授課講師學經歷

姓名	王偉
課程名稱（主題）	胃水球置放術之減肥成效
服務單位(包含職稱)	台北醫學大學附設醫院體重管理中心主任
學歷	陽明大學醫學系
經歷	台北醫學大學附設醫院體重管理中心主任

授課內容摘要

肥胖對於健康的危害是眾所週知的，對於嘗試過保守治療而屢屢失敗的「非病態型」肥胖的患者，就可考慮使用非藥物、侵入性的「非手術」來進行治療，故可利用胃內水球來減重。

本篇目的主要針對胃內水球的背景、適應症、禁忌症、治療過程、安全性與合併症加以探討。胃內水球是將胃部空間加以佔據，進而達到減少食量、增加飽足感的效果，可避免食物過量攝取而達到減重目的。

胃內水球目前建議適用在 BMI 大於 30 kg/m2，且經過保守治療無效的族群，但對於此種治療的確切定位，目前仍有爭議。目前已有共識的適應症包括：
針對超級病態型肥胖（BMI≧50 kg/m2）在接受減重手術治療前先使用水球做為第一階級治療，待體重下降部份後，再進行減重手術以提高手術安全。
BMI 大於 30 kg/m2 而對於保守治療包括減重藥物、低卡代餐及行為調整成效不彰者。
應當手術但因潛在疾病過於嚴重而無法接受手術者

胃內水球對於下列狀況的病患不建議使用：
目前正有胃潰瘍。
曾經有過胃部手術者。
中度或重度的食道炎。
發炎性的腸胃炎，如克隆氏症。
裂孔疝氣大於 5 公分。
毒品或酒精成癮。
胃內水球的治療安全性相當高，但在安置後的第一個星期會有明顯嘔吐及噁心的症狀，因此術前必須排除絕對禁忌的族群，告知可能出現之不適情況，並在術後提供病患舒緩不適症狀的醫療支持，且胃內水球建議不要放至超過六個月，因此術後的定期追蹤，教育正確的飲食觀念，養成良好的飲食習慣，以期在水球移除後，體重可以繼續保持而不復胖。

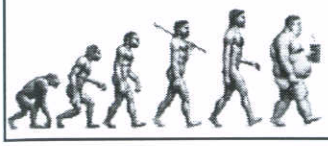
胃內水球對肥胖患者的效果是被肯定，因此身為醫療人員，需更清楚了解並給予肥胖患者另一種非藥物減重方法的選擇。

臺北醫學大學附設醫院

微創手術中心
TAIPEI MEDICAL UNIVERSITY HOSPITAL
MINIMAL INVASIVE SURGERY CENTER

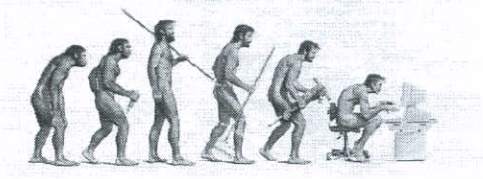
Intragastric Balloon for the Treatment of Obesity

