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何鴻燊博士醫療拓展基金會 醫學研討會

Update on Metabolic & Bariatric Surgery 代謝與減重手術的最新發展

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The Chinese University of Hong Kong (CUHK)

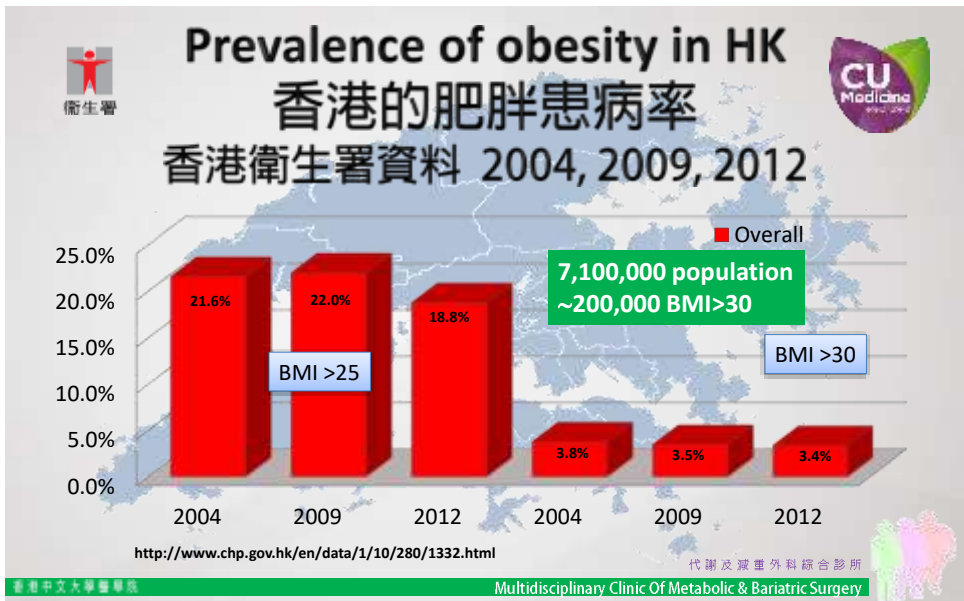


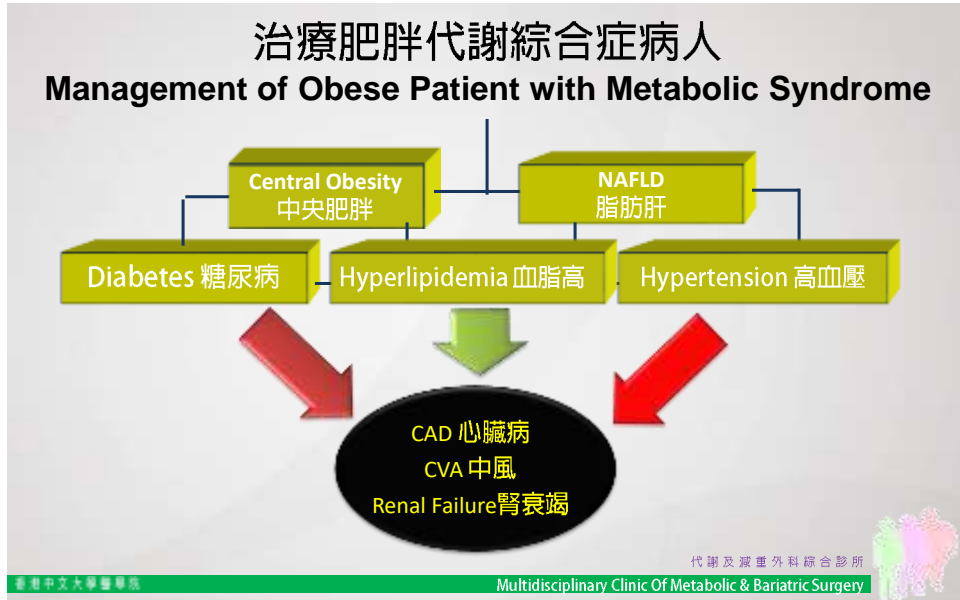
Consultant Surgeon,
Upper GI & Metabolic Surgery Division PWH

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治療肥胖代謝綜合症病人

Management of Obese Patient with Metabolic Syndrome

- Depression 抑鬱
- Non-Alcoholic Liver Disease
非酒精性肝病 (脂肪肝)
- Gall bladder disease 膽囊疾病
- Gastroesophageal reflux
胃酸反流
- Erectile dysfunction
勃起功能障礙
- Osteoarthritis 骨性關節炎
- Pulmonary embolism,
Deep vein thrombosis
肺動脈栓塞, 深靜脈血栓
- Venous insufficiency
靜脈血液供血不足
- Hyperuricaemia & gout
高尿酸血症及痛風

- Diabetes 糖尿病
- Hypertension 高血壓
- Stroke 中風
- Heart disease 心臟病
- Cardiovascular risk factors
心血管風險要素
- Cancer (Colon, Breast, Uterus...)
癌症 (大腸癌, 乳腺癌, 子宮癌...)
- Obstructive Sleep Apnea
睡眠窒息
- Polycystic Ovarian Syndrome
卵巢多囊症
- Infertility 不育

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治療肥胖代謝綜合症病人 Management of Obese Patient with Metabolic Syndrome

Control Comorbidity
控制肥胖疾病



Control Body Weight
控制體重

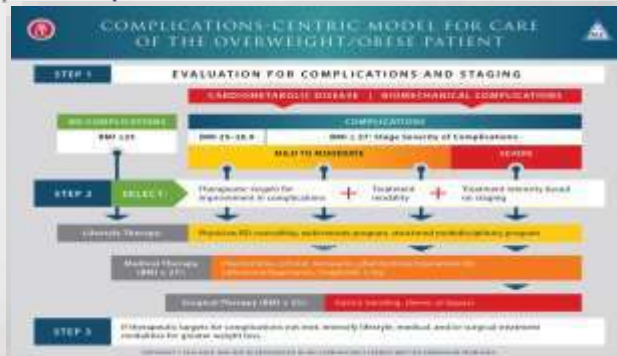
Psychosocial burden
控制心理和社交負擔

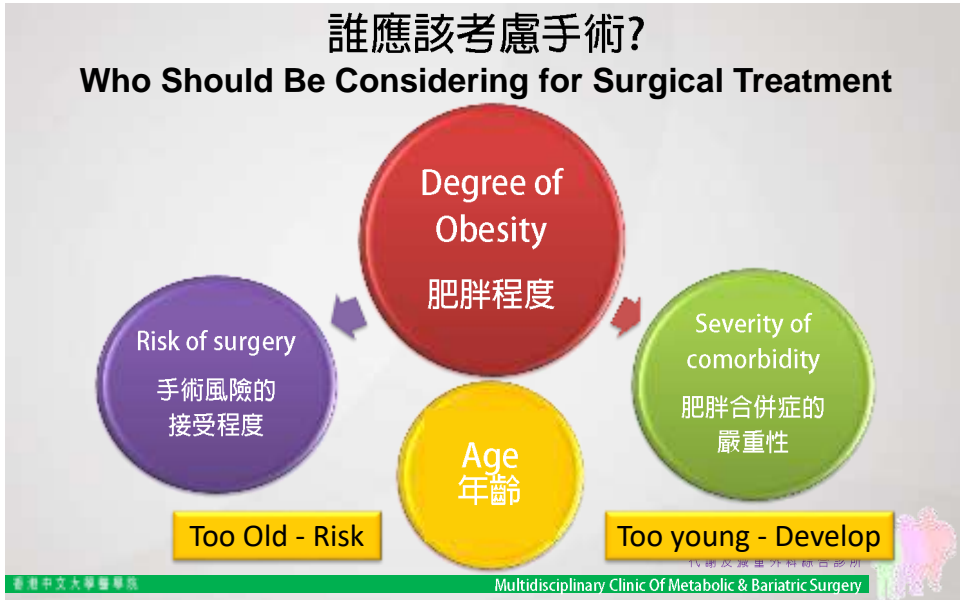


治療肥胖代謝綜合症病人 Management of Obese Patient with Metabolic Syndrome



June 18, 2013 – American Medical Association officially recognizes Obesity as a Disease
2013 美國醫學會正式承認肥胖是一種疾病





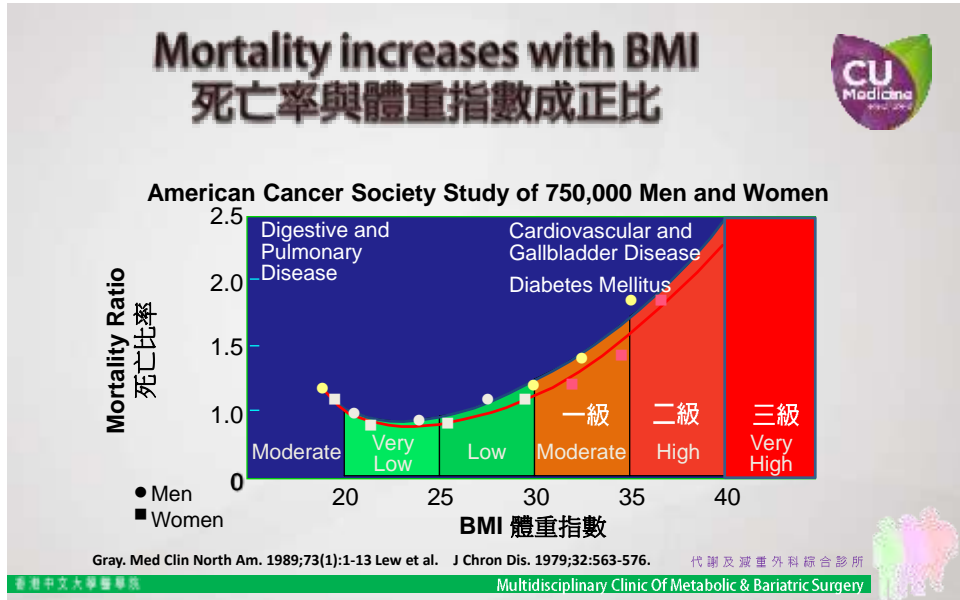
誰應該考慮手術?

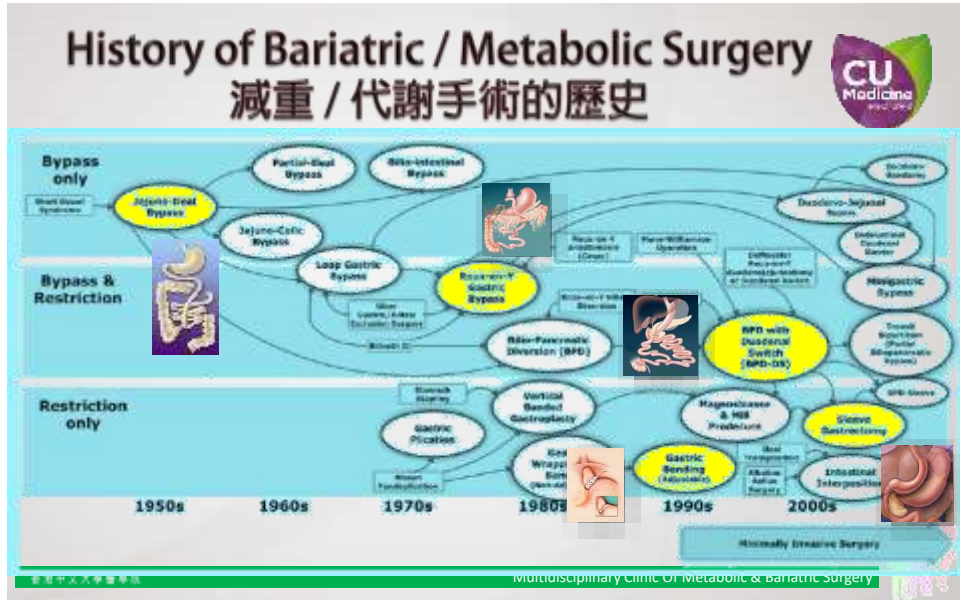
Who Should Be Considering for Surgical Treatment

Degree of Obesity
肥胖程度

| WHO definition Obesity | 西方 (Caucasian) BMI (kg/m ²) 體重指數 | Risk of co-morbidities 肥胖相關的發病風險 |
|------------------------|--|----------------------------------|
| Normal weight 正常體重 | 18 – 24.9 | Average 一般 |
| Overweight 過重 | >25 | |
| At risk 危險期 | 25 - 30 | Increased 增加 |
| Obese I 一級肥胖 | 30 - 35 | Moderate 中度增加 |
| Obese II 二級肥胖 | 35 - 40 | Severe 嚴重增加 |
| Obese III 三級肥胖 | >40 | Very Severe 非常嚴重增加 |

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What is Bariatric Surgery ? 減重手術是什麼？

- Surgery to loss weight
(Weight Reduction / Bariatric Surgery)

≠ Fat removal surgery
≠ 脂肪切除手術

“Behavioral Surgery”
“行為手術”

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What is Bariatric Surgery ? 減重手術是什麼？



- Surgery to loss weight
(Weight Reduction / Bariatric Surgery)

“Behavioral Surgery”

- eating less
- eating slow
- eating healthy

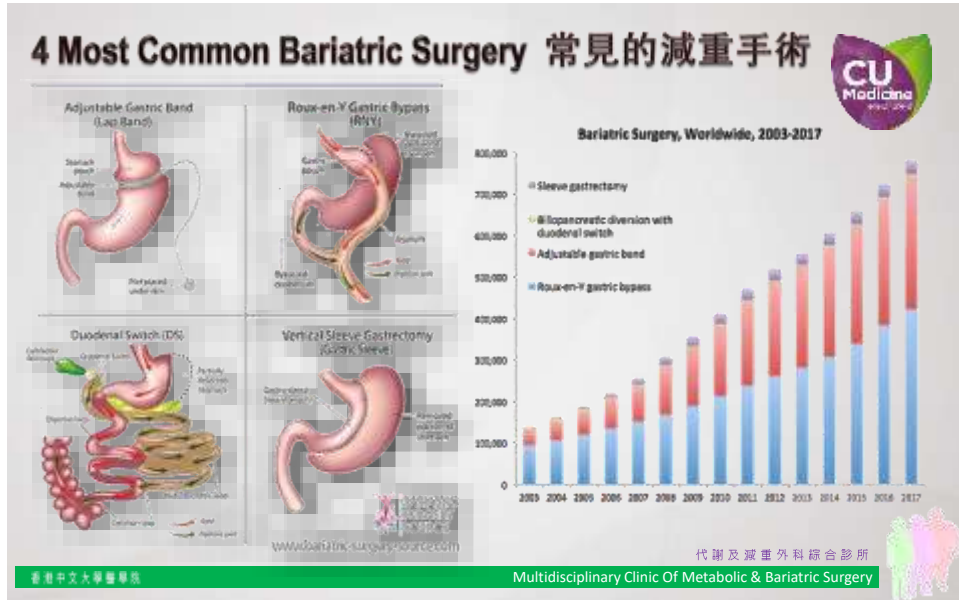


What is Bariatric Surgery ? 減重手術是什麼？



- Surgery to loss weight
 - Improve comorbidity
改善肥胖相關的合併症
 - Improve survival
提高生存率
 - Improve quality of life
提高生活質素





Background of Bariatric / Metabolic Surgery 減重/代謝手術的背景

- **Bariatric surgery is considered as an effective treatment for morbid obesity over >50 years in Caucasian countries** 在過去50年，減肥手術被在西方國家視為一種有效的治療病態肥胖症方法
- **Bariatric / metabolic surgery is a high-risk surgery requires expertise and a comprehensive team management** 是一種高風險的手術，需要有專業知識和全面的團隊管理
- **Bariatric / Metabolic surgery development in Asia / HK is slow** 減重/代謝手術在亞洲/香港的發展依舊緩慢

