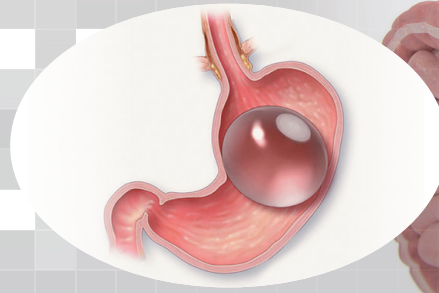



1st Endoscopic Bariatric and Metabolic Therapies Workshop

2022 **12/11** sun 08:30~16:00

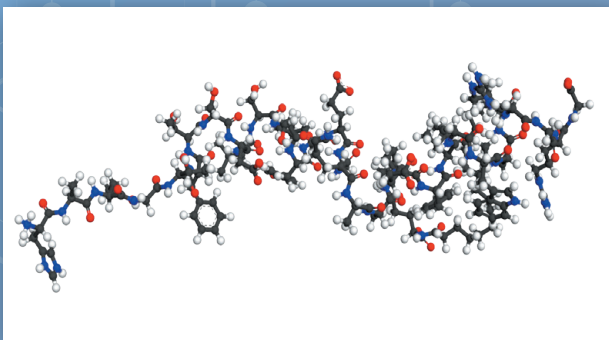
亞東紀念醫院
北棟 6F 階梯教室
6F 超音波暨內視鏡中心



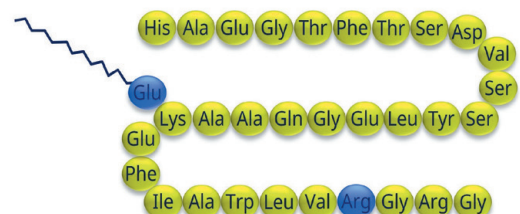
主辦單位  台灣消化系內視鏡醫學會

協辦單位  亞東紀念醫院 超音波暨內視鏡中心 / 形美體雕減重中心

Program Book



C-16 fatty acid
(palmitoyl)



1st Endoscopic Bariatric and Metabolic Therapies Workshop

Lecture (北棟 6F 階梯教室) 60位學員

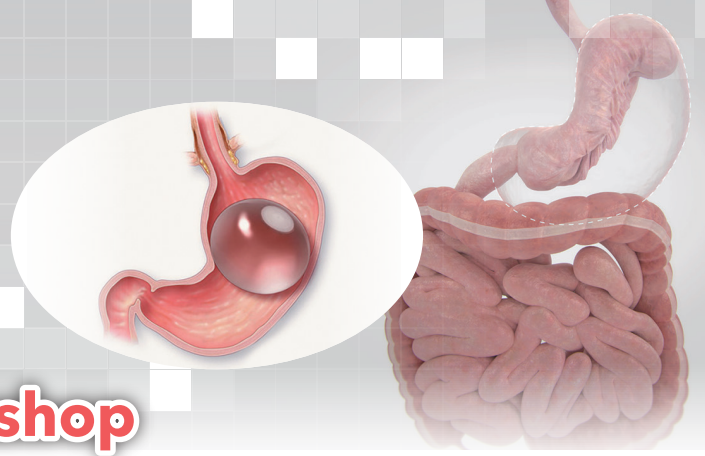
Time	Course	Speaker	Moderator
08:30-08:45	Registration		
08:45-08:55	Welcome Opening remarks	邱冠明 院長 邱正堂 理事長	
08:55-09:10	Pharmacological treatment for obesity	黃雪晶 主任	陳建全 醫師 陳鵬仁 主任
09:10-09:25	Dietary approaches to obesity management	周佳慧 營養師	
09:25-09:40	History and rationale of EBMT and MDT care	高崧碩 主任	
09:40-09:55	Discussion	All	
09:55-10:10	Intragastric balloon and injection of botulinum toxin A for obesity management: pros and cons	戴啟明 部長	陳建華(慈濟) 主任 曾屏輝 教授
10:10-10:25	Endoscopic sleeve gastropasty for obesity management: pros and cons	鍾承軒 主任	
10:25-10:40	Bariatric surgeries: indications and outcomes	陳盛世 主任	
10:40-10:55	Discussion	All	
10:55-11:15	Break		
11:15-13:00	Live demonstration	鍾承軒 主任 陳建全 醫師	陳盛世 主任
12:00-13:00	Lunch		
13:00-13:20	Dressing (moving to 6F 超音波暨內視鏡中心)		
13:20-13:30	Orientation	陳冠至 醫師	
13:30-15:30	Hands-on workshop	All	
15:30-15:45	Dressing (moving to 北棟 6F 階梯教室)		
15:45-15:55	Discussion	All	All Tutors
15:55-16:00	Closing remarks and certification	邱瀚模 教授	

動物實驗ESG Hands-on (北棟 6F 超音波暨內視鏡中心) 12位學員

Time	Course	Hands-on tutor	Assistant
13:30-15:30	A組 (3人) Dry lab & Ex-vivo model	鍾承軒	朱允義
13:30-15:30	B組 (3人) Dry lab & Ex-vivo model	周莒光	戴維震
13:30-15:30	C組 (3人) Dry lab & Ex-vivo model	陳盛世	高崧碩
13:30-15:30	D組 (3人) Dry lab & Ex-vivo model	鄒永寬	王彥博

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**Endoscopic Bariatric and
Metabolic Therapies Workshop**

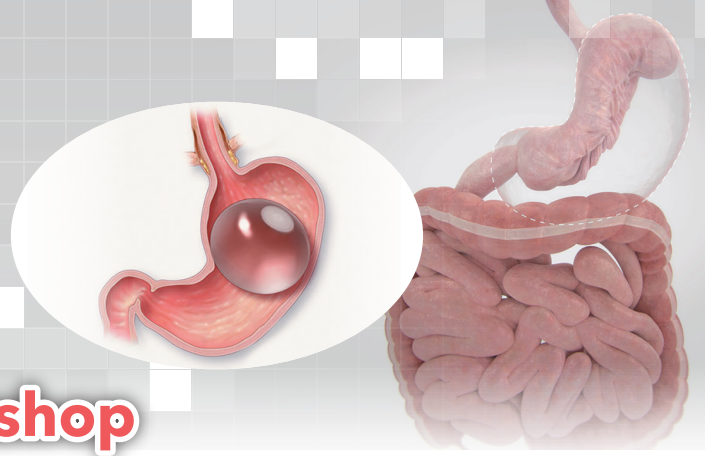


08:55-09:55

Moderator: 陳建全 醫師
陳鵬仁 主任

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**Endoscopic Bariatric and
Metabolic Therapies Workshop**