體重管理中心主任 - 王 偉 醫師



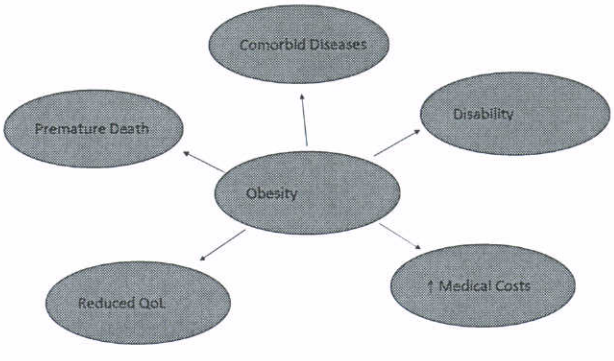
Energy Imbalance

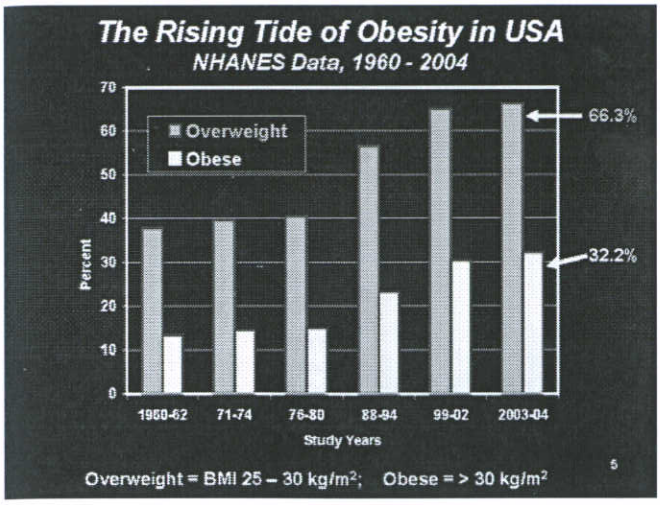
A modern society with stone age genes

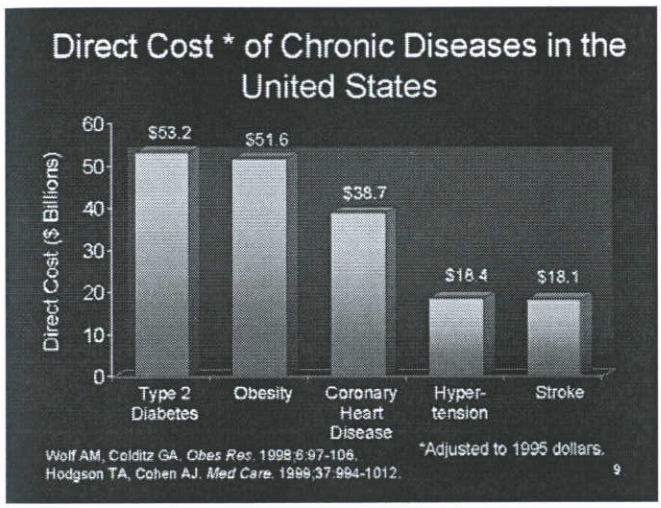


- Copious supply of food
- Labor-saving technologies - activity is optional
- The net result is Calories In > Calories Out

Impact of Obesity



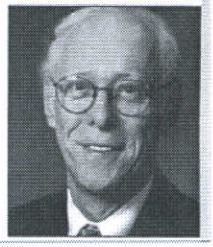




Why do we treat obesity??

- Co-morbidities
- Quality of life
- Survival – Life Expectancy

Obesity Management Vol.1, No.1



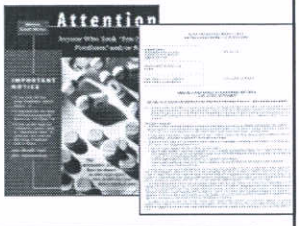
"We aren't going to cure obesity with diets."

George Bray
Pennington Biomedical Research Center

Medical Therapy

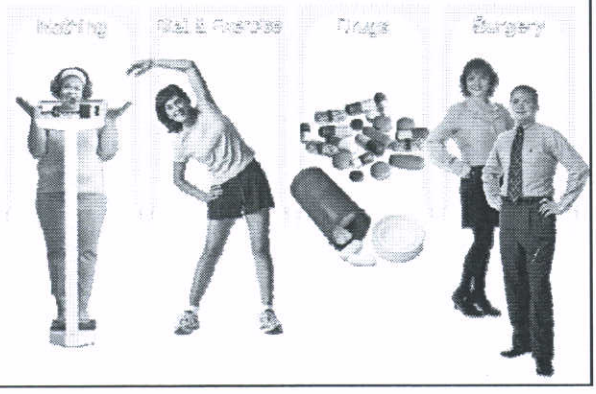
Minimal Long-term Weight Loss

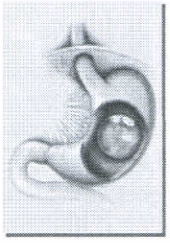
- A two-year randomized study of Orlistat among 892 Adults 30-43 kg/m2 found weight loss of 10% at one year and 8% at two years.*
- Medical complications with weight loss medicines and dietary supplements has lead the FDA to prohibit sale and distribution of certain drugs.



*Davidson, MH, et al. JAMA. 1999;281:235-242

What Are My Options?