Bariatric Surgery in HK

減重手術在香港

Before year 2000 年前

Unheard
聞所未聞

FIRST BARIATRIC SURGERY IN HK (HA) 香港首個減重手術 (醫管局)



Research Project CUHK 中文大學研究項目 (2002)





PWH

Introduces various bariatric treatments to Hong Kong
引入各種減肥手術

| | | | |
|--|---|--|---|
|  胃帶減重手術 Gastric banding 2002 |  胃六式球 Intragastric balloon 2004 |  胃腸繞道手術 Gastric bypass 2005 |  胃腸縮窄 Sleeve gastrectomy 2006 |
|--|---|--|---|

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2002 FIRST BARIATRIC SURGERY CLINIC IN HK 香港第一所減重手術診所 COMBINED OBESITY CLINIC 綜合體重控制門診



- Clinical & Research 臨床及學術研究
- Patient centered - Multidisciplinary Approach 多學科
- Medical Perspective (Not Cosmetic) 醫療性質 (非美容)
- No extra-funding 沒有額外資源





Prince of Wales Hospital, CUHK
威爾斯親王醫院 - 香港中文大學



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MDT for Patients with Obese Metabolic Syndrome 肥胖代謝綜合症外科治療團隊





Bariatric Surgeon



Case Manager / research



Dietitian
Clin. Psychologist



**Operation Theater team/
anesthetist**



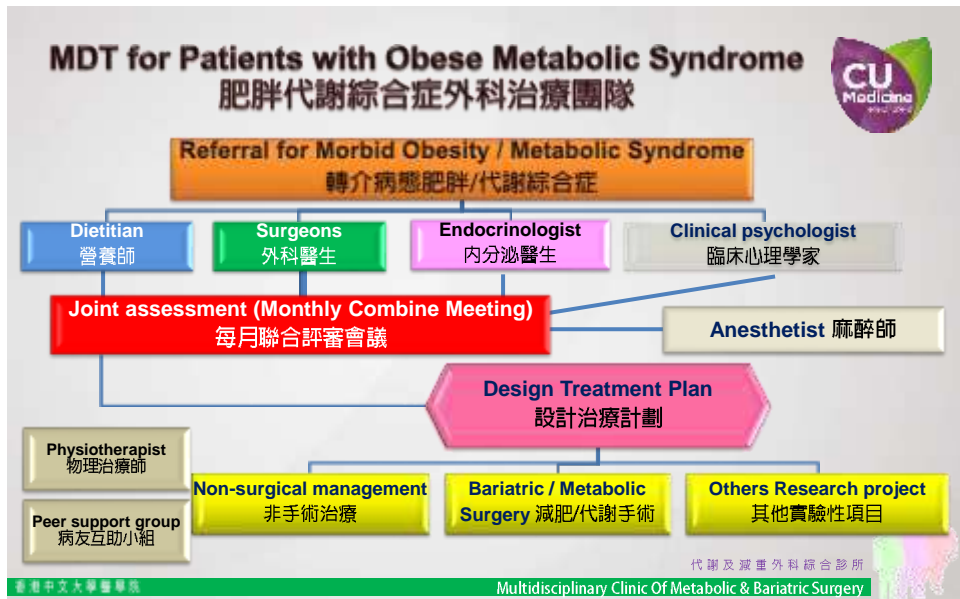
Physiotherapist



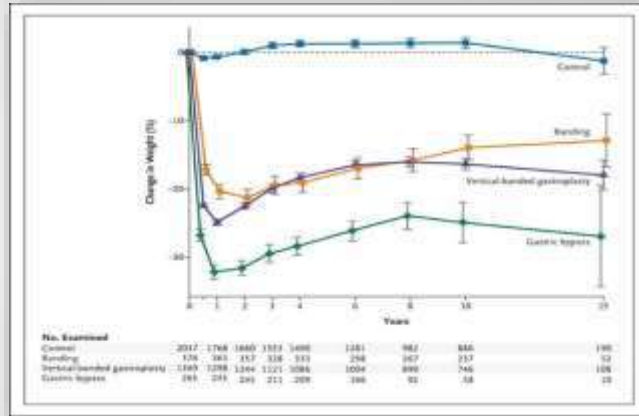
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Swedish Obesity Subjects (SOS) Interventional Study - 15 years follow up



LAGB ↓14%

VBG ↓16%

RYGB ↓25%

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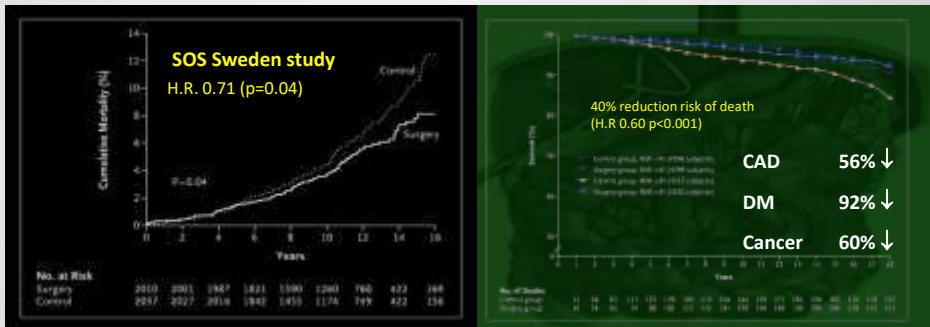
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Sjostrom LL et al. N Eng J Med 2007

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Improve survival Bariatric Surgery



Sjostrom LL et al. N Eng J Med 2007

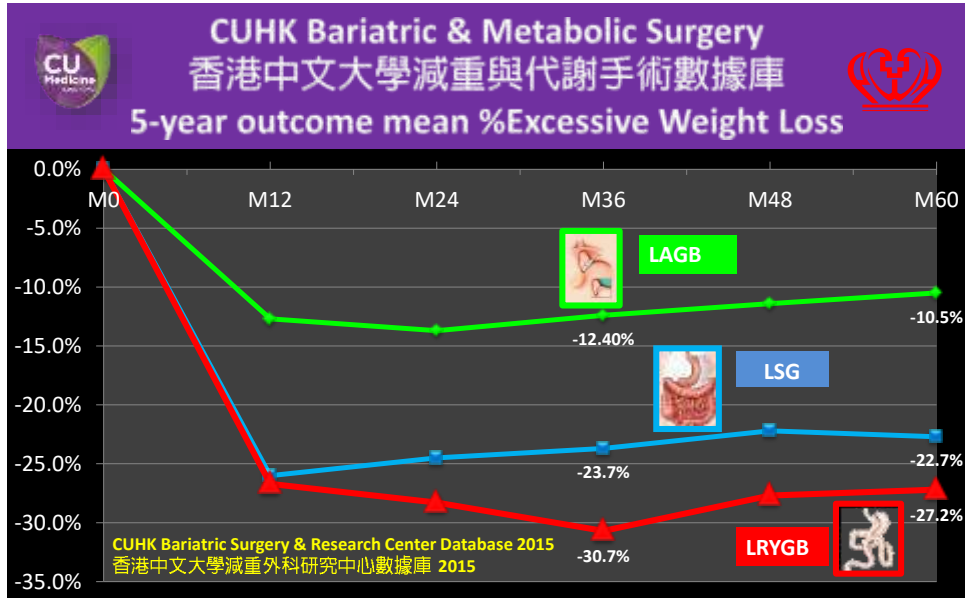
Adams TD et al. N Eng J Med 2007

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Adjustable gastric banding 可調節式束胃帶手術

CU
Medicine

缺點 disadvantage

- Slow weight loss 減重慢較少,
- Require adjust band regularly 須覆診調節束帶。

併發症

- 嚴重的併發症是不常見
- 例如:
 - 束胃帶發炎 band infection
 - 調節束胃帶的注水孔漏 leakage
 - 束胃帶滑脫 band slippage
 - 束胃帶侵蝕胃部 band erosion

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Sleeve Gastrectomy 袖狀縮胃手術

缺點 disadvantage

- Irreversible 不可還原
- GERD 胃酸倒流

手術風險 risk

- Staple-line leak 吻合處滲漏
- Bleeding 吻合處流血
- Gastric tube stricture 胃管收窄

胃縮小手術



Laparoscopic Assoc
Of San Francisco

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Gastric Bypass 胃繞道手術

缺點 disadvantage

- Irreversible 不可還原
- Affect micronutrient absorption 影響營養吸收

手術風險 risk

- Anastomosis leak 接合處的滲漏及出血
- Anastomosis stenosis / ulcer 吻合處收窄
- Intestinal obstruction / herniation 胃腸道阻塞

長期後遺症

- Iron / vitamin / Calcium / micronutrient deficiency 鐵劑不足, 維他命, 鈣質及微量營養素有缺乏
- Dumping syndrome / diarrhoea 傾倒症候群、肚瀉



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Surgical Outcomes Monitoring & Improvement Program (SOMIP) Report

5 HA Hospitals (PWH, QMH, UCH, PYNEH, TMH)

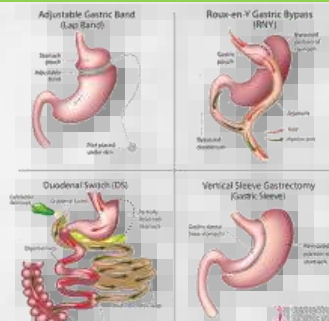
| Year | 09-10 | 10-11 | 11-12 | 12-13 | 13-14 | 14-15 |
|--------------------------|---------------|---------------|---------------|----------------|---------------|----------------|
| Number of case | 49 | 55 | 79 | 61 | 53 | 84 |
| BMI (kg/m ²) | 37.3 | 37.9 | 39.7 | 39.9 | 37.8 | 40.1 |
| Mortality | 2% (0-9.1%) | 0% | 0% | 0% | 0% | 0% |
| Complication | 14.3% (0-25%) | 14.5% (0-50%) | 6.3% (0-100%) | 3.3% (0-33.3%) | 7.5% (0-100%) | 8.3% (0-15.4%) |
| Hospital Stay (days) | 5.0 (4-9) | 5.0 (4-7) | 5.0 (4-28) | 4.0 (4-7) | 5.0 (4-9) | 5.0 (4-7.5) |

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Bariatric Surgery



Why Metabolic Surgery ?

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What is Metabolic Surgery (80'-90')?



The concept of metabolic surgery was defined by Buchwald and Varco in 1978 in their book "Metabolic Surgery" as the

"Operative manipulation of a normal organ or organ system to achieve a biological result for a potential health gain"



H. Buchwald and R. L. Varco, Eds., *Metabolic Surgery*, Grune and Stratton, New York, NY, USA, 1978.



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What is Metabolic Surgery (80'-90')?



"Operative manipulation of a normal organ or organ system to achieve a biological result for a potential health gain"



Vagotomy / Antrectomy for Peptic ulcer disease (before 1990)

Program on the Surgical Control of the Hyperlipidemias (POSCH) - Partial Ileal Bypass (1975 – 1983)



Buchwald H et al. N Eng J Med 1990

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Metabolic Surgery (2017)



Surgical Procedure to treat Metabolic Syndrome

- **Visceral (Central) Obesity**
- **Dysglycemia / Type 2 DM**
- **Dyslipidemia / Hypercholesterolemia**
- **High blood pressure / Hypertension**



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Weight and Type 2 Diabetes after Bariatric Surgery: Systematic Review and Meta-analysis

BMI 48kg/m²

THE AMERICAN JOURNAL of MEDICINE

Meta-analysis (2009)

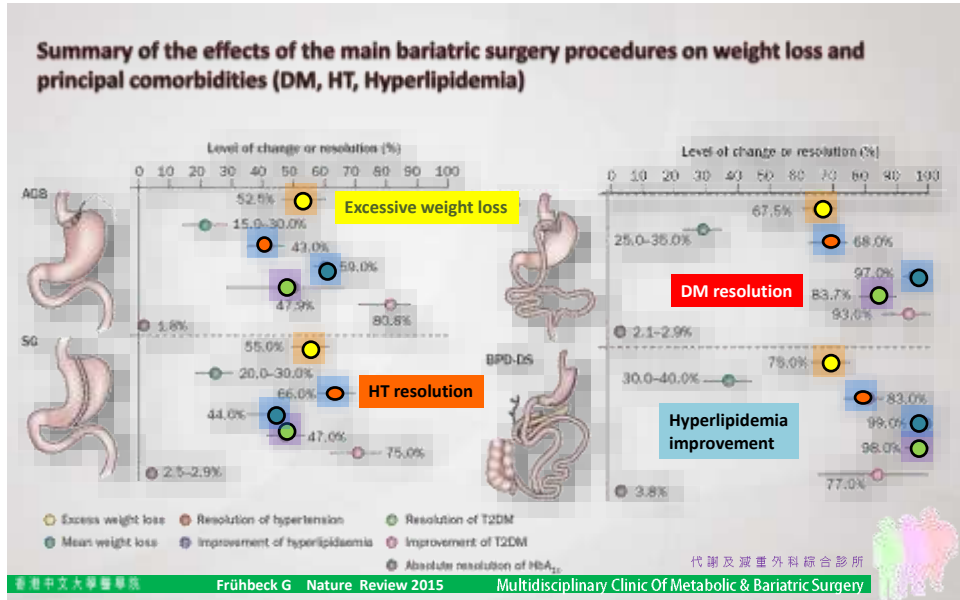
- 621 studies with 888 treatment arms and 135,246 patients; 103 treatment arms with 3188 patients reported on resolution of diabetes

| Definitions | |
|---------------------|---|
| Partial remission | Hyperglycemia below diagnostic thresholds for diabetes At least 1 year's duration No active pharmacologic therapy or ongoing procedures |
| Complete remission | Normal glycermic measures At least 1 year's duration No active pharmacologic therapy or ongoing procedures |
| Prolonged remission | Complete remission of at least 5 years' duration |


| Gastric banding | Gastroplasty | Gastric bypass | BPD / DS |
|-----------------|--------------|----------------|----------|
| 56% (Slow) | 70% | 80% | 95% |

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Buchwald II et al. Am J Med 2009
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Bariatric Vs Metabolic Surgery



Bariatric Surgery

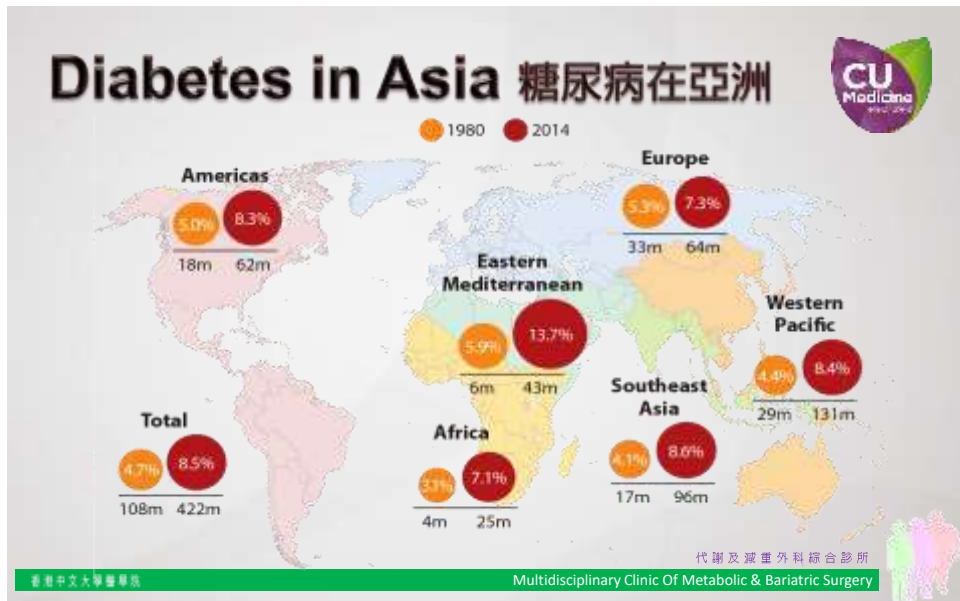
- Bring down BMI
- Reduce body weight
- May associate with improve DM



