<td>4 weeks</td>
<td>15.8 (15.0-15.6)</td>
<td>Negative</td>
<td></td>
<td>Negative</td>
</tr>
</tbody>
</table>

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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

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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**

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HCG Diet – The Products

http://2.bp.blogspot.com/-Rzk-BE1wuPY/Tt-jqbzJwWI/AAAAAAAAATw/NapNgGKRG-U/s1600/120611_HCGProductsFDA.jpg

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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

"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

- 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

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.

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

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

Questions?

[Image: http://snip.ly/qZdJ.png]