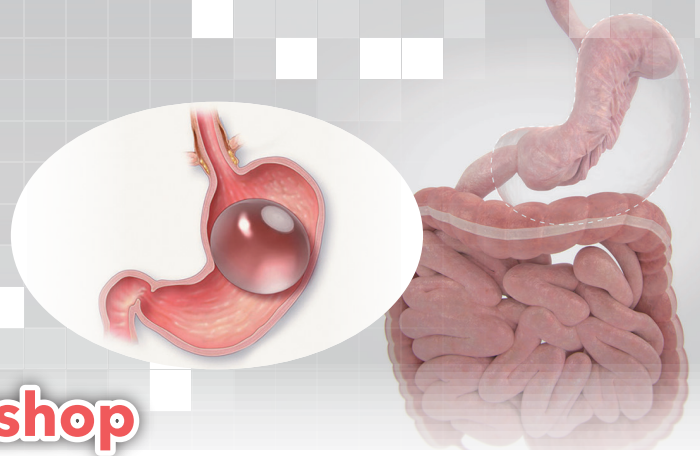
08:55-09:10

**Pharmacological
treatment for obesity**

Speaker: 黃雪晶 主任

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Endoscopic Bariatric and Metabolic Therapies Workshop

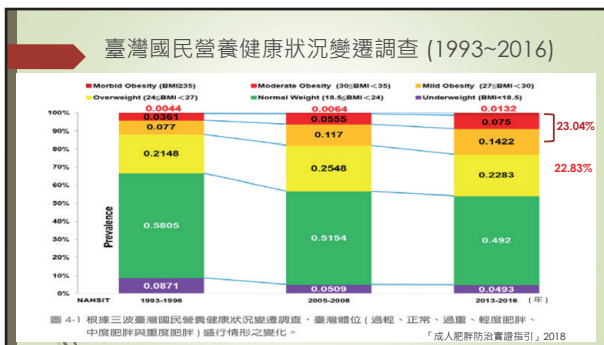


Obesity general consideration & pharmacotherapy

基隆長庚新陳代謝科黃雪晶

臺灣肥胖的流行趨勢·近三次的國民營養調查 (Nutrition and Health Survey in Taiwan (NAHSIT) 結果

年度 / 身體質量指數 (BMI) 分類	1993-1996	2005-2008	2013-2016
BMI < 18.5	8.7%	5.1%	5.4%
18.5 ≤ BMI < 24	58.1%	51.5%	50%
24 ≤ BMI < 27 overweight	21.5%	25.5%	22.4%
27 ≤ BMI obese	9.7%	17.9%	22.3%

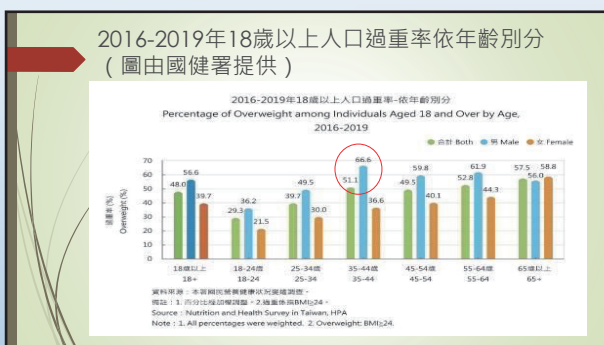


Obesity prevalence 2017-2000

表1·成人過重及肥胖盛行率(以身體質量指數為標準)(2017-2020)

性別	年齡 (歲)	樣本數 (人)	BMI 分類			
			BMI ≥ 35	30 ≤ BMI < 35	27 ≤ BMI < 30	24 ≤ BMI < 27
男性	19-30	258	3.64	9.00	10.63	26.41
	31-44	292	3.26	13.21	17.87	31.17
	45-64	651	1.12	9.17	19.08	30.79
	65 -	1052	0.52	6.26	15.35	33.97
	≥ 19	2253	2.12	9.78	16.45	30.52
女性	19-30	275	1.48	7.31	5.86	17.91
	31-44	322	1.48	6.72	9.43	18.30
	45-64	698	0.39	8.09	11.57	24.83
	65 -	962	1.21	8.58	17.59	32.78
	≥ 19	2257	1.03	7.67	10.95	23.15

資料來源：2017-2020年國民營養健康調查。
註：有效樣本數按實際受訪樣本數之最大可利用值，分析結果經加權調整。
製表日期：2022/06/15



何謂肥胖？ 台灣定義

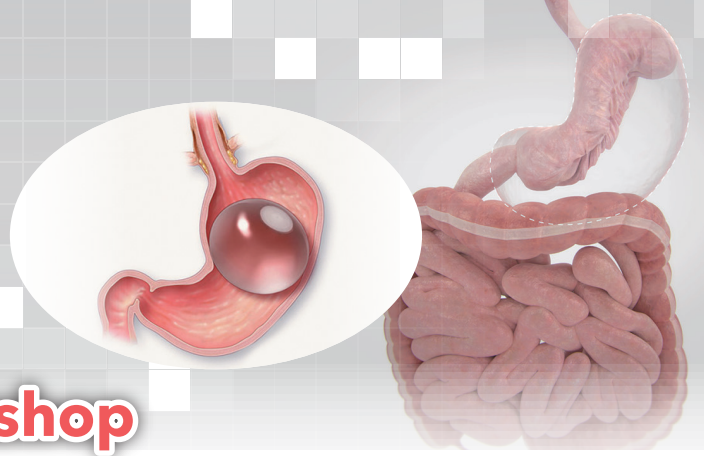
- 肥胖的定義：異常或過量脂肪累積，以致損害健康。
- 根本原因：攝入卡路里與消耗卡路里之間的能量不平衡。
- 考量以共病程度、發病死亡率及公衛流病學等研究結果，以BMI ≥ 24 kg/m²及BMI ≥ 27 kg/m²分別為台灣成人過重及肥胖的診斷切點。

身體質量指數 (BMI)*	腰圍 Waist Circumference*
體位定義	身體質量指數 (BMI) (kg/m²)
體重過輕	BMI < 18.5
健康體位	18.5 ≤ BMI < 24
體位異常	過重：24 ≤ BMI < 27
	輕度肥胖：27 ≤ BMI < 30
	中度肥胖：30 ≤ BMI < 35
	重度肥胖：BMI ≥ 35
	腰圍 (公分)
	男性：≥ 90公分
	女性：≥ 80公分