Metabolic Surgery

- Bring down HbA1c
- Reduce medication use
- May associate with weight loss

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Countries with the highest estimates of number of cases of diabetes in 2015 and 2040



| Rank | Country/territory | 2015 Number of people with diabetes |
|------|--------------------------|---|
| 1 | China | 109.6 million (99.6-133.4) |
| 2 | India | 69.2 million (56.2-84.9) |
| 3 | United States of America | 29.3 million (27.6-30.9) |
| 4 | Brazil | 14.3 million (12.9-15.8) |
| 5 | Russian Federation | 12.1 million (6.2-17.0) |
| 6 | Mexico | 11.5 million (6.2-13.7) |
| 7 | Indonesia | 10.0 million (8.7-10.9) |
| 8 | Egypt | 7.8 million (3.8-9.0) |
| 9 | Japan | 7.2 million (6.1-9.6) |
| 10 | Bangladesh | 7.1 million (5.3-12.0) |

| Rank | Country/territory | 2040 Number of people with diabetes |
|------|--------------------------|---|
| 1 | China | 150.7 million (138.0-179.4) |
| 2 | India | 123.5 million (99.1-150.3) |
| 3 | United States of America | 35.1 million (33.0-37.2) |
| 4 | Brazil | 23.3 million (21.0-25.9) |
| 5 | Mexico | 20.6 million (11.4-24.7) |
| 6 | Indonesia | 16.2 million (14.3-17.7) |
| 7 | Egypt | 15.1 million (7.3-17.3) |
| 8 | Pakistan | 14.4 million (10.6-20.4) |
| 9 | Bangladesh | 13.6 million (10.7-24.6) |
| 10 | Russian Federation | 12.4 million (6.4-17.1) |

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IDF DM World Atlas 2015

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The Y - Y Paradox



Higher fat percentage , More central obesity

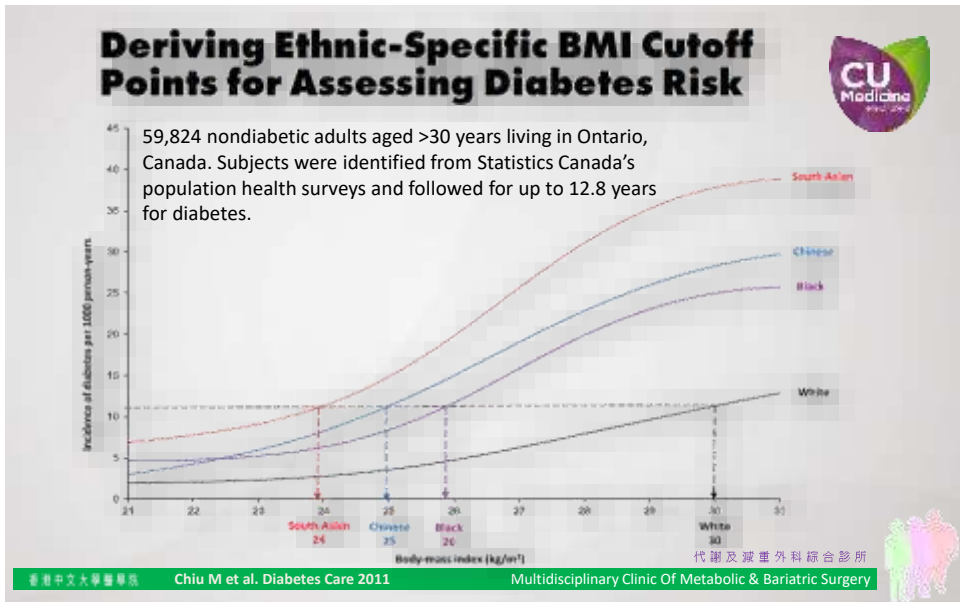
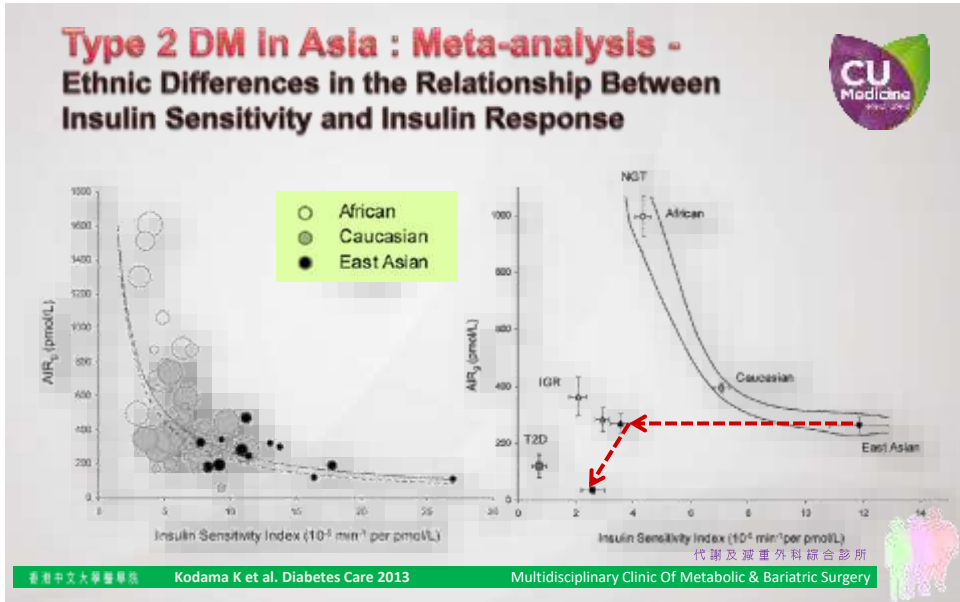
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Yudkin and Yanik et al Lancet 2004;

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WHO criteria for obesity In Asia



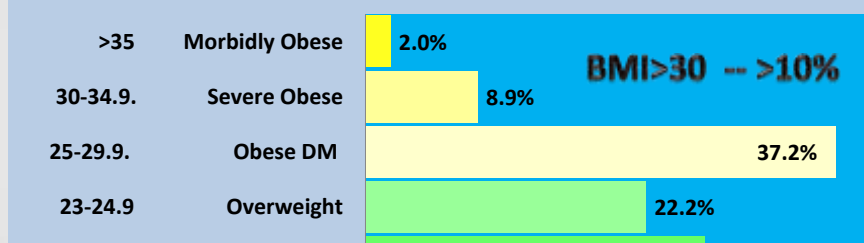
| | 西方 BMI (kg/m ²) 體重指數 | 亞洲 BMI (kg/m ²) 體重指數 | Risk of co-morbidities 肥胖相關的發病風險 | |
|-----------------------|--|--|-------------------------------------|----------------------------------|
| | | | Waist circumference 腰圍 | |
| | | | < 90cm (M男) < 80cm (F女) | ≥ 90cm (M男) ≥ 80cm (F女) |
| Normal weight 正常體重 | 18 – 24.9 | 18.2 - 22.9 | Average 一般 | Increased 增加 |
| Overweight 過重 | 25 - 30 | 23.0 - 24.9 | Increased 增加 | Moderate 中度增加 |
| | | 25.0 - 27.4 | | |
| Obese I 肥胖 | 30 - 35 | 27.5 - 29.9 | Moderate 中度增加 | Severe 嚴重增加 |
| | | 30.0 - 32.4 | | |
| | | 32.5 - 34.9 | | |
| Obese II 嚴重肥胖 | 35 - 40 | 35.0 - 37.4 | Severe 嚴重增加 | Very Severe 非常嚴重增加 (病態型肥胖) |
| | | 37.5 - 39.9 | | |
| Obese III 超級肥胖 | >40 | >40 | Very Severe 非常嚴重增加 (病態型肥胖) | Very Severe 非常嚴重增加 (病態型肥胖) |

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Diabetes Mellitus Registry in Prince of Wales Hospital

9556 Type 2 Adult Diabetic Patients Age ranged from 18 — 93 years old

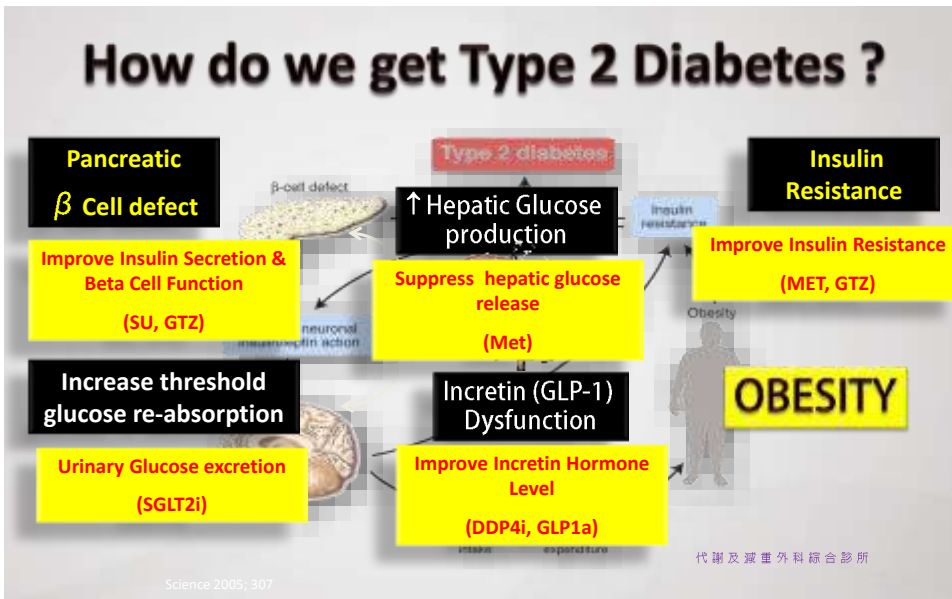
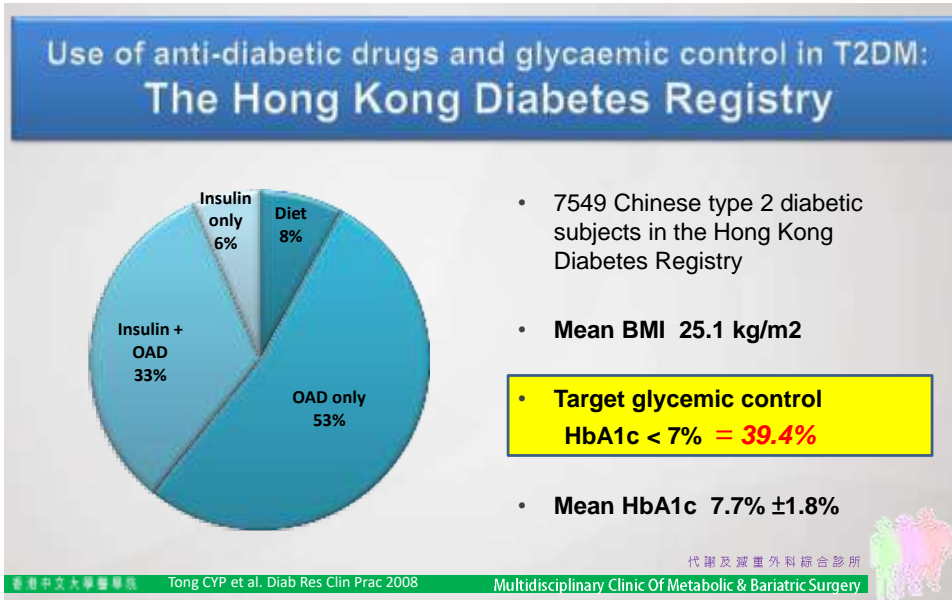


~ 50% diabetes patients obesity (BMI>25)

~70% diabetes patients BMI >23

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Management of Obese T2DM



Vs

What is the current Status?



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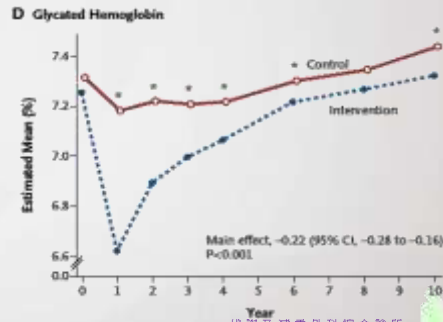
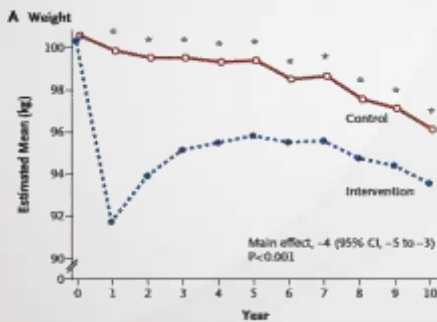
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Cardiovascular Effects of Intensive Lifestyle Intervention in Type 2 Diabetes



The Look AHEAD Research Group*

| Variable | Control Group (N=2575) | Intervention Group (N=2576) |
|---|------------------------|-----------------------------|
| Body-mass index ^{kg/m²} | 36.0±5.8 | 35.9±6.0 |



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Look AHEAD Group NEJM 2013

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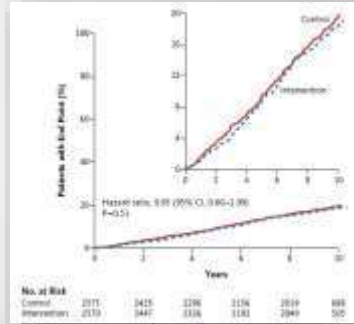
Cardiovascular Effects of Intensive Lifestyle Intervention in Type 2 Diabetes



The Look AHEAD Research Group*

| Variable | Control Group (N = 2575) | Intervention Group (N = 2570) |
|---|-----------------------------|----------------------------------|
| Body mass index ^{kg/m²} | 36.0 ± 5.8 | 35.9 ± 6.0 |

| Outcome | Patients with Event | Control Group | Intervention Group | Hazard Ratio [95% CI] | P Value |
|---|---------------------|---------------|------------------------------------|-----------------------|---------|
| | no. | no. | no. of events (rate/100 person-yr) | | |
| Primary outcomes | | | | | |
| Death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for angina | 421 | 418 (1.90) | 403 (1.83) | 0.95 (0.83-1.08) | 0.51 |
| Secondary outcomes | | | | | |
| Death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke | 550 | 283 (1.29) | 267 (1.17) | 0.93 (0.79-1.10) | 0.42 |
| Death from any cause, nonfatal myocardial infarction, or nonfatal stroke | 1025 | 528 (2.41) | 484 (2.21) | 0.93 (0.82-1.05) | 0.23 |
| Death from any cause, nonfatal myocardial infarction, nonfatal stroke, hospitalization for angina, CABG, PCI, hospitalization for heart failure, carotid endarterectomy, or peripheral vascular disease | 1377 | 508 (2.41) | 577 (2.67) | 0.94 (0.84-1.05) | 0.29 |