BioEnterics Intragastric Balloon

Endoscopic Treatment of Obesity Device Categories

1. Occupy a space in the gastric lumen
2. Create a restriction in the gastric lumen
3. Alter food absorption

Hashiba, Gastrointest Endoscopy Clin N Am 17 (2007) 545-557

Gastric Volume - Displacing Weight Loss Device:

Balloon History

1921:	**Davies (U.K.)** Bezoar
Early 1980s:	**Ballobes** Polyurethane, Air-Filled, 400-500 ml
1982:	**Frimbergen (Germany)** 11 patients with latex balloon
1982:	**Nieben/Harboe (Denmark)** 5 patients with rubber balloon
1982:	**Miller (USA)** Dog study with polyethylene bottles

Garren-Edwards Bubble

History

- Sept. 1985: FDA approved Garren-Edwards Balloon
- ☐Jan. 1986: American Edwards initiated 5-center trial and sales
- ☐20,000 sold the first year
- ☐Between 1986 & 1988 complications presented and increased in frequency:
- ☐1988 FDA restricted the use to "investigation trials"
- ☐May 15, 1988 the company withdrew the product from the market

Features of Balloons Used in the 1980's

Complications

GASRIC EROSION	26%
GASTRIC ULCERS	14%
SMALL BOWEL OBSTRUCTION	2%
MALLORY-WEISS TEAR	11%
ESOPHAGEAL LACERATIONS	1%

- Not effective
- Unsafe

Benjamin SB et al. Gastroenterology,1988 Sep;95(3):581-8
Meshkinpour H et al. Gastroenterology,1988 Sep;95(3):589-92
Kramer FM et al. Arch Int Med,1989 Feb;

Tarpon Springs Scientific Conference - 1987

- Scientific conference held with 75 international experts from the fields of gastroenterology, surgery, obesity, nutrition and behavior medicine to develop a general consensus on this technology/treatment option
- Conference Conclusions with respect to a Gastric Volume - Displacing Weight Loss Device:
  - Be effective at promoting weight loss
  - Be filled with liquid (not air)
  - Be capable of adjustment to various sizes
  - Have smooth surface and low potential for causing ulcers and obstructions
  - Contain a radiopaque marker that allows proper follow-up of the device if it deflates
  - Be constructed of durable materials that DOES NOT LEAK

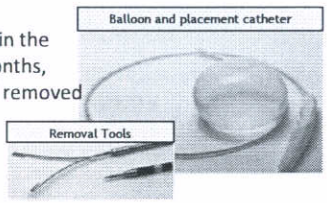
BioEnterics Intragastric Balloon System

- 1980's developed by Dr. Fred Gau and IDC
  - Intended to be part of a comprehensive program:
    - medical evaluation, behavior modification therapy, psychological test, nutritional counseling and dietary instruction
- 1991: first European clinical trial completed
- 1991 to present: the Balloon is sold to limited centers in Europe , Australia, South America and certain countries in Asia

BioEnterics Intragastric Balloon

The Intragastric Balloon is:

- a spherical silicone balloon placed within the stomach
- filled, under endoscopic guidance, with up to 700 ml of normal saline
- designed to remain within the stomach for up to six months, and is then deflated and removed under endoscopic vision



Bioenteric Intragastric Balloon Package Insert

Old and Current Devices

Comparison

	Garren Edwards	Heliosphere	Intragastric Balloon
Shape	Cylinder with sharp edges	Sphere	Sphere
Fill	Air	Air - as balloon is overfilled, it become more rigid and pressurized	Liquid - remains flexible throughout placement
Volume	220cc	650-1000cc	400-700cc
Material	Polyurthane	Polymer covered with silicone envelope	Silicone
Radiopaque	No		Yes
Duration	3 mths	6 mths	6 mths
Ulcer	Yes		rare
Occlusion	13-20%		0.5%

BioEnterics Intragastric Balloon

- The true mechanisms are inconclusive
- Hypothesis for weight loss include:
  - Delayed gastric emptying
  - Mechanical volume reduction resulting in a reduction in the capacity to store food
  - Hormonal changes which may lead to appetite suppression and satiety
  - Neuronal changes leading to the feeling of satiety

Hashiba, Gastrointest Endoscopy Clin N Am 17 (2007)545-557

BioEnterics Intragastric Balloon

Indications

In patients:

- ☐ Who failed to achieve and maintain weight loss with a supervised weight control program
  - ☐ In patients (BMI 30-39) who have significant health risks related to their weight
- ☐ In patients (BMI 40 or BMI 35 with comorbidities) who are not candidates for obesity surgery
- ☐ Pre-surgical temporary use in patients (BMI 40 and above or a BMI of 35 with comorbidities) prior to obesity or other surgery, in order to reduce surgical risk