*BMI 不適用於兒童、18歲以下青少年、孕婦及病後、老年人、運動員

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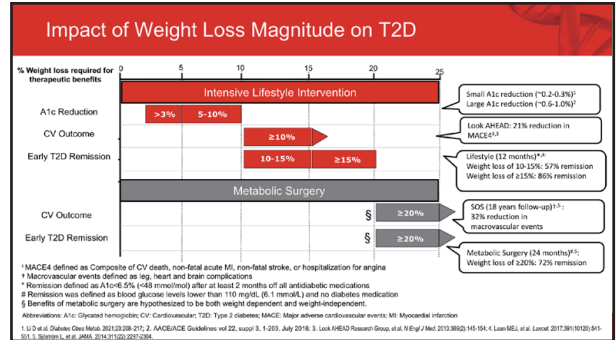
Endoscopic Bariatric and Metabolic Therapies Workshop



肥胖的治療目標

7 體重過重或肥胖者 (BMI ≥ 25 kg/m² 或 BMI ≥ 23 kg/m² [特定種族]) 且合併重要相關併發症

體重相關併發症	體重減輕目標	臨床目標
糖尿病前期/代謝症候群	10%	預防第二型糖尿病
第二型糖尿病	5% to ≥ 15%	(1) 降低A1C (2) 減少降血糖藥物數量或劑量
血脂異常	5% to ≥ 15%	(1) 降低三酸甘油酯 (2) 增加高密度脂蛋白 (3) 降低低密度脂蛋白
高血壓	5% to ≥ 15%	(1) 降低收縮壓與舒張壓 (2) 減少降血壓藥物數量或劑量
非酒精性肝病疾病	5% or more	降低肝脂肪的累積 (2) 減少降血脂藥物數量或劑量
多囊性卵巢	5% to ≥ 15%	(1) 排卵 (2) 規律經期 (3) 減少多毛 (4) 增加胰島素敏感性 (5) 降低血清雄激素濃度
女性不孕症	≥ 10%	(1) 排卵 (2) 懷孕
男性性腺低症	5% to ≥ 10%	增加血清睪酮濃度
阻塞性睡眠呼吸中止	7% to ≥ 11%	(1) 改善症狀 (2) 降低呼吸暫停-低通氣指數
氣喘/反應性呼吸道疾病	7% to ≥ 8%	(1) 改善一秒用力呼氣容積 (2) 改善症狀
骨質疏鬆	≥ 10% • 5% to ≥ 15% (運動配對)	(1) 改善症狀 (2) 增加功能
壓力性尿失禁	5% to ≥ 10%	減少失禁頻率
胃食管逆流	≥ 10%	減少症狀頻率與嚴重度
憂鬱症	Uncertain	(1) 減少憂鬱症狀 (2) 改善憂鬱分數



台灣肥胖醫學會—藥物治療指引 (2020)

GRADE 建議等級	臨床建議內容
1C	適用於肥胖病人 BMI ≥ 30 kg/m ² 或是 BMI ≥ 27 kg/m ² 且至少有一種合併症 (高血壓、第二型糖尿病或血脂異常等)。 (強建議，證據等級低)
1A	目前在我國核准適用於肥胖治療的藥物且有長期療效之證據主要有 Orlistat 以及 liraglutide。 (強建議，證據等級高)

目前坊間尚有下列非適應症性的藥品作為減重用藥，包括瀉藥、麻黃素、抗憂鬱劑、利尿劑、降血糖藥、降血脂藥、甲狀腺素、纖維等，其主要用途及適應症，並非衛生福利部核准使用於減重。因此，利用上述等藥品於減重，除屬於藥品「仿單核准適應症外的使用」，依衛生福利部2002年公告之「仿單核准適應症外的使用原則」不建議使用，以共同保障病人用藥權益。

減重的方法

- 【1】飲食控制
- 【2】規律運動
- 【3】修正行為模式 (細嚼慢嚥、爬樓梯代替搭電梯)
- 【4】減重藥物 (身體質量指數 > 27 kg/m²)
- 【5】極低熱量飲食 (<800 Kcal/day)
- 【6】外科手術 (身體質量指數 > 30 kg/m²)

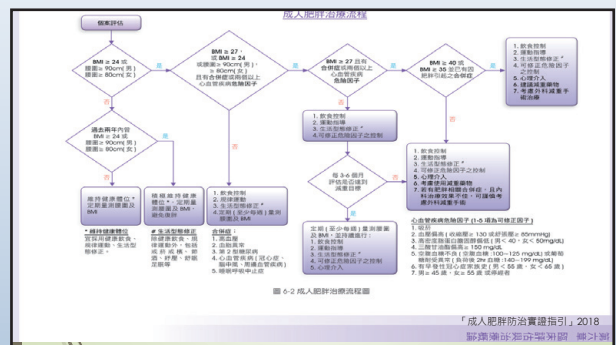
減重手術之健保給付規範 (2019年5月修訂)

- BMI 大於 37.5 kg/m²，或 BMI 大於 32.5 kg/m² 且合併有重要併發症，內科治療仍大於 7.5%。
- 減重門診治療 (或門診相關治療) 滿半年，規律運動及飲食控制平常以上。
- 年齡在 20 至 65 歲之間。
- 無其他內分泌疾病引起之病態性肥胖。
- 無酗酒、癮癮及其他精神疾病。
- 精神狀態健全，經由精神科專科醫師評估認定無異常。