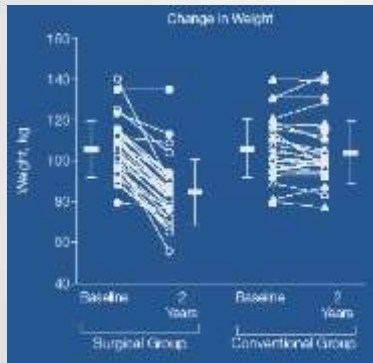


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Look AHEAD Group NEJM 2013

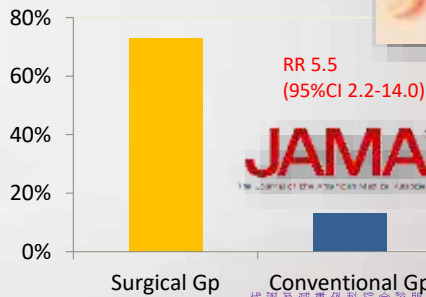
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Surgery Vs Best Medical Rx Gastric Banding for T2DM



BMI 30-40 ; DM < 2 years

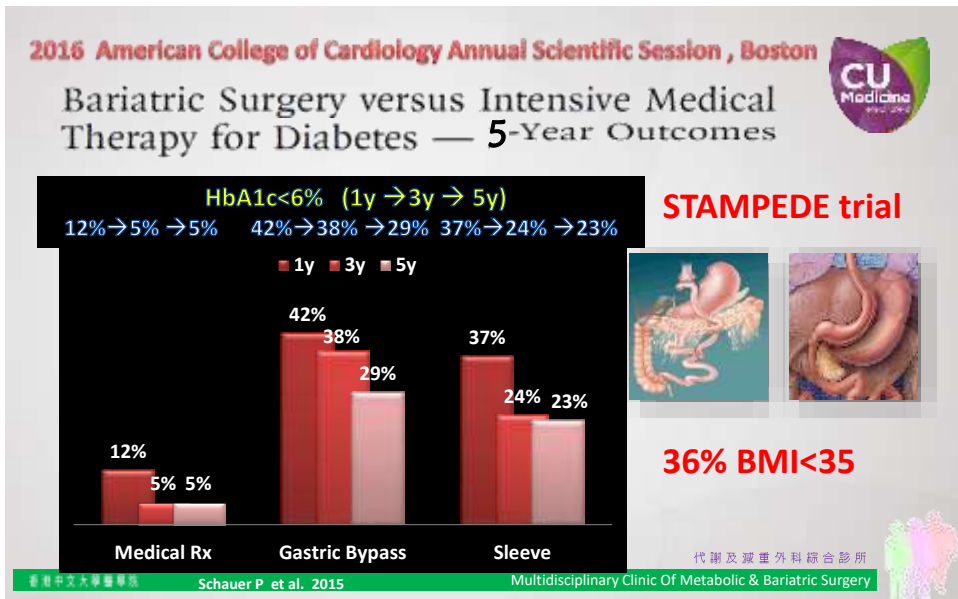
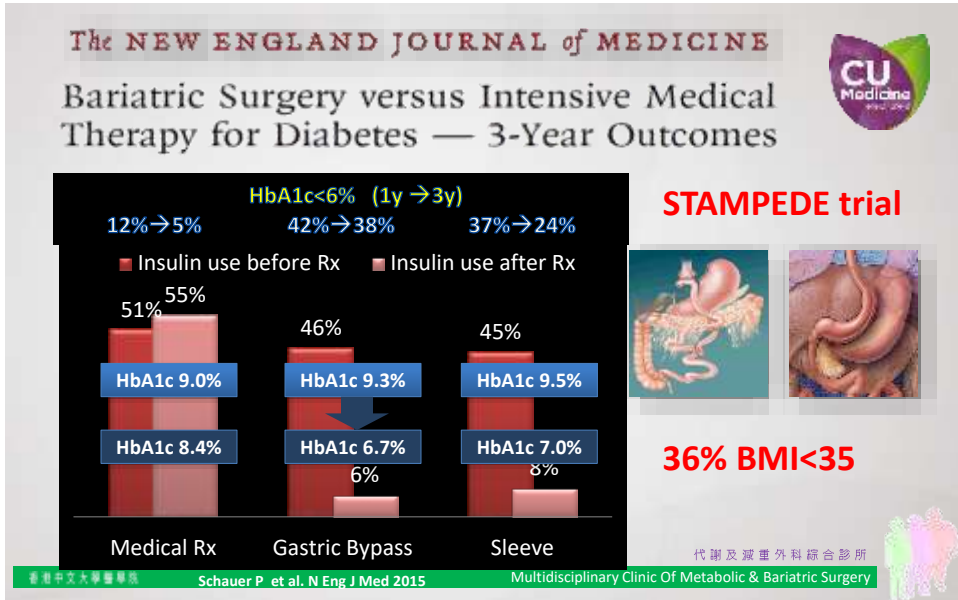
Remission



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Dixon JB et al. JAMA 2008

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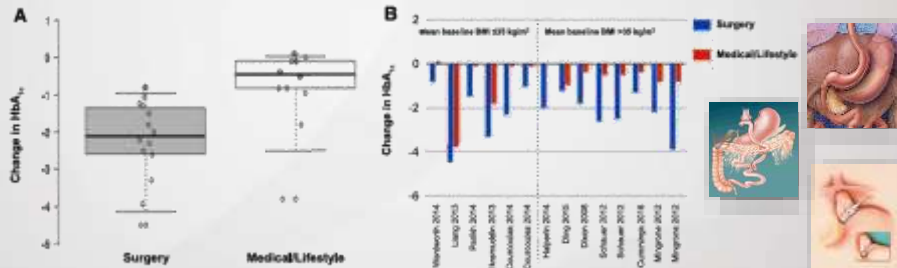


Evidence Supporting Surgical Treatment of T2D



Outcome >12m weight loss & DM Remission

- 14 RCT;FU 1-5y; N= Sx 624 Vs Med Rx 426
- Median HbA_{1c} ↓2.0% for Sx Vs ↓0.5% for conventional therapies (p<0.001)



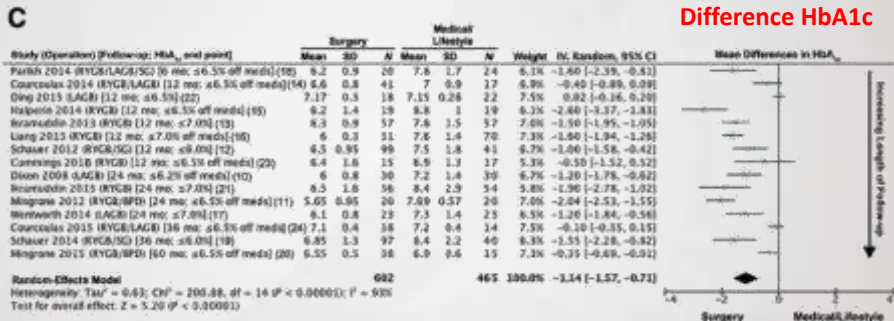
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Rubinos et al. Diabetes Care 2016

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Evidence Supporting Surgical Treatment of T2D



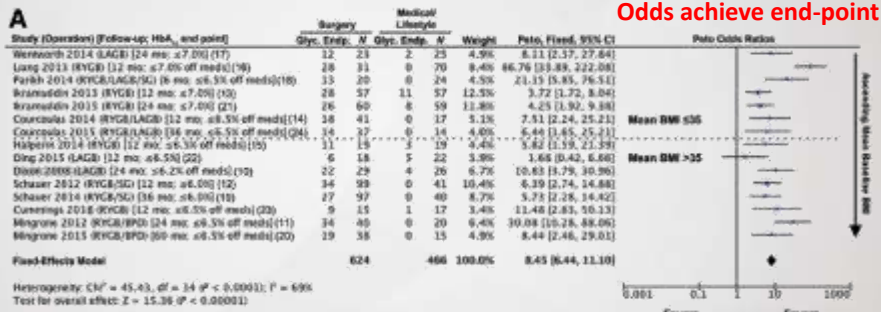
代謝及減重外科綜合診所

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Rubinos et al. Diabetes Care 2016

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Evidence Supporting Surgical Treatment of T2D



Conclusion Clinical Trials on Metabolic Surgery



Surgery provide better short-term DM control + metabolic risk factors than medical Rx in Obese pt

Medium & long-term trials show maintained benefit over medical Rx




What should we do next?



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Facts about Surgery for T2DM




We know it works

Present
We are trying to know WHY it works

Future
We try to apply what we did without surgery

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Facts about Surgery for T2DM

We know it works

HOW
to integrate surgery
into daily management
of T2DM

How?

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Why Surgery Works? Traditional concept

Weight-Loss dependent

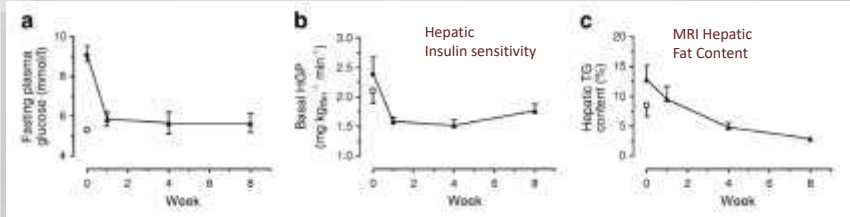
增加胰島素
敏感度
Decrease Insulin resistance

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Multidisciplinary Clinic Of Metabolic & Bariatric Surgery

Reversal of type 2 diabetes: normalisation of beta cell function in association with decreased pancreas and liver triacylglycerol



- 11 T2DM patients (mean BMI 33, DM duration 4y)
- 8 week calories restricted diet (600kcal/d)



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香港中文大學醫學院

Lim EL et al. Diabetologia 2011

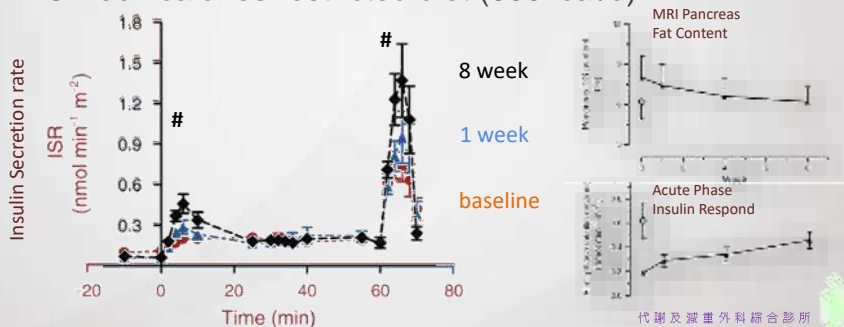
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Reversal of type 2 diabetes: normalisation of beta cell function in association with decreased pancreas and liver triacylglycerol



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Lim EL et al. Diabetologia 2011

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Gut Hormone Profiles Following Bariatric Surgery Favor an Anorectic State, Facilitate Weight Loss, and Improve Metabolic Parameters

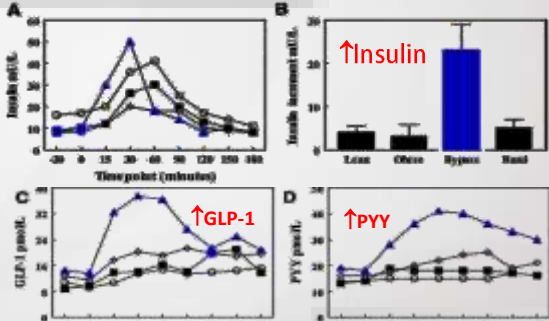


| Single-Meal Tests | Control Subjects | | Surgical Patients | | P |
|--|------------------|--------------|-------------------|-------------|-----------|
| | Lean | Obese | Bypass | Bandage | |
| N (Males) | 17 (33) | 17 (34) | 8 (16) | 8 (16) | |
| Age (yr) (mean (SD)) | 34.8 (9.90) | 37.8 (13.34) | 29.3 (10.0) | 40.2 (10.7) | .263 |
| Baseline (BMI) (kg/m ²) (mean (SD)) | 23.8 (3.13) | 47.1 (13.76) | 49.8 (10.8) | 45.1 (8.78) | P < 0.05 |
| Minimally postoperative (mean (SD)) | | | 33.2 (8.5) | 37.2 (10.3) | P = 0.009 |
| Postoperative (BMI) (kg/m ²) (mean (SD)) | | | 35.8 (7.38) | 36.3 (8.13) | .928 |

RYGB = 6
LAGB = 6

Mean 11m /19m
post Rx

Same Wt loss



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Le Roux C. et al Ann Surg 2006
Multidisciplinary Clinic Of Metabolic & Bariatric Surgery

Why Surgery Works?

Traditional concept

Weight-Loss
dependent

改善血糖

↑ glycemic control

Weight-loss
independent

增加胰島素
敏感度

Decrease Insulin resistance

改變胰島素
製造及分泌功能

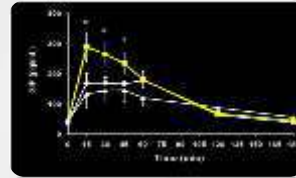
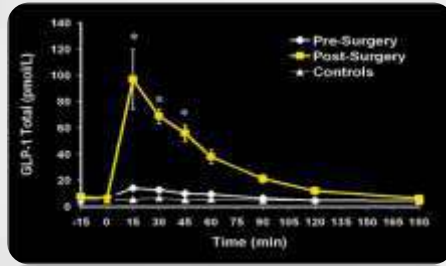
Alter insulin
Production & release

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Metabolic & Bariatric Surgery

Incretin Hormone



Effect of GLP-1 & GIP 1 month after gastric bypass



Incretin levels and effect are markedly enhanced 1 month after Roux-en-Y gastric bypass surgery in obese patients with type 2 diabetes.

代謝及減重外科綜合診所

香港中文大學醫學院

Laferrere B et al. Diabetes Care 2007

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OBES SURG (2012) 22:740–748
DOI 10.1007/s11695-012-0622-3

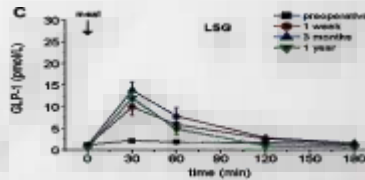
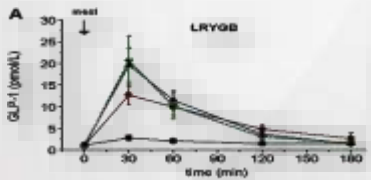
CLINICAL RESEARCH



Metabolic and Hormonal Changes After Laparoscopic Roux-en-Y Gastric Bypass and Sleeve Gastrectomy: a Randomized, Prospective Trial

GLP-1 ↑↑

GLP-1 ↑



RY Gastric Bypass

Sleeve Gastrectomy

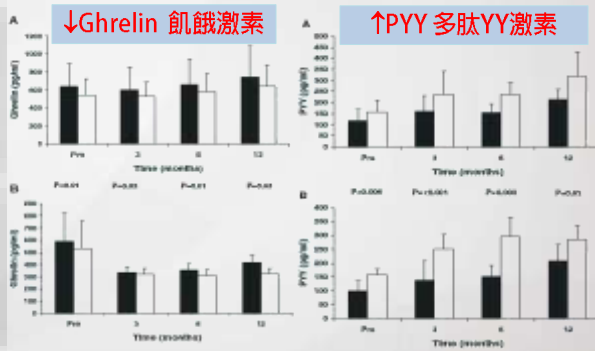
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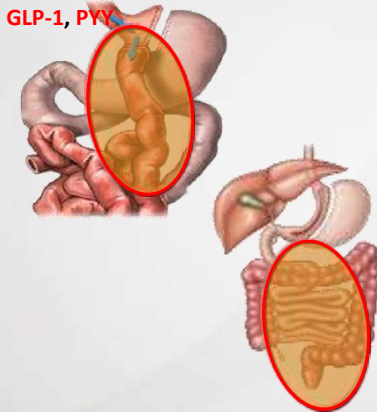
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Weight loss, appetite suppression, and changes in fasting and postprandial ghrelin and peptide-YY levels after Roux en-Y gastric bypass and sleeve gastrectomy: a prospective, double blind study.