Bioenteric Intragastric Balloon Package Insert

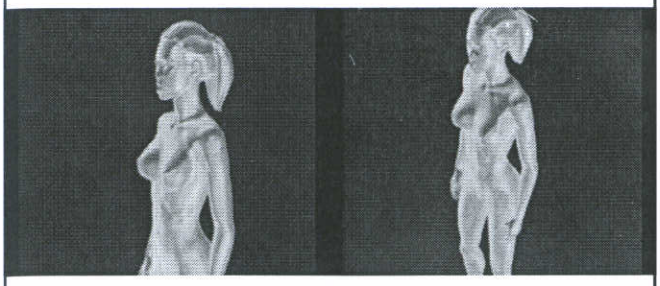
BioEnterics Intragastric Balloon

ContraIndications

- Use of the BIB System is contraindicated for weight loss in patients with a BMI less than 30, unless accompanied by comorbidities associated with obesity that would be expected to improve with weight loss
- Contraindications include:
  - Patients with previous gastrointestinal surgery
  - Any inflammatory disease of the gastrointestinal tract
  - Potential upper gastrointestinal bleeding conditions
  - A large hiatal hernia
  - A structural abnormality in the esophagus or pharynx
  - Any other medical condition which would not permit elective endoscopy
  - Major prior or present psychological disorder
  - Alcoholism or drug addiction.
  - Patients unwilling to participate in an established medically-supervised diet and behavior modification program, with routine medical follow-up
  - Patients receiving aspirin, anti-inflammatory agents, anticoagulants or other gastric irritants, not under medical supervision
  - Patients who are known to be pregnant or breast-feeding

Bioenteric Intragastric Balloon Package Insert

Intragastric Balloon



ITALIAN EXPERIENCE WITH THE INTRAGASTRIC BALLOON

18 Center s May 2000 – July 2007

Patients Comorbidities: 3824

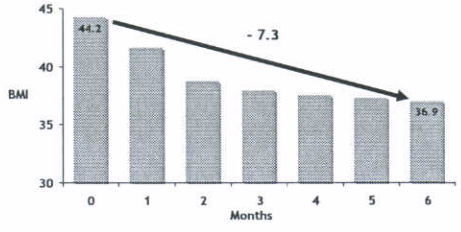
Diabetes	Night apnea
Hipertension	GERD
Arthrosis	Phlebitis
Dislipidemia	Amenorrea
Resp. Disf.	Others

Single Comorbidities	Multiple Comorbidities
63.1%	36.9%

Italian experience (G.I.L.B)

Study Results

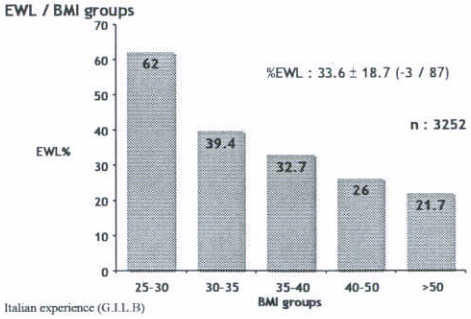
Results (n = 3824)
6 months BMI: 36.9±6.4 (range:27-50 Kg/m²)



Italian experience (G.I.L.B)

Study Results

EWL / BMI groups



Italian experience (G.I.L.B)

Study Results

Failures
As defined by weight loss < 10 % of initial weight

12.4 %
pts. 474/ 3824
sweet eaters, bulimic, grazing pts.

Italian experience (G.I.L.B)

Study Results

Weight Loss Effects on Comorbidities

n = 2179 / 3824

Cleared up comorbidities: (stopped drug treatment)	980	(44.3%)
Improved comorbidities: (reduction of drug treatment)	1002	(45.8%)
Unchanged:	197	(9.9%)

Italian experience (G.I.L.B)

Study Results

Minor Complications

73 / 3824 (1.9%)

Early removal (no compliance)	13	(0.33%)
Early rupture	20	(0.52%)
Esophaghitis	40	(1.04%)

Italian experience (G.I.L.B)

Study Results

Major Complications

37 / 3824 (0.96%)

Gastric Occlusion	19	(0.49%)
Gastric Perforation	5	(0.13%)*
Gastric Ulcer	10	(0.26%)
Bowel Occlusion (Prior Gynecological surgery)	3	(0.07%)

Italian experience (G.I.L.B)

BIOENTERICS INTRAGASTRIC BALLOON (BIB®):
A SHORT-TERM, DOUBLE-BLIND, RANDOMISED, CONTROLLED, CROSSOVER STUDY ON WEIGHT REDUCTION
IN MORBIDLY OBESE PATIENTS.

Genco A, Cipriano M, Bacci V, Cuzzolaro M, Materia A, Raparelli L, Docimo C, Lorenzo M, Basso N.

International Journal of Obesity (2006) 30, 129-133