Obesity assessment

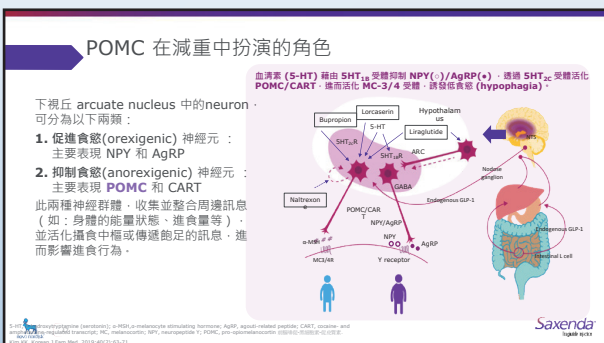
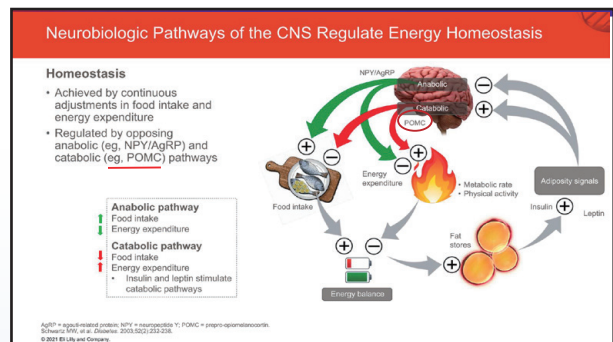
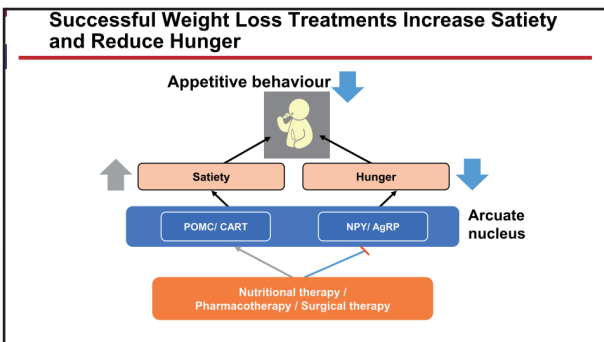
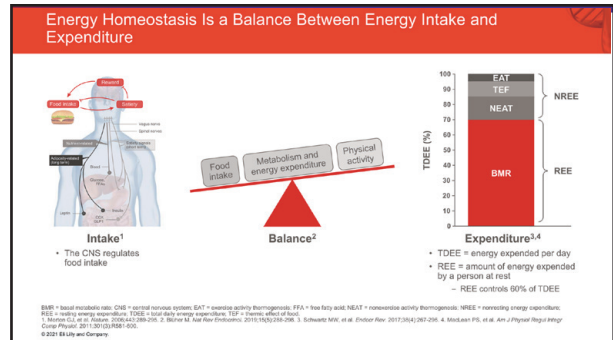
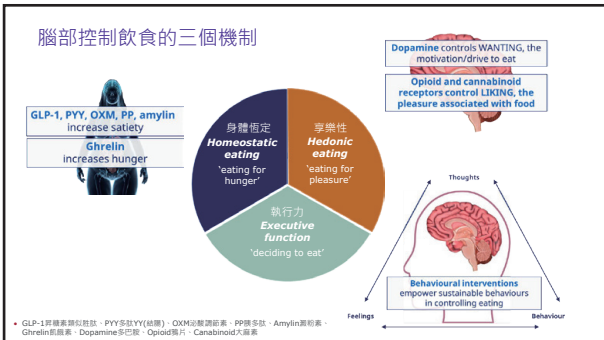
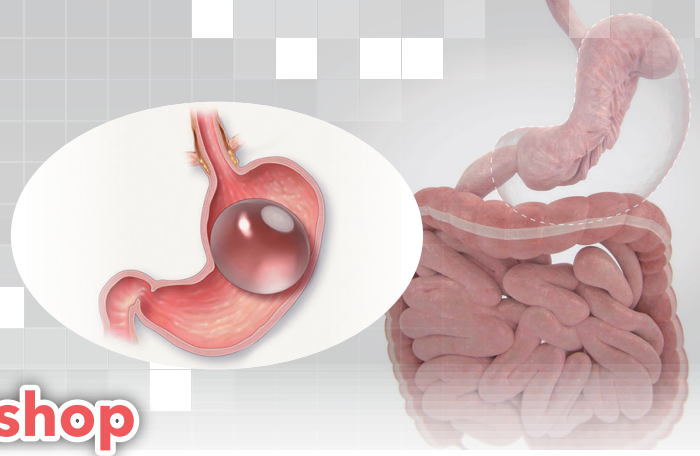
SPECIALIZED 建議等級	臨床建議內容
1A	成人 BMI 大於 30 kg/m ² 或 BMI 大於 27 kg/m ² 且至少有一種合併症 (高血壓、第二型糖尿病或血脂異常等)。 (強建議，證據等級高)
2B	成人 BMI 大於 30 kg/m ² 或 BMI 大於 27 kg/m ² 且至少有一種合併症 (高血壓、第二型糖尿病或血脂異常等)。 (弱建議，證據等級低)
1B	成人 BMI 大於 30 kg/m ² 或 BMI 大於 27 kg/m ² 且至少有一種合併症 (高血壓、第二型糖尿病或血脂異常等)。 (強建議，證據等級低)
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成人肥胖治療指引 | 2018



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美國藥物食品管理局允許上市的減重藥物

藥物種類	作用機制
胰臟脂肪酶分解抑制劑	如Orlistat(Xenical)可減少腸道內脂肪分解酶作用且無中樞神經的作用,約可減少體重 2.5-3.4公斤。
擬交感神經作用藥	如芬特明 (Phentermine) 可降低食慾,增加靜息時間的能量消耗,但有增加血壓、心跳等類似安非他命興奮劑的風險,另外芬特明及托必拉美 (Phentermine-Topiramate) 的複方劑可抑制食慾產生飽足感,常見副作用有感覺異常、頭暈、味覺障礙、失眠、便秘及口乾。
鴉片拮抗劑/氨基酮抗抑鬱藥組合	Bupropion是非典型抗憂鬱劑, naltrexone是單純鴉片類受體拮抗劑, bupropion/naltrexone 如 Contrave, 藉由增加下視丘促黑素皮質素神經元 (食慾調節中心) 的放電速率來調節減少食物的攝取,可減2-4公斤,常見副作用有噁心、頭痛及便秘等。
類升糖素拮抗-1 受體的促效劑	如Liraglutide 3mg、Semaglutide 2.4mg相較於安慰劑組約可下降6.2-16.0%的體重。此類藥物可以減緩胃排空,增加飽足感以及降低食慾,進而減少個人糖類的攝取與吸收,同時達到控制血糖及減輕體重的效果。

Black, S. M., et al. (2020). "Using a New Generation for the Management of Obesity." *Pharmacotherapy*, 40(5), 575-578.

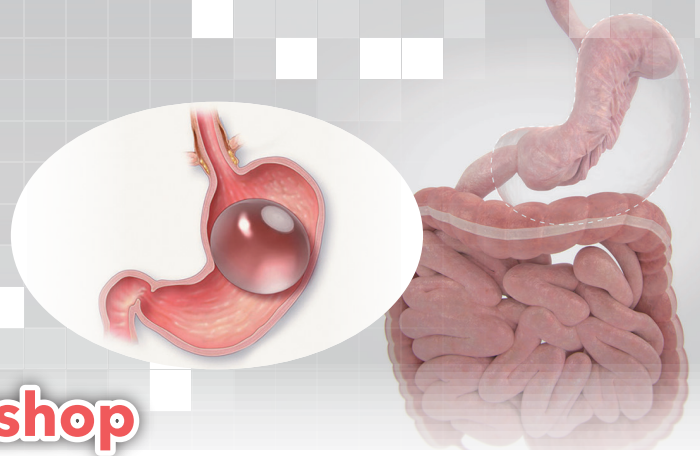
Arora, S., et al. (2021). "Systematic Review of Weight Loss and Health Outcomes in Adults." *Pharmacotherapy*, 41(1), 1-10.