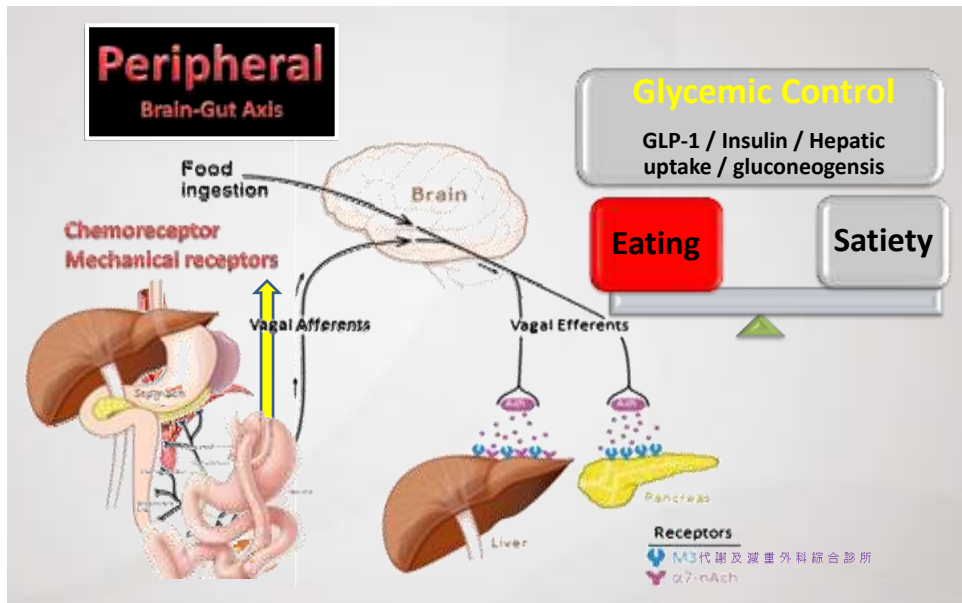
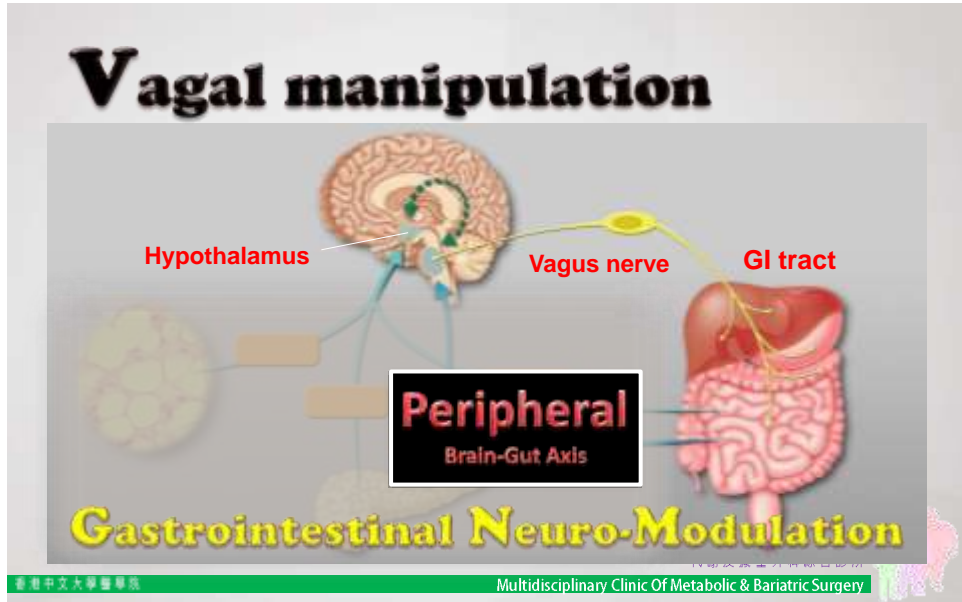
The Entero-insular Axis



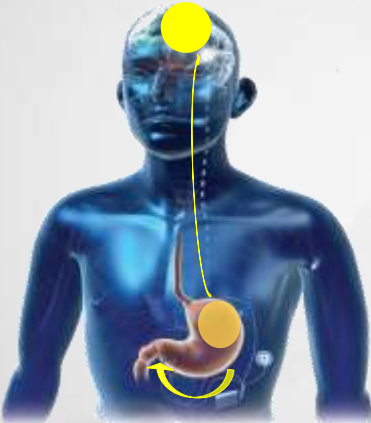
The Hindgut Stimulation Theory


The rapid & early delivery of undigested nutrients to the distal bowel up-regulates the production of L-cell derivatives like **GLP-1, PYY**

GUT HORMONE





Neuro-modulation Gastric Stimulation





**Tantalus – DIAMOND™
System**





Meal Initiated Stimulation

- OFF in between meal
- Synchronize AP with slow-wave
- Increase antral contraction



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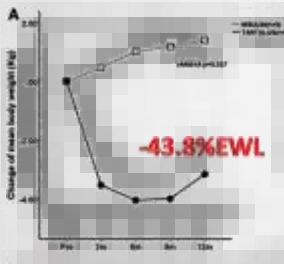
Metabolic & Bariatric Surgery



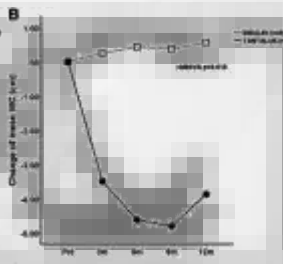
ORIGINAL ARTICLE

A Pilot Study to Compare Meal-Triggered Gastric Electrical Stimulation and Insulin Treatment in Chinese Obese Type 2 Diabetes

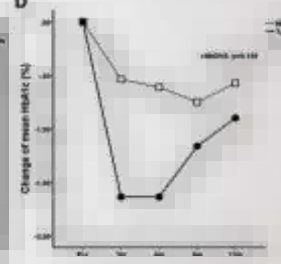





Body weight



**Waist Circumference
12 months outcome**




HbA1c

香港中文大學醫學院

Wong SK et al. Diab Tech Thera 2015

Metabolic & Bariatric Surgery



Vagotomy Dissociates Short- and Long-Term Controls of Circulating Ghrelin

DIANA L. WILLIAMS, HARVEY J. GRILL, DAVID E. CUMMINGS, AND JOEL M. RAPLAN

| Hours of deprivation | Sham-operated (ng/ml) | Vagotomized (ng/ml) |
|----------------------|-----------------------|---------------------|
| 0 | ~0.7 | ~0.7 |
| 24 | ~1.1* | ~0.8 |
| 48 | ~1.3* | ~0.9 |
| Re-fed | ~0.8 | ~0.8 |

代謝及減重外科綜合診所

香港中文大學醫學院 Williams et al. Endocrinology, December 2003 Multidisciplinary Clinic Of Metabolic & Bariatric Surgery

Neuro-modulation Vagal Nerve Blockade

Neuro-Blocking – VBLOC™

- Electrical impulse directly applied to vagal trunks to modulate GI neuro-physiology
- Reversible “Vagotomy”

Enteromedics

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Neuro-modulation – Vagal Block



VBLOC™ ReCharge Trial

- multi-center study (USA + Australia)
- ~240 pts (2:1 Rx Vs Sham)
- BMI 35-45; RCT (implanted with Vs without lead)
- New design – implant >12h/day automatic delivery

- At 12 months
- **Primary end-point :**
 - 55% Rx group >20%EWL; 45% Rx group >25%EWL



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Ikramuddin, S et al. JAMA 2015

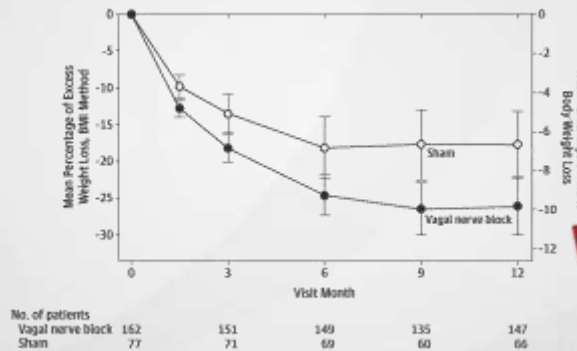
Multidisciplinary Clinic Of Metabolic & Bariatric Surgery



Neuro-modulation – Vagal Block



VBLOC™ ReCharge Trial



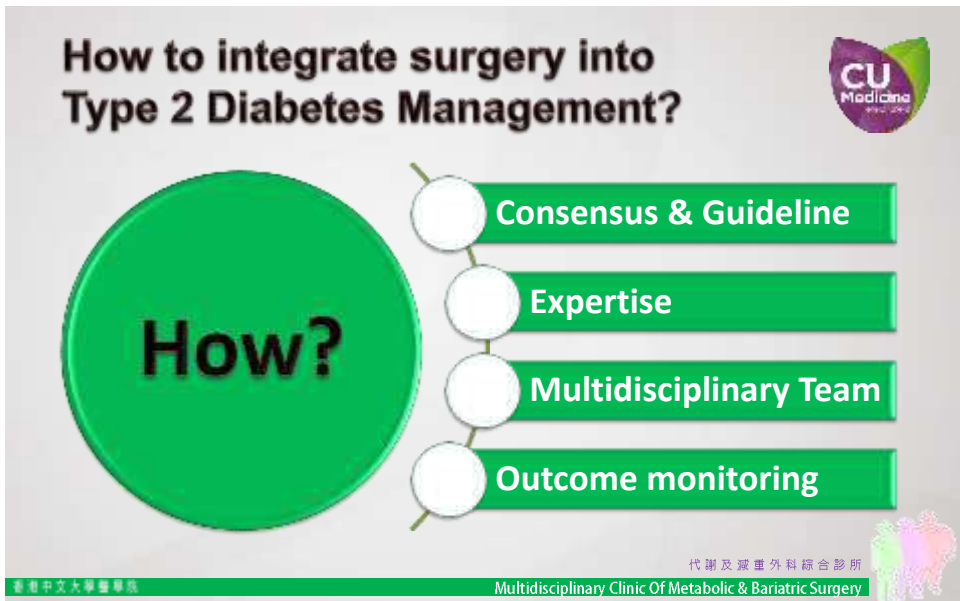
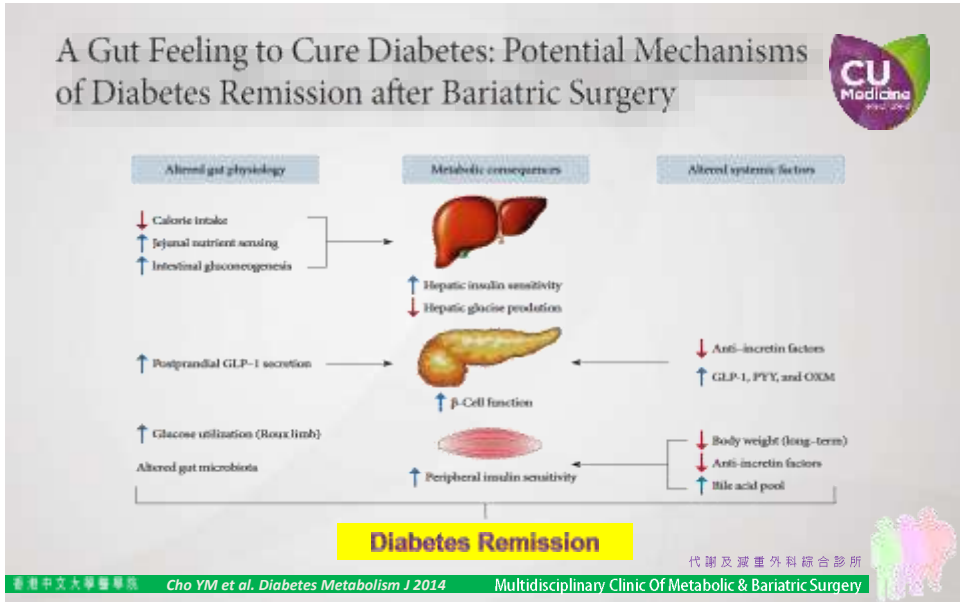
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Ikramuddin, S et al. JAMA 2015

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National or International Guideline for eligibility of bariatric surgery in Adult



| | NIH ¹ (USA) | NHMRC ² (Australia) | NICE ³ (UK) | European ⁴ | ADA ⁵ (USA) | SIGN ⁶ (Scotland) |
|------------------|---|---|--|---|---|---|
| Year | 1991 | 2003 | 2006 | 2007 | 2010 | 2010 |
| Recommended: | | | >50 | | | |
| BMI | | | | | | |
| Eligible (A):BMI | >40 | >40 | >40 | >40 | >40 | |
| Eligible (B):BMI | 35 - 40 with 1 serious weight loss responsive comorbidity | 35 - 40 with 1 serious weight loss responsive comorbidity | 35-40 with disease that could improve with weight loss | 35 - 40 with 1 weight loss responsive comorbidity | 35-40 if control of diabetes and comorbidity is difficult | >35 with 1 serious weight loss responsive comorbidity |

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The Y - Y Paradox



Higher fat percentage , More central obesity

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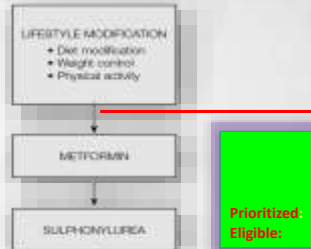
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Yudkin and Yanik et al Lancet 2004;

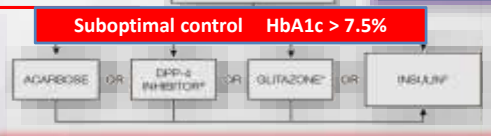
IDF Position Statement 2011

Bariatric Surgical and Procedural Interventions in the Treatment of Obese Patients with Type 2 Diabetes



| Surgery | |
|--------------|-----------------------------------|
| Prioritized: | Caucasian BMI > 40 Asian >37.5 |
| Eligible: | BMI > 35 >32.5 |

| Surgery | |
|---|-----------------------------------|
| Prioritized: | Caucasian BMI > 35 Asian >32.5 |
| Eligible: | BMI > 30 >27.5 |
| HbA1c > 7.5 % despite fully optimize conventional therapy | |



***Referral to bariatric expertise with multi-disciplinary team**

IFSO-APC Consensus Meeting 2011 Rusutsu, Hokkaido, Japan



Bariatric Surgery should be consider in Asian if

1. **BMI ≥ 35** with or without comorbidity
2. **BMI ≥ 30** severe comorbidities, poor control DM / MES, failed life-style & medical Rx

Metabolic surgery maybe consider in Asian if

1. **BMI ≥ 27.5** poor control DM or MES
2. Under approval from IRB with inform consent from patient

Recommended Procedures

Gastric Bypass/ Sleeve Gastrectomy/ Gastric Banding / BPD/DS

IFSO-APC Consensus Meeting 2011 Japan

London Consensus (2015)



DSS PARTNERS



ENDORING SOCIETIES

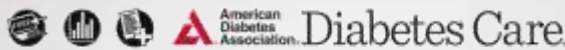


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Diabetes Care Volume 39, June 2016



Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations

Diabetes Care 2016;39:861-877 | DOI: 10.2337/dc16-0236

Endorsement by >40 National Societies On Diabetes/Obesity/Bariatric Surgery

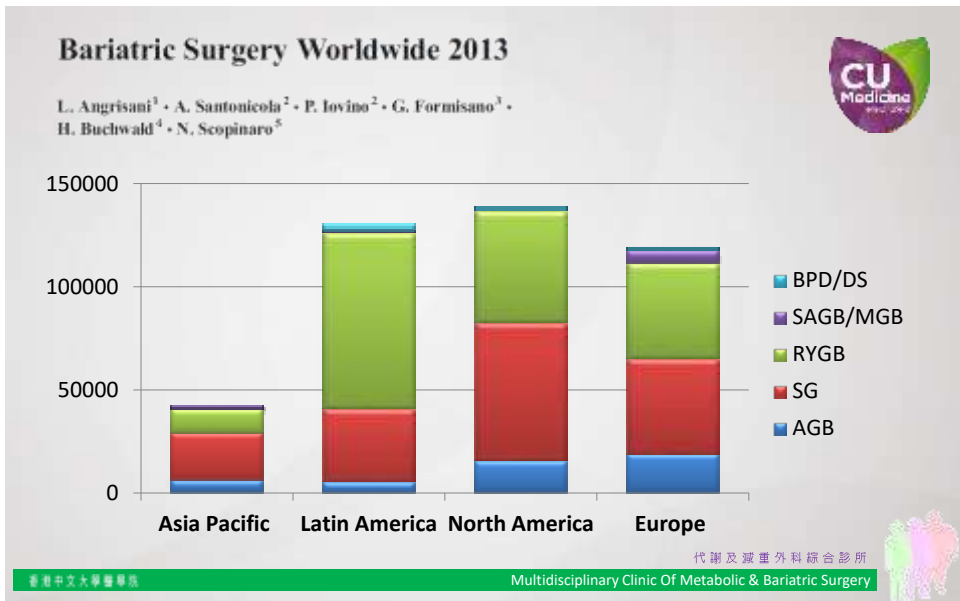
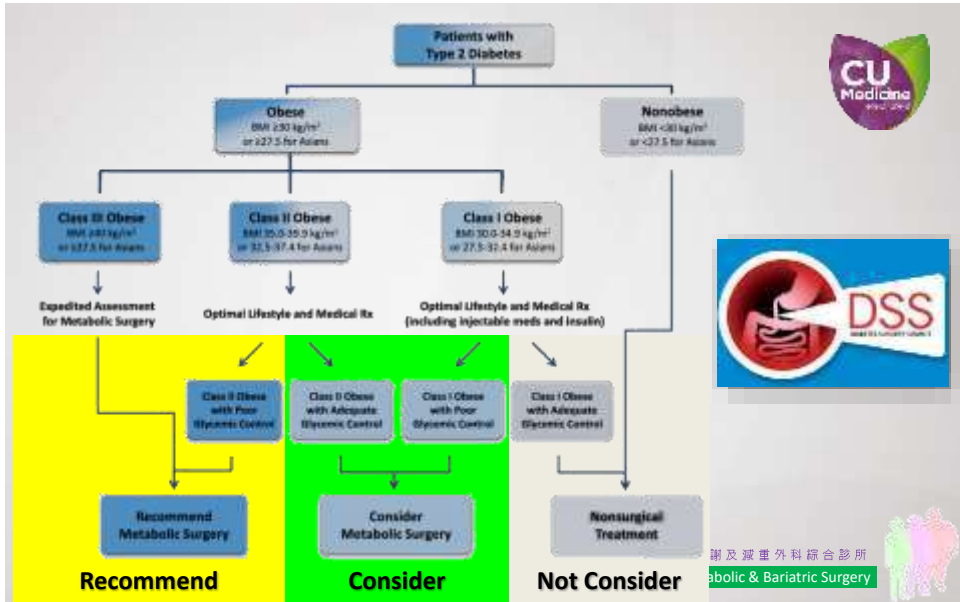
Other organizations that formally subscribe to the DSS II consensus statements and guidelines are listed below:

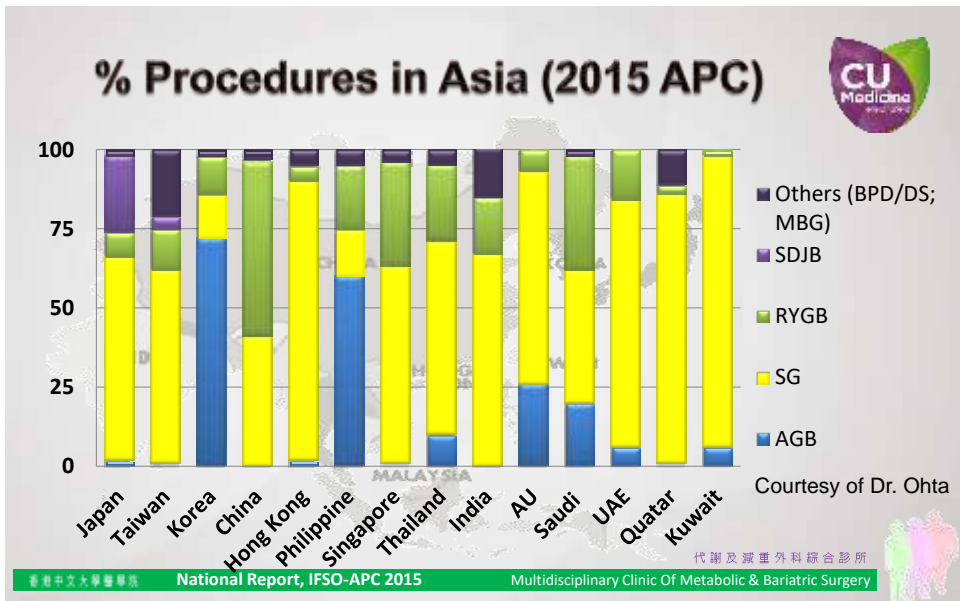
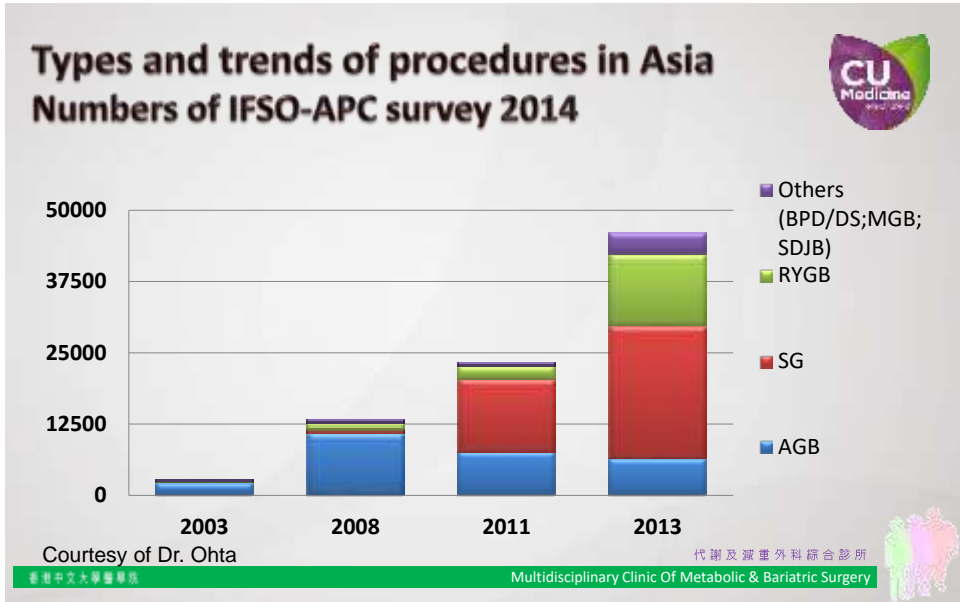
| | |
|---|---------------|
| American Association of Clinical Endocrinologists (AAACE) | USA |
| American College of Surgeons (ACS) | USA |
| American Geriatrics Society (AGS) | USA |
| American Society for Metabolic and Bariatric Surgery (ASMBS) | USA |
| Argentine Society of Diabetes (SAD) | Argentina |
| Argentine Society for Bariatric and Metabolic Surgery (ASBMS) | Argentina |
| Austrian Society for Bariatric and Metabolic Surgery (ASBMS) | Austria |
| Australian Diabetes Society (ADS) | Australia |
| Belgian Diabetes Association (BDA) | Belgium |
| British Society of Diabetology (BSD) | UK |
| British Society of Metabolic and Bariatric Surgery (BSMBMS) | UK |
| British Society of Metabolic Surgery Society (BSMS) | UK |
| British Society for the Study of Obesity (BSO) | UK |
| British Society of Endocrinology and Diabetology (BSOED) | UK |
| Chinese Society for Bariatric and Metabolic Surgery (CSBMS) | China |
| Endocrine Society | USA |
| European Association for the Study of Diabetes (EASD) | International |
| French Society of Diabetes (SFD) | France |
| French Society of Bariatric and Metabolic Surgery (SFBMS) | France |
| German Endocrine Society (DES) | Germany |
| German Society for Obesity Surgery (GASO) | Germany |
| Italian Diabetes Association (IDA) | Italy |
| International Association for the Study of Obesity & Metabolic Disorders (IASO) | International |
| Italian Diabetes Association (IDA) | Italy |
| Italian Society of Bariatric and Metabolic Surgery (ISBMS) | Italy |
| Italian Society of Endocrinology (ISE) | Italy |
| Japan Diabetes Society (JDS) | Japan |
| Latin American Association of Diabetes (LAD) | International |
| Malaysian College of Nutrition and Metabolic Surgery (MCMNS) | Malaysia |
| Malaysian Society of Endocrinology and Diabetology (MSED) | Malaysia |
| Spain Diabetes Association (EDA) | Spain |
| Saudi Diabetes and Endocrine Association (SDEA) | Saudi Arabia |
| Society for Pediatric Endocrinology and Metabolic Disorders (SPEMD) | USA |
| Society for Endocrinology (SfE) | UK |
| Society for Surgery of the Alimentary Tract (SSAT) | USA |
| South African Society for Surgery Obesity and Metabolism (SASO) | South Africa |
| Spanish Society for Bariatric and Metabolic Surgery (SSBMS) | Spain |
| Spanish Society of Endocrinology (SSE) | Spain |
| The Obesity Society (OS) | USA |

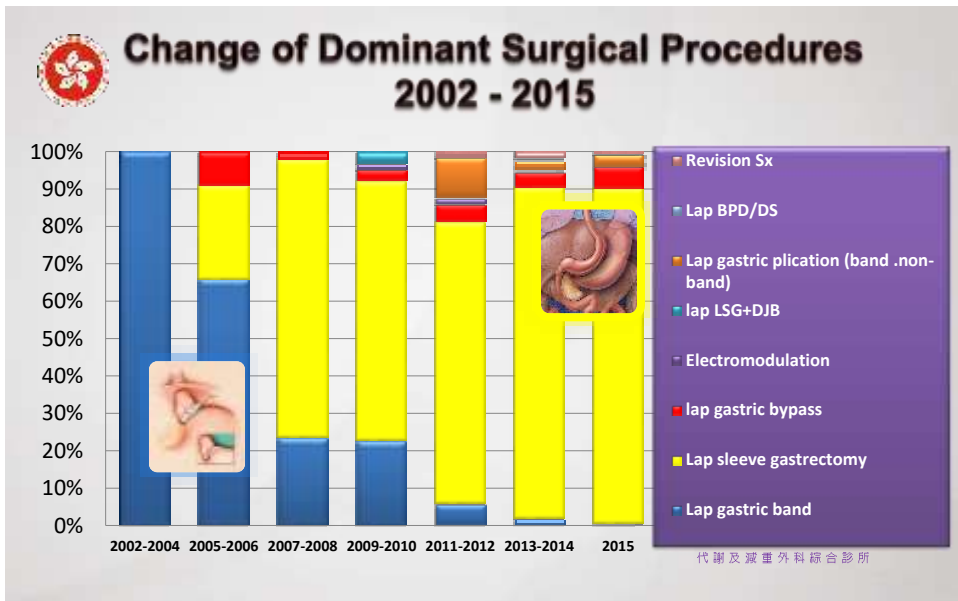
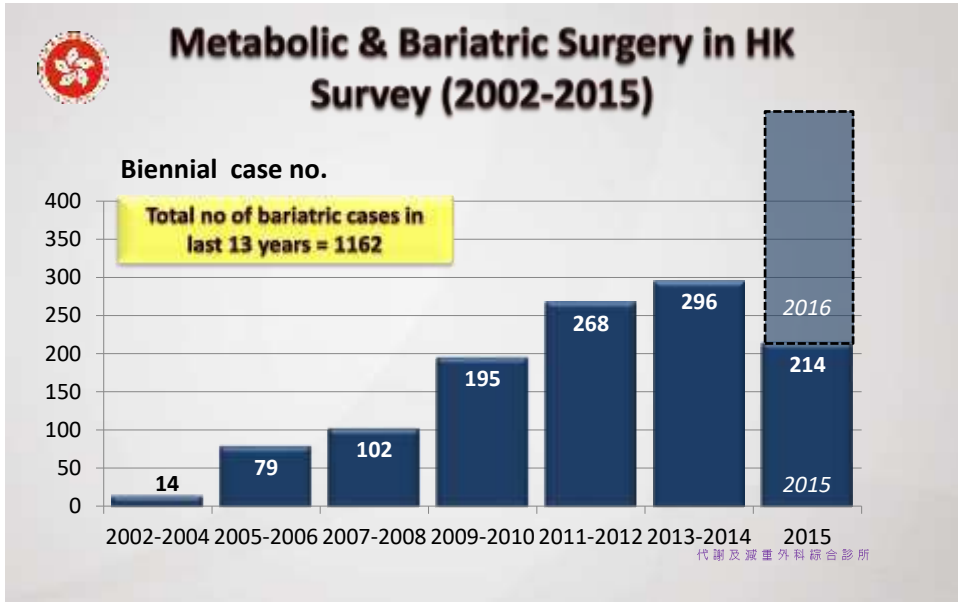
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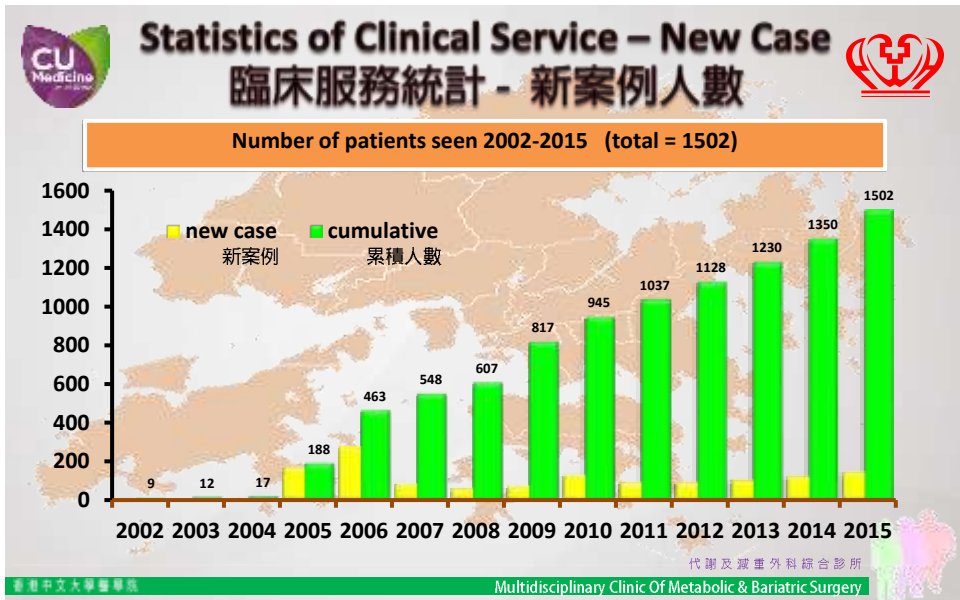
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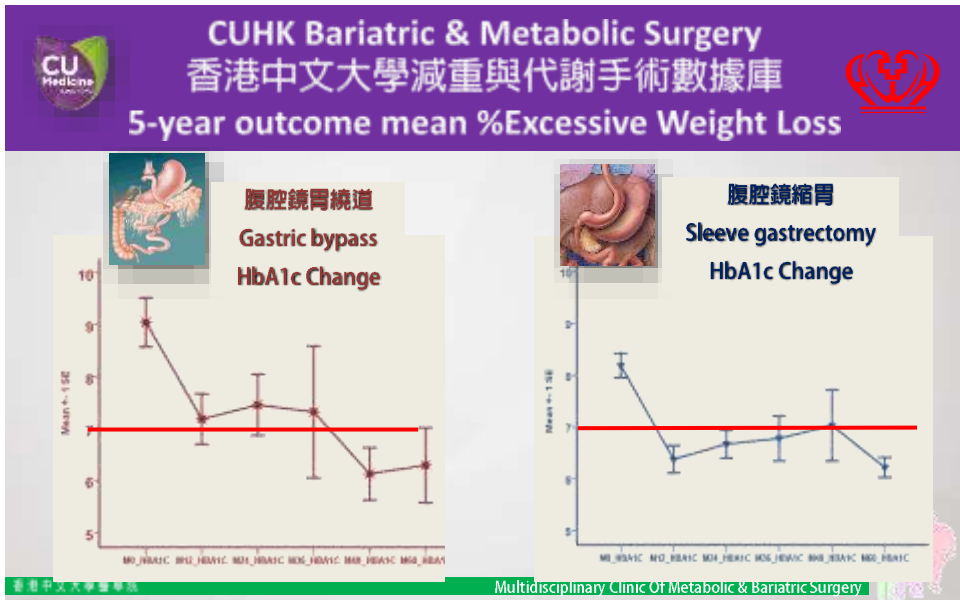
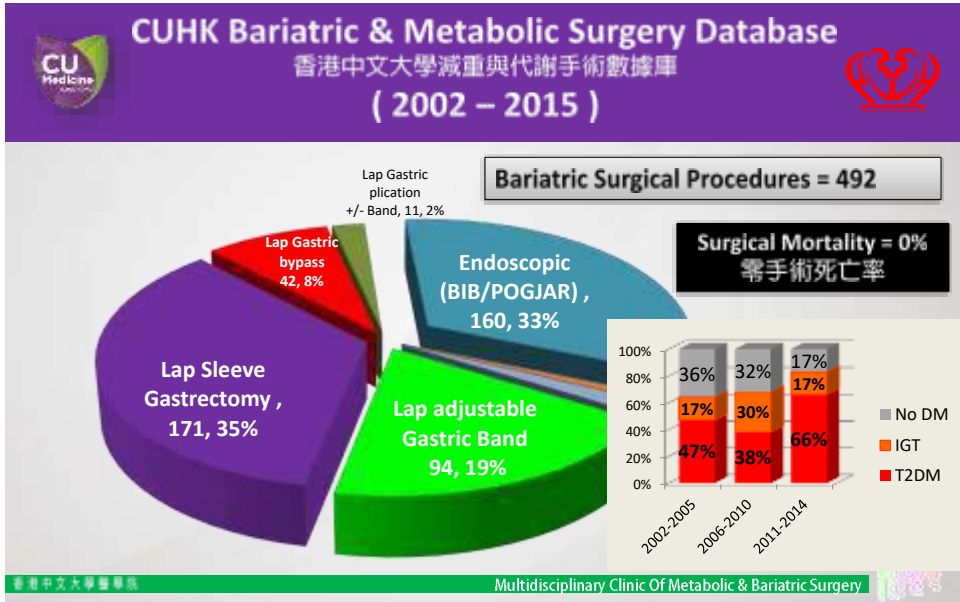
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Multidisciplinary Management Team for Patients with
Obese Metabolic Syndrome – Patient Outcome