Wadden, T. A., et al. (2021). "Effect of Subcutaneous Semaglutide in Patients with an Atherogenic Metabolic Profile: Results from the STEP 1 Randomized Clinical Trial." *Diabetes Care*, 44(1), 1-10.

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Regulatory Status of Incretin-based Therapies

	USA	EU	TAIPEI
T2DM			
Liraglutide	V	V	V
Dulaglutide	V-4.5mg	V-4.5mg	V-1.5mg
Semaglutide	V-2.0mg	V-2.0mg	V-1.0mg
Oral Semaglutide	V	V	V
Tirzepatide	V		
Obesity			
Liraglutide	V	V	V
Semaglutide	V	V	
Oral Semaglutide			
Tirzepatide			

藥物治療 (TFDA核可)

成分/含量	Naltrexone/Bupropion 8/90 mg	Orlistat 120 mg	Liraglutide 6 mg/mL
商品名	Contrave	XENICAL	Saxenda
用法用量	目標劑量為每日口服兩次，一次口服 8/90 mg 錠劑	每日口服三次，每次 60 或 120 mg	每日皮下注射，起始劑量 0.6 mg，以每週增加 0.6 mg 至目標劑量 3 mg
TFDA 核准適應症	CONTRACE 作為低熱量飲食與增加體重之輔助療法，用於以下初始身體質量指數 (BMI) 之成人長期體重管理： • 30 kg/m ² 或超過 (肥胖)；或 • 27 kg/m ² 或超過 (體重過重) 且至少有一項相關臨床併發症 (如高血壓、第二型糖尿病或血脂異常)。	成人，配合低卡減量飲食，適合肥胖患者之治療，包括有與肥胖相關危險因子之青少年。 青少年，對於肥胖青少年，只有體重 6歲以上患者治療方式(包括體重指數過高的青少年及體重增加行為的運動計畫)失敗時才可使用 orlistat 治療。	用於體重控制，作為低熱量飲食及增加體能活動之輔助療法。適用於成人與大兒童長期體重管理 (BMI) 為： • ≥ 30 kg/m ² 或 • ≥ 27 kg/m ² 且 ≥ 30 kg/m ² ，且成人至少有一項相關臨床併發症，例如第二型糖尿病、高血壓或血脂異常。 以每天 3.0 mg 劑量 12 週後，若病人長期體重並未減輕至少 5%，應停止繼續治療。
FDA 核准	2014 年	1999 年	2014 年
EMA 核准	2015 年	2012 年	2015 年
TFDA 核准	2022 年	2000 年	2020 年

Orlistat (120mg) XENICAL 羅氏鮮

- 2000年TFDA核可上市膠囊。
- 為Pancreatic lipase inhibitors (胰脂酶抑制劑)，減少小腸對食物中脂肪分解，及被吸收，並經腸道排出。
- 可減重及改善血糖、膽固醇、三酸甘油酯及血壓。
- 常見副作用有忍不住的便意、放屁漏油便、脹氣。由於降低脂肪吸收，影響脂溶性維生素 (A、D、E、K、β胡蘿蔔素) 的吸收，長期服用時，宜補充脂溶性維他命。
- 禁用於懷孕、膽汁淤積、腸道吸收不良、及草酸鈣腎結石患者。

Liraglutide (3.0mg) SAXENDA 善鮮達 (俗稱:瘦瘦筆)

- 預填式注射減重筆，主成分GLP-1 agonist，是一種腸道質爾蒙，能活化胰臟β細胞，刺激胰島素分泌，降低血糖，也能抑制胰臟α細胞分泌胰素，降低肝臟糖質新生。當初Liraglutide (1.2、1.8mg Victoza @胰安善) 發明用於治療T2DM，FDA 2010年核准。
- 作用在調節食慾的下視丘，可降低食慾；延遲胃排空，增加飽足感；臨床研究發現有減重效果，其實隨著血糖變化才作用，不易引起低血糖，故適合為慢性體重管理藥物。
- 2015年美國FDA批准Liraglutide 3.0mg(劑量較高)用於非糖尿病者的減重，減重效果優於Orlistat，可改善心臟代謝風險指標，TFDA 2020年核准。
- 禁忌於≤18歲、懷孕、哺乳中、膽囊炎、胰臟炎、個人或家族有甲狀腺髓質癌病史、多發性內分泌腫瘤症候群。
- 台灣市面上兩種劑型皆有。

Glucagon-like peptide-1 (GLP-1)

- An incretin hormone secreted from enteroendocrine L cells
- to decrease BG levels in a glucose-dependent manner by enhancing the secretion of insulin.
- GLP-1 reduces circulating levels of glucose via stimulating insulin secretion.
- It also acts by inhibiting glucagon secretion, thus reducing endogenous glucose production, reducing food intake and slowing gastric emptying

使用Saxenda® 的患者在1年試驗期間減輕且維持體重1

72% 服用使用 Saxenda® (Liraglutide) 的體重增加者 64% 服用安慰劑的體重增加者 (N=1244)¹

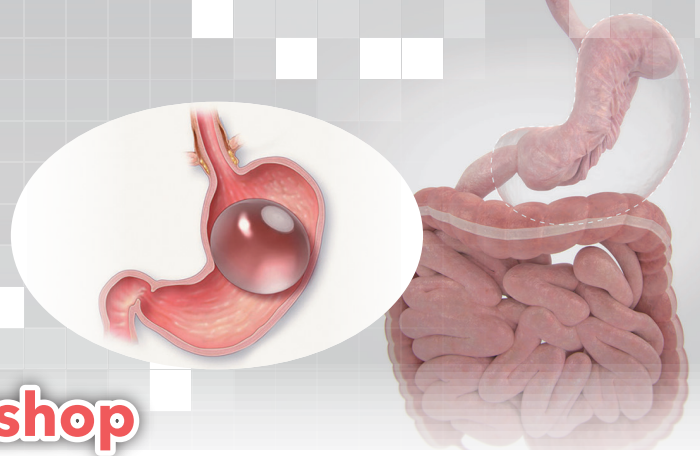
接受Saxenda® 治療的標準：平均體重減輕 減少 8.2 cm，而使用安慰劑的標準則減少 3.9 cm (P < 0.001) ^{1,2}