肥胖代謝綜合症外科治療團隊 - 病人概況




Typical Patient Profile 典型的病人檔案

陸小姐，47歲
體重93公斤，體重指數39

很長的肥胖史，吃藥減肥失敗
偶爾在面對壓力時暴食

- 2009診斷糖尿病一
HbA1c 7.8% (兩種口服藥)
- 高血壓，三種的血壓藥
- 高血脂 - 甘油三酯 2.2mmol/l
- 脂肪肝，睡眠窒息
- 月經不調 (每幾個月一次)




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術前
Preop
107公斤
HbA1c 12%



術後一年(束胃帶)
1y LAGB
100公斤
HbA1c 9.8%



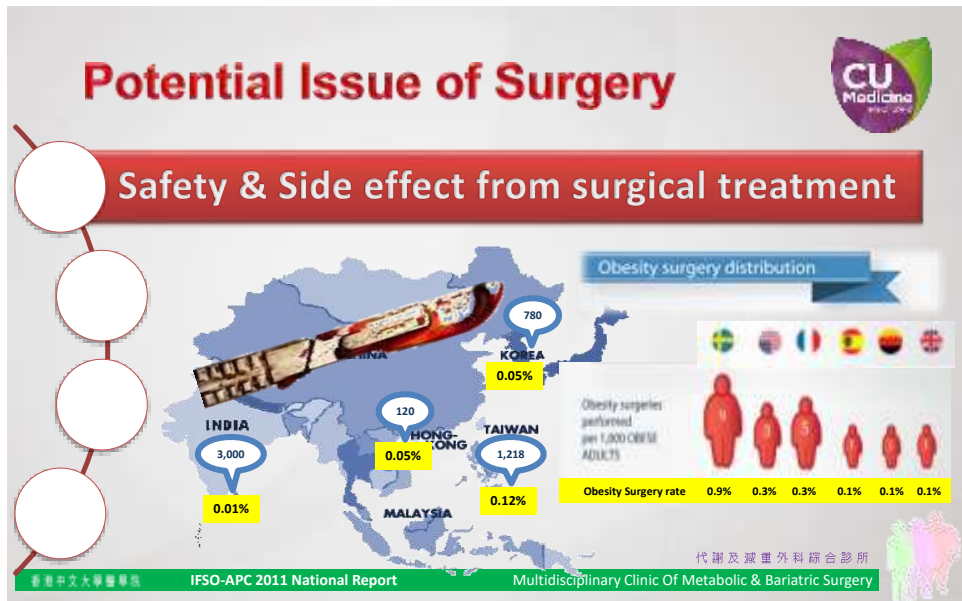
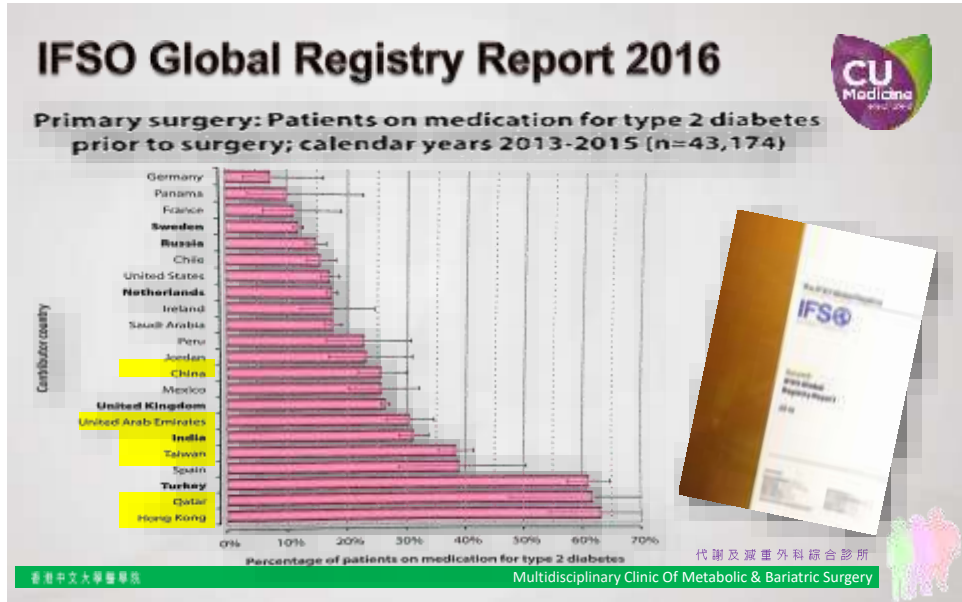
術後一年(胃繞道手術)
1y (gastric bypass)
87公斤
HbA1c 5.9%

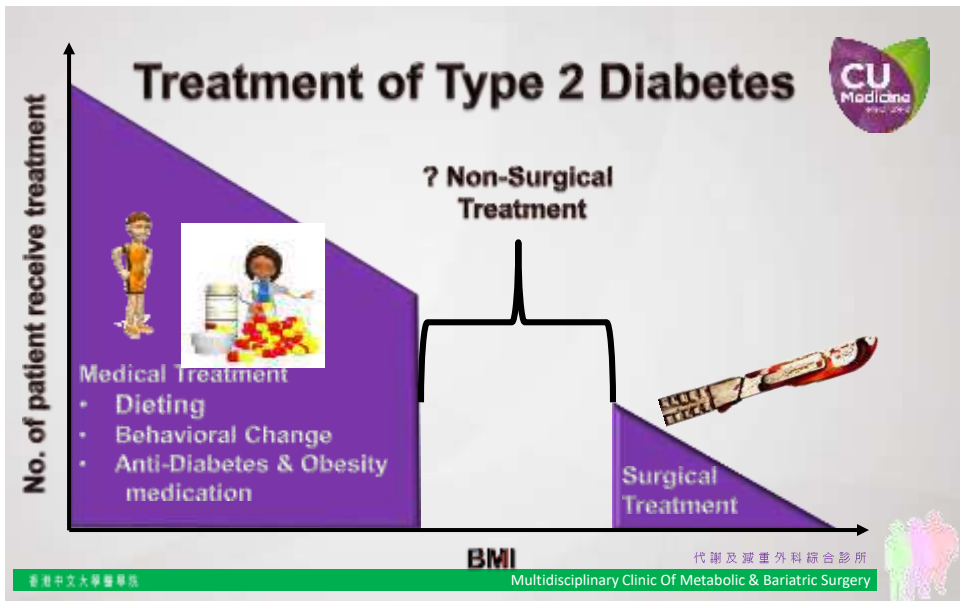
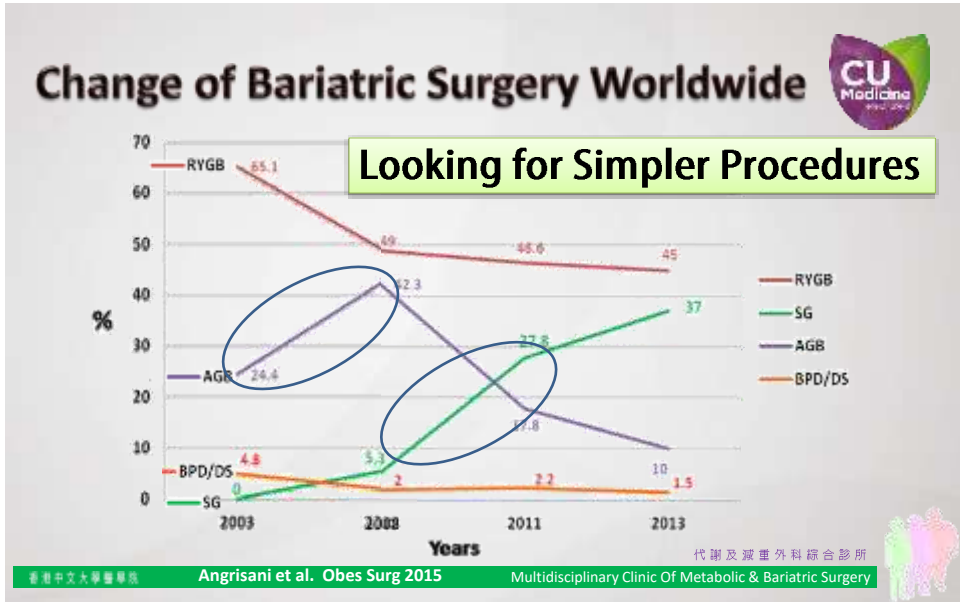




代辦


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Safer Option ?

RISE OF ENDOSCOPY



Peptic Ulcer Bleeding

Bile duct stone


Colon adenoma

Early gastric cancer

Achalasia

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Metidisciplinary Clinic Of Metabolic & Bariatric Surgery

Mechanism of Metabolic Surgery



Non-Surgical Method ?

Gastric Volume Reduction

- Meal size
- Calories restriction

Reduce Absorption

- Alter small bowel transit time
- Change of GI Endocrine environment (Gut Hormone)


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Metidisciplinary Clinic Of Metabolic & Bariatric Surgery

EndoLuminal Rx

- Very Safe
- Less weight Loss

Primary Intention?

- Temporary -
→ Permanent
- DM improvement –
less Med / remission
- Test drive before Sx






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Metabolic & Bariatric Surgery

Intra-gastric Balloon (IGB)


- 1999 – Silicon Balloon (Bioenteric Balloon - BIB)
- Placement & Removal – Under Endoscopy guidance
- Inflated with 500-700cc Saline
- Methylene blue added to indicate rupture
- Remove 6m after insertion



>200,000 placement



1999 HEALTH



2006

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Metabolic & Bariatric Surgery

Intra-gastric Balloon



Safety and Effectiveness of the Intra-gastric Balloon for Obesity. A Meta-Analysis

Meta-analysis 15 studies, 3680 patient of BIB

Table 3 Reported complications of 3,429 patients treated with BIB®

| | N ^a | % ^b |
|--|----------------|----------------|
| Nausea and vomiting after first week | 295 | 8.6 |
| Abdominal pain and other mild digestive disorders ^c | 171 | 5.0 |
| Deflation and displacement of the balloon ^d | 87 | 2.5 |
| Inflammation or lesions in digestive lining ^e | 73 | 2.1 |
| Gastro-esophageal reflux | 63 | 1.8 |
| Dehydration | 54 | 1.6 |
| Deflation without displacement of the balloon ^f | 29 | 0.9 |
| Obstruction in the digestive tract | 26 | 0.8 |
| Diarrhea and/or constipation | 23 | 0.7 |
| Gastric ulcer | 12 | 0.4 |
| Gastric perforation | 4 | 0.1 |
| Mortality related with balloon (gastric perforation) | 2 | 0.1 |

Table 5 Effectiveness of BIB® to loss weight at the end of treatment

| | Studies/Groups/Patients | Mean (95% CI) |
|-----------------|-------------------------|------------------|
| K _g | 15/18/3,608 | 14.7 (12.4-17.1) |
| P _{kg} | 11/13/3,358 | 12.2 (10-14.3) |
| BMI | 9/11/3,200 | 5.7 (4.4-6.9) |
| PEW | 11/13/3,513 | 32.1 (26.9-37.4) |

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Imaz I et al. *Obes Surg*. 2008

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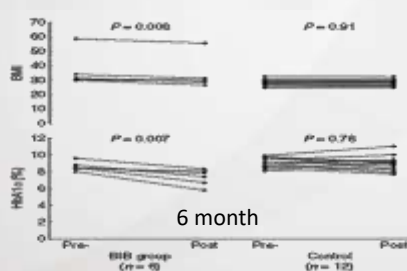
Intra-gastric Balloon



Table 5 Metabolic parameters and quality of life outcome

| | Before IGB (baseline), n=119 | After IGB (6 months), n=119 | Z |
|-----------------------------------|------------------------------|-----------------------------|----------|
| Metabolic syndrome (%) | 42.9 | 15.1 | <0.0005* |
| Metabolic parameters ^a | | 6 month | |
| Fasting blood glucose (mmol/L) | 6.1±2.0 | 5.3±1.7 | <0.0005* |
| HbA1c (%) (DM patients) | 7.4±1.6 | 5.8±0.7 | <0.0005* |
| Total cholesterol (mmol/L) | 5.1±0.9 | 4.7±0.9 | <0.0005* |
| Triglyceride (mmol/L) | 1.7±1.0 | 1.3±0.7 | <0.0005* |
| HDL (mmol/L) | 1.4±0.3 | 1.4±0.3 | 0.217 |
| Systolic blood pressure (mmHg) | 145.4±19.7 | 133.2±20.6 | <0.0005* |
| Diastolic blood pressure (mmHg) | 84.3±12.6 | 78.8±15.4 | 0.0005* |
| CRP (mg/L) | 6.9±6.5 | 5.3±6.5 | |