1. 減重目標是真正的健康又安全安心，那麼為什麼 Saxenda® 讓我瘦了十斤呢？

SARAH | Age: 43 | BMI: 37
併發症: 高血壓、認知性障礙及

1st

Endoscopic Bariatric and Metabolic Therapies Workshop



Semaglutide (2.4m) Wegovy (台灣尚未引進)

- 亦屬於GLP-1受體促劑，但為長效性，每周一次皮下注射劑。
- 目前市面上可見的Semaglutide (0.5、1.0mg Ozempic胰受讚)，TFDA只核准於治療T2DM病患。其不論在降血糖或減重效果，都優於Liraglutide (1.2mg、1.8mg)。但目前Ozempic尚未取得TFDA核准用作肥胖治療，若在國內用於減重，是屬於仿單標示外使用。
- 2021年6月美國FDA核准Semaglutide (2.4mg 劑量較高)用於非糖尿病者的肥胖治療，可改善心臟代謝風險指標(血糖、血脂、CRP)。
- 常見副作用噁心、嘔吐、腹瀉、便秘，偶見膽囊相關(結石、發

Bupropion/Naltrexone (8 / 90) Contrave

為Dopamine, serotonin, Norepinephrine reuptake inhibitors/opioid receptor antagonist (類抗憂鬱劑/鴉片拮抗劑)，可增加多巴胺及正腎上腺素的活性，抑制食慾，增加能量消耗，減少誘食。

CONTRAVE 可減少飢餓感與降低食物渴望

CONTRAVE

CONTRAVE 持續性釋放錠

- Naltrexone hydrochloride 8 mg
- Bupropion hydrochloride 90 mg

適應症和用途

CONTRAVE 作為低熱量飲食與增加體能活動之輔助療法，用於以下初始身體質量指數 (BMI) 之成人長期體重管理：

- 30 kg/m² 或超過 (肥胖)，或者
- 27 kg/m² 或超過 (體重過重) 且患有至少一項體重相關共病 (如高血壓、第二型糖尿病或血脂異常)。

使用限制

- CONTRAVE 對於心血管致病率和死亡率的影响尚未確立。
- CONTRAVE 併用其他減重產品 (包括處方藥、非處方藥及草藥製劑) 時的安全性及有效性尚未確立。

CONTRAVE 臨床試驗

	COR-I ¹ N = 1,742	COR-II ² N = 1,496	COR-BMOD ³ N = 793	COR-DM ⁴ N = 505
發表期刊/年份	Lancet, 2010	Obesity, 2013	Obesity, 2011	Diabetes Care, 2013
研究設計	為期 56 週，安慰劑對照，包含 3 種的劑量遞增 (COR-I 試驗主要試驗終點在第 28 週)			
研究族群	BMI 30-45 kg/m ² BMI 27-45 kg/m ² (高血壓和/或血脂異常)			BMI 27-45 kg/m ² - 伴隨第二型糖尿病
飲食與生活型態調整	低熱量飲食和體力活動		強化 BMOD	低熱量飲食和體力活動
劑量	NB16 和 NB32		NB32	
隨機分派	1:1:1	2:1	3:1	2:1
共同主要試驗終點	<ul style="list-style-type: none"> 體重自基線 (baseline) 的變化百分比 總體重減輕 ≥ 5% 的受試者比例 			

COR-I NB32 相比安慰劑可使體重顯著降低

體重變化

治療第 56 週總體重減輕率 ≥ 5%、10%、15%

總體重減輕率	Placebo	NB16	NB32
≥ 5%	14	39	48
≥ 10%	7	20	25
≥ 15%	2	9	12

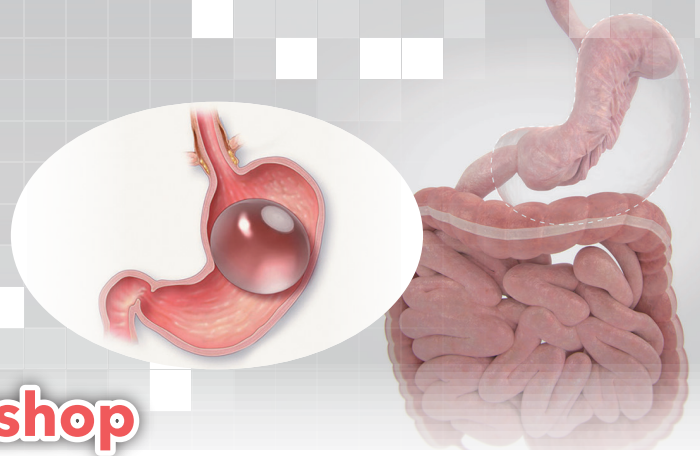
COR-I NB 組改善飲食控制和減少食物渴望效果較佳

第 56 週飲食控制問卷結果

NB16: Naltrexone 16 mg + Bupropion 360 mg daily
 NB32: Naltrexone 32 mg + Bupropion 360 mg daily
 *p < 0.05 compared with placebo.

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CONTRACE 常見不良反應

- 雖有常見副作用，但大多會在開始治療後 4 週內緩解²
- 建議病人還在週末開始服用，並採取緩解措施，如補充水分、少量多餐等
- 噁心副作用與 CONTRACE 造成之體重下降無關²

臨床試驗中噁心副作用的發生時間與嚴重度²

噁心/嘔吐 (12.2%)

便秘 (15.2%)

頭痛/頭暈 (9.9-17.6%)

失眠 (9.2%)

口乾 (6.1%)

CONTRACE 禁忌症

未受控制的高血壓
(請參閱仿單說明書和注意事項 (5.3))

有痛風症或痛風發作的病史
(請參閱仿單說明書和注意事項 (5.3))

已知有中樞神經系統藥物
(請參閱仿單說明書和注意事項 (4.3))

已知有肝腎症病史
(請參閱仿單說明書和注意事項 (4.3))

對 CONTRACE 的任何成分過敏
(請參閱仿單說明書和注意事項 (5.6))

嚴重肝功能不全
(請參閱仿單說明書和注意事項 (4.3))

使用其他含 bupropion 的藥品
(4)

長期使用鴉片類或鴉片類之受效劑或部分受效劑
(請參閱仿單說明書和注意事項 (5.4) 以及藥物交互作用 (7.2))

目前突發的停用酒精、benzodiazepine 類藥物、barbiturate 類藥物、抗焦慮藥物
(請參閱仿單說明書和注意事項 (5.3) 以及藥物交互作用 (7.2))

使用單胺氧化酶抑制劑 (MAOI)
(請參閱仿單說明書和注意事項 (4.3) 以及藥物交互作用 (7.2))

CONTRACE 注意事項 (1/2)

自殺	<ul style="list-style-type: none"> • CONTRACE 含有 bupropion，這是與某些抗憂鬱藥物相同的活性成分。 • 在短期試驗中，抗憂鬱藥物會提高兒童、青少年與年輕人出現自殺想法和行為的風險。¹ (請參閱仿單說明書和注意事項 (5.1))
戒菸治療中的神經精神性不良事件及自殺風險	<ul style="list-style-type: none"> • 過去在使用 bupropion 戒菸的病人中曾發生嚴重神經精神性不良事件。 • 包括情緒變化 (如憂鬱和躁症)、攻擊、殺人衝動、驚悸、焦慮和恐慌，以及自殺意念、自殺嘗試和自殺成功等。¹ (請參閱仿單說明書和注意事項 (5.2))
痲瘋發作	<ul style="list-style-type: none"> • Bupropion 可導致痲瘋發作。痲瘋發作的風險具有劑量相關性。 • 臨床試驗接受 CONTRACE 的病人中，痲瘋發作的發生率約為 0.1%，而安慰劑組為 0%。¹ (請參閱仿單說明書和注意事項 (5.3))
接受鴉片類止痛劑	<ul style="list-style-type: none"> • 鴉片類用藥過量的易感性：CONTRACE 由於含有 naltrexone 成分 (屬於鴉片類受體拮抗劑)，因此不應用於長期使用鴉片類藥物的病人。 • 如需實施長期鴉片類療法，應停用 CONTRACE 治療。¹ (請參閱仿單說明書和注意事項 (5.4) 以及藥物交互作用 (7.2))
血壓和心跳速率的上升	<ul style="list-style-type: none"> • CONTRACE 可導致收縮壓和/或舒張壓上升，以及休息時心跳速率的上升。 • 在接受含 bupropion 藥品於臨床試驗期間中曾發生過低血壓，而且部分案例嚴重且需要急性治療。¹ (請參閱仿單說明書和注意事項 (5.3))

CONTRACE 注意事項 (2/2)

過敏反應	<ul style="list-style-type: none"> • 在 bupropion 的臨床試驗中，曾通報較為瘙癢、痲瘋疹、血管性水腫和呼吸困難等症狀且需要治療的全身性過敏/全身性過敏反應。¹ (請參閱仿單說明書和注意事項 (5.6))
肝毒性	<ul style="list-style-type: none"> • 曾在接受 naltrexone 劑量到肝功和有臨床意義之肝功不全的案例。 • 也曾觀察到嗜食、無症狀的肝臟轉氨酶上升現象。¹ (請參閱仿單說明書和注意事項 (5.7))
躁症的活化	<ul style="list-style-type: none"> • Bupropion 抗憂鬱治療可使躁症、混合型或雙相性事件突然出現。 • 此風險似乎在接受治療病人或有躁症危險因子的病人中較高。¹ (請參閱仿單說明書和注意事項 (5.8))
兩角閉鎖型青光眼	<ul style="list-style-type: none"> • Bupropion 等多種抗憂鬱藥物發生的取藥作用，可能在解剖學上兩角狹窄且沒有構造之紅膜切口的病人中，誘發兩角閉鎖型。¹ (請參閱仿單說明書和注意事項 (5.9))
接受抗糖尿病藥物的第二型糖尿病病人發生低血糖的潛在風險	<ul style="list-style-type: none"> • 在接受與曲酸和/或磺胺基分泌促進劑 (如 sulfonylureas 類) 治療的第二型糖尿病病人中，體重減輕可能提高低血糖的發生風險。 • 針對第二型糖尿病病人，建議定期測量血糖濃度。¹ (請參閱仿單說明書和注意事項 (5.10))
藥物導致之紅斑性狼瘡	<ul style="list-style-type: none"> • 發生頻率未知，曾通報服用後出現疑似皮膚紅斑性狼瘡和系統性紅斑性狼瘡發作之不良反應。¹ (請參閱仿單說明書 (6.1))

Phentermine/Topiramate (台灣未上市)

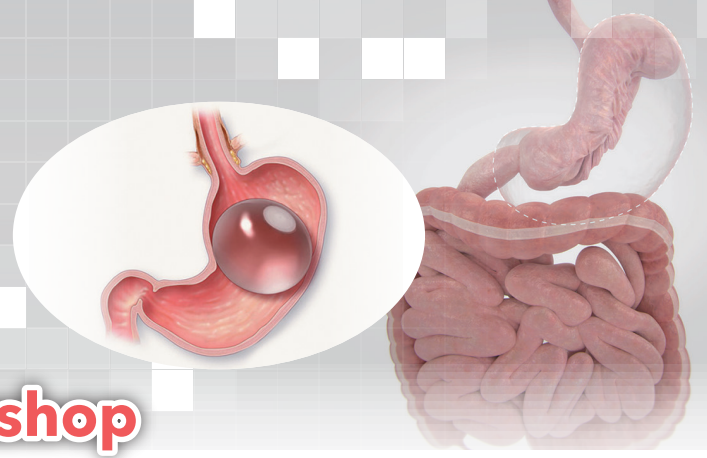
- 美國 FDA 已核上市，但 TFDA 未核可。
- 屬正腎上腺素促進素/抗癲癇藥，可抑制食慾。
- 不建議用於高血壓、冠心病、青光眼、孕婦。副作用為心悸、感覺異常、憂鬱焦慮、注意力不集中
- TFDA 的其他減重藥物尚有：

Anti-obesity Medications in people with T2D and obesity or overweight

Medication	Mechanism of action	≥52 Week Data in people with T2D ^{a†}	
		PBO adjusted effect on HbA1c ^a	PBO adjusted effect on Weight ^a
Orlistat ^a	Inhibitor of gastric and pancreatic lipases	-0.34%	-2.6%
Lorcaserin ^b (Withdrawn from market in Feb 2020 ¹)	5-HT _{2c} receptor agonist	-0.5%	-3%
Phentermine-Topiramate ^c	TAAR1 agonist + anticonvulsant (Sodium channel blocker)	-0.56%	-6.9%
Naltrexone-bupropion ^d	Opioid receptor antagonist + dopamine, serotonin and norepinephrine reuptake inhibitor.	-0.5%	-2%
Liraglutide 3.0 mg ^e	GLP-1 receptor agonist	-0.2%	-3.9%
Semaglutide 2.4 mg ^f	Glucagon-Like Peptide-1 Receptor agonist	-1.2%	-6.2%