Mui LM et al. *Obes Surg* 2009



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Chan AOO et al. *Aliment Pharmacol Ther* 2008

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ASMB **Joint Task Force on Define Threshold on Safety & Efficacy on Endoscopic Bariatric Therapy (EBT)** **ASGL**

Orbera **apollo endosurgery** **FDA APPROVED**

Think Safe... Work Safe... Be Safe

Less than 5% Serious Adverse Events

Primary Obesity intervention for Class II/III obese (BMI>35)

- Minimal 25% EWL at 12 months
- mean %EWL difference between a "primary" EBT and control groups should be a minimum of 10% EWL

Non-primary EBT (early intervention, bridge to metabolic therapy)

- Minimal 5% Total Body Weight Loss (%TBWL)

EBT for Obese I (BMI 30-35)



- Must achieved significant impact on ≥ 1 obese-related comorbidity

香港中文大學醫學院 Abu Dayyeh et al. Gastrointest Endosc 2015 Multidisciplinary Clinic Of Metabolic & Bariatric Surgery

Intra-gastric Balloon **CU Medicine**

THE ELIPSE™ **Procedureless Gastric Balloon "Balloon Pills"**

A

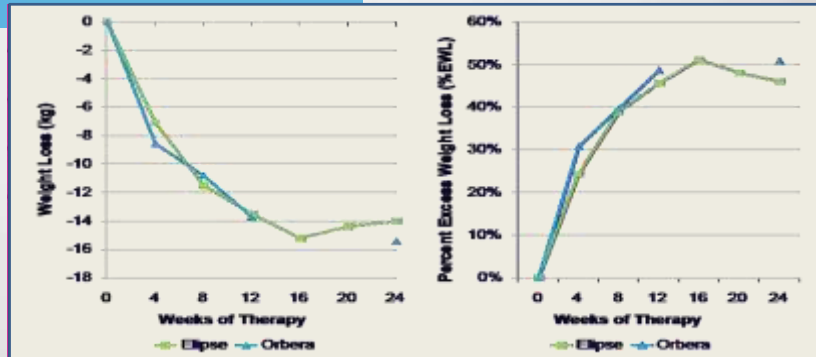
Elipse™, a Procedureless Gastric Balloon for Weight Loss: a Proof-of-Concept Pilot Study

香港中文大學醫學院 Machytka E et al. Obes Surg 2016 Multidisciplinary Clinic Of Metabolic & Bariatric Surgery

Intra-gastric Balloon



THE ELIPSE™



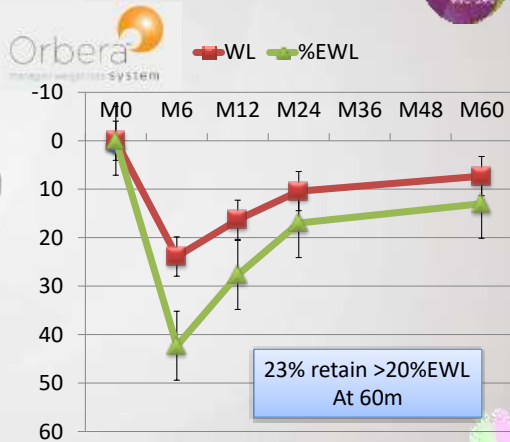
香港中文大學醫學院 Ram Chuttani et al. DDW San Diego 2016 Multidisciplinary Clinic Of Metabolic & Bariatric Surgery

500 Intra-gastric Balloons: What Happens 5 Years Thereafter?

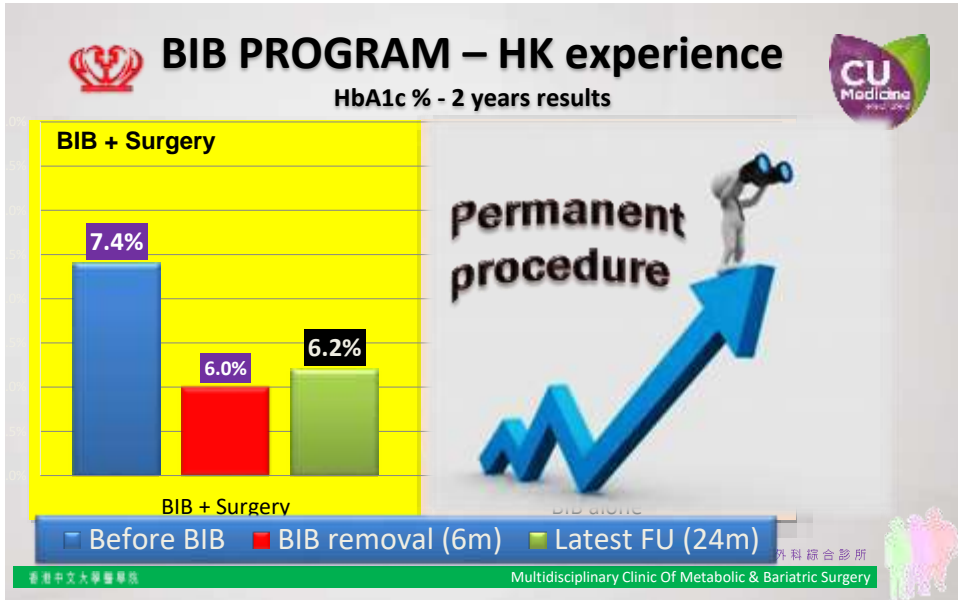


2003-2009 – 500 BIB
Mean BW 126kg BMI 44


- Exclude 17% <20% EWL at 6m + 4% early removal
- 6m removal result – 395 (79%)
- 12m FU & 24m FU – 352 (70%)
- 60m FU – 195 (29%)



香港中文大學醫學院 Kotzampassi K et al. Obes Sug 2012 Multidisciplinary Clinic Of Metabolic & Bariatric Surgery




Gastroplasty / Gastric Partition



Endoscopic Stapling

- Transoral Gastroplasty (TOGa)



Endoscopic Plication

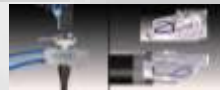
- Gastric volume reduction

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Endoscopic Sleeve Gastroplasty



Endoscopic Sleeve Gastroplasty: How I Do It?



綜合診所

香港中文大學醫學院 Lopez-Nava Gontrand et al. *Obes Surg* 2015 Multidisciplinary Clinic Of Metabolic & Bariatric Surgery



Endoscopic Sleeve Gastroplasty



Endoscopic sleeve gastroplasty (the Apollo method): a new approach to obesity management

Table I. Evolution of weight parameters after endoscopic sleeve gastroplasty

| Variable | Baseline (n = 55) | 1 month (n = 55) | 3 months (n = 55) | 6 months (n = 55) |
|--------------------------|-------------------|------------------|-------------------|-------------------|
| Weight (kg) | 106.6 ± 18.3 | 98.9 ± 16.4 | 92.2 ± 15.6 | 87.6 ± 14.7 |
| BMI (kg/m ²) | 37.7 ± 4.5 | 35.0 ± 4.2 | 32.7 ± 4.3 | 31.1 ± 4.5 |
| TWL (kg) | | 7.7 ± 2.9 | 13.3 ± 4.0 | 18.9 ± 9.5 |
| %TWL | | 7.1 ± 2.2 | 13.3 ± 4.0 | 17.3 ± 7.0 |
| %EWL | | 23.1 ± 10.2 | 43.0 ± 16.2 | 55.3 ± 23.8 |

TWL: Total weight loss; %TWL: % of total weight loss; %EWL: % of excess weight loss.




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香港中文大學醫學院 Lopez-Nava G et al. *Rev Esp Enferm Dig* 2016 Multidisciplinary Clinic Of Metabolic & Bariatric Surgery




EndoLumenal Rx Targets



Stomach

- Reduce gastric size
- Weight Reduction




Duodenum Small Bowel


- Foregut exclusion
- Hindgut stimulation

Isolated Duodenal Exclusion Increases Energy Expenditure and Improves Glucose Homeostasis in Diet-induced Obese Rats

Rodrigo Muñoz^{1,2}, Jill S. Carmody¹, Nicholas Stylopoulos¹, Philip Davis¹,
Leo M. Kaplan¹




B)




C)


1 cm ELS (ELS-1)



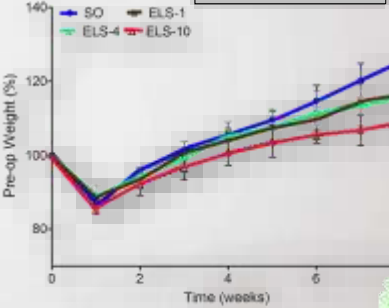
4 cm ELS (ELS-4)



10cm ELS (ELS-10)




Body Weight

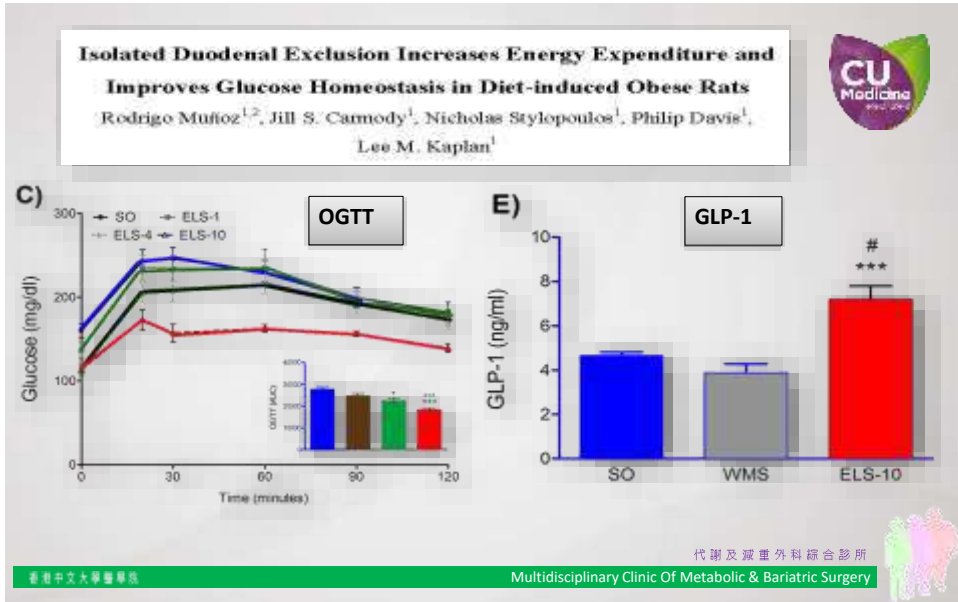


| Time (weeks) | SO | ELS-1 | ELS-4 | ELS-10 |
|--------------|-----|-------|-------|--------|
| 0 | 100 | 100 | 100 | 100 |
| 1 | 88 | 88 | 88 | 88 |
| 2 | 95 | 95 | 95 | 95 |
| 4 | 105 | 102 | 102 | 100 |
| 6 | 115 | 108 | 108 | 105 |
| 8 | 125 | 115 | 115 | 110 |


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Endolumenal Bypass



- Endoscopic Duodeno-Jejunal Bypass Liner



The EndoBarrier[®] System



Glycemic Control Weight Loss


endoBarrier[®]

Endolumenal Duodeno-Jejunal Bypass Liner

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RANDOMIZED CONTROLLED TRIAL

The Effect of the Endoscopic Duodenal-Jejunal Bypass Liner on Obesity and Type 2 Diabetes Mellitus, a Multicenter Randomized Controlled Trial




- Multicenter DJBL Vs Control (6m implantation + 6m explantation)
 - 35 DJBL Vs 39 control
- 6 M HbA1c
 - DJBL **7.0%** Vs Control **7.9%** (p<0.05)
- 6 M after removal
 - DJBL **7.3%** Vs Control **8.0%** (p = ns)

| Time point (mo) | DJBL (%) | Control (%) |
|-----------------|----------|-------------|
| 0 | ~8.5 | ~8.5 |
| 1 | ~7.8 | ~8.2 |
| 2 | ~7.5 | ~8.0 |
| 3 | ~7.2 | ~7.8 |
| 4 | ~7.0 | ~7.6 |
| 5 | ~7.0 | ~7.6 |
| 6 | ~7.0 | ~7.9 |
| 7 | ~7.0 | ~7.8 |
| 8 | ~7.2 | ~7.8 |
| 9 | ~7.2 | ~7.8 |
| 10 | ~7.2 | ~7.8 |
| 11 | ~7.2 | ~7.8 |
| 12 | ~7.2 | ~7.8 |

代謝及減重外科綜合診所


香港中文大學醫學院 Koehestanie P et al Ann Surg 2014 Multidisciplinary Clinic Of Metabolic & Bariatric Surgery

Other Strategy?



Stomach

- Reduce gastric size
- Weight Reduction




Duodenum Small Bowel

- Foregut exclusion
- Hindgut stimulation


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Endoscopic Intestinal Bypass ?



Is it Possible?




**EUS Guided GJ
Cross-luminal Stent**

Itoi et al. GUT 2016



**Self-assembling magnets
Incisionless Anastomosis System [IAS]**



GI WINDOWS™
A Platform for Patient Health

香港中文大學醫學院

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Minimally invasive entero-enteral dual-path bypass using self-assembling magnets






When deployed, the GI Windows device self-assembles to form an octagonal geometry.

**Jejuno-colonic
Anastomosis**





Day 12
Two octagons are positioned in two sections of the bowel, and they couple together.



Day 90
An anastomosis is formed between the octagons before they are retracted into the GI tract.

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Ryou, M et al. Surg Endosc 2016

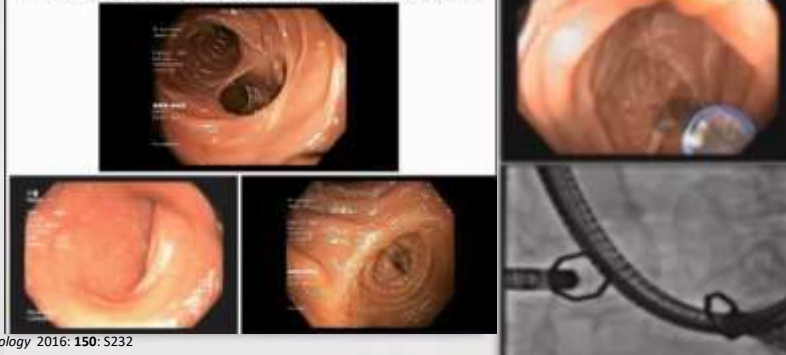
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Endoscopic Dual-Path Anastomosis

Self-assembling Magnet



Endoscopic Evaluation of Anastomosis



Gastroenterology 2016; 150: S232

香港中文大學醫學院 Thompson CC et al. DDW San Diego 2016

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Conclusion



History of Bariatric Surgery is short but it develops rapidly in Asia

Metabolic Risk in Asian is higher and BMI Criteria for surgery is different from Western Society

Demand and choices of procedure depends on special needs in Asian Population

Sleeve gastrectomy & gastric bypass is the main-stream of surgery but NOT IDEAL, novel procedure is investigational but promising

Endoscopic procedure is developing in order to meet the unmet needs

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Role of GI physician / surgeon in Future ? In Diabetes & Obesity Treatment



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