SHT2c = 5-Hydroxytryptamine 2c; TAAR1 = Trace amine associated receptor 1; GLP-1 = Glucagon-like peptide-1; PBO = placebo.
^a PBO = placebo controlled release.
^b FDA/EMA/Health Canada (naltrexone-bupropion) was a 6-week trial. (SHT2c) 2 mg daily (semaglutide 2.4 mg) are reported at 68 weeks.
^c Xarelto® Prescribing Information 2018. Last accessed July 2020.
^d Bupropion Prescribing Information May 2017. Last accessed July 2020. (data shown for 20 mg dose)
^e Ozempic® Prescribing Information, March 2018. Last accessed July 2020 (data shown for 3.0 mg/48 mg)
^f Contrave® Prescribing Information, June 2018. Last accessed July 2020 (data shown for 152 mg/300 mg)
[†] Saxenda® Prescribing Information March 2020. Last accessed July 2020
¹ WEGOVY® Prescribing Information, July 2020
 1. <https://www.fda.gov/oc/ovp/ovp-obesity-safety-and-efficacy-requests-withdrawn>

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Medication name	Typical adult maintenance dose	Average wholesale price (US \$/day supply) (N=30)	National Average Drug Acquisition Cost (US \$/day supply) (N=30)	Treatment arms	Weight loss (%, loss from baseline)	Common side effects (132-136)	Possible safety concerns/considerations (132-136)
Short-term treatment (12-16 weeks) bupropion/naltrexone (Xencon)	8-37.5 mg q.d.	\$5-\$44 (37.5 mg dose)	\$9 (37.5 mg dose)	15 mg q.d. 7.5 mg q.d. PBO	6.1 3.3 1.1	Dry mouth, insomnia, dizziness, increased blood pressure, increased heart rate	• Contraindicated for use in combination with monoamine oxidase inhibitors
Long-term treatment (32-52 weeks) liraglutide (Saxenda)	60 mg b.i.d. (30T2) 120 mg b.i.d. (60T2)	\$41-\$82 \$43	\$41 \$50	120 mg b.i.d. PBO	5.6 3.6	Abdominal pain, flatulence, heart urgency	• Potential malabsorption of fat-soluble vitamins (A, D, E, K) • GI (constipation, nausea, vomiting, acid reflux, flatulence, abdominal pain, diarrhea, etc.) • Risk of acute liver injury • Cholelithiasis • Dehydration • Contraindicated for use in combination with monoamine oxidase inhibitors
Long-term treatment (32-52 weeks) semaglutide (Wegovy)	2.4 mg once weekly	\$1,639	\$1,302	2.4 mg weekly PBO	9.6 3.4		• Gastrointestinal side effects (nausea, vomiting, diarrhea, esophageal reflux, injection site reactions, elevated heart rate, hypoglycemia) • Pancreatitis has been reported in clinical trials but causality has not been established. Discontinue if pancreatitis is suspected. • Use caution in patients with history of acute pancreatitis. • Risk of thyroid C-cell tumors in rodents; human relevance not determined. Black box warning: • Risk of thyroid C-cell tumors in rodents; human relevance not determined.
Dual antihypertensive/metabolic combination nephazodol (Xenlyze)	15 mg/180 mg b.i.d.	\$284	\$271	15 mg/180 mg b.i.d. PBO	5.0 1.8	Constipation, nausea, headache, insomnia, elevated heart rate and blood pressure	• Contraindicated in patients with uncontrolled hypertension and/or serum albuminuria. • Acute angle-closure glaucoma • Black box warning: Monitor in patient younger than 28 years old who have depression.

Medication name	Typical adult maintenance dose	Average wholesale price (US \$/day supply) (N=30)	National Average Drug Acquisition Cost (US \$/day supply) (N=30)	Treatment arms	Weight loss (%, loss from baseline)	Common side effects (132-136)	Possible safety concerns/considerations (132-136)
Long-term treatment (32-52 weeks) tirzepatide (Zepbound)	3 mg q.d.	\$1,639	\$1,296	3.0 mg q.d. 1.8 mg q.d. PBO	6.0 4.9 2.0		• Gastrointestinal side effects (nausea, vomiting, diarrhea, esophageal reflux, injection site reactions, elevated heart rate, hypoglycemia) • Pancreatitis has been reported in clinical trials but causality has not been established. Discontinue if pancreatitis is suspected. • Use caution in patients with history of acute pancreatitis. • Risk of thyroid C-cell tumors in rodents; human relevance not determined. Black box warning: • Risk of thyroid C-cell tumors in rodents; human relevance not determined.

Agents	Phase	Outcome measures	Total number
GLP-1R agonists	Phase I	FX/active	NCT02339363
GLP-1R/agonists	Phase I	FX/active & HxAb	NCT02870333
GLP-1R/agonists	Phase I	FX/active & bupropion	NCT02949392
GLP-1R/agonists	Phase I	FX/active	NCT02566723
GLP-1R/agonists	Phase II	A bodyweight; 0.5% and 1.0% bodyweight loss	NCT02568330
GLP-1R/agonists	Phase II	FX/active	NCT02599793
GLP-1R/agonists	Phase II	FX/active	NCT02565098
GLP-1R/agonists	Phase II	A bodyweight; 0.5%, 1.0%, and 1.5% bodyweight loss	NCT02563977
GLP-1R/agonists	Phase II	A bodyweight; 0.5%, 1.0%, and 1.5% bodyweight loss & HxAb	NCT02563977
GLP-1R/agonists	Phase II	A bodyweight; 0.5%, 1.0%, and 1.5% bodyweight loss & FX/active & HxAb	NCT02563977
GLP-1R/agonists	Phase II	A bodyweight; 0.5%, 1.0%, and 1.5% bodyweight loss & FX/active & HxAb & bupropion	NCT02563977
GLP-1R/agonists	Phase II	A bodyweight; 0.5%, 1.0%, and 1.5% bodyweight loss & FX/active & HxAb & bupropion	NCT02563977
GLP-1R/agonists	Phase II	A bodyweight; 0.5%, 1.0%, and 1.5% bodyweight loss & FX/active & HxAb & bupropion	NCT02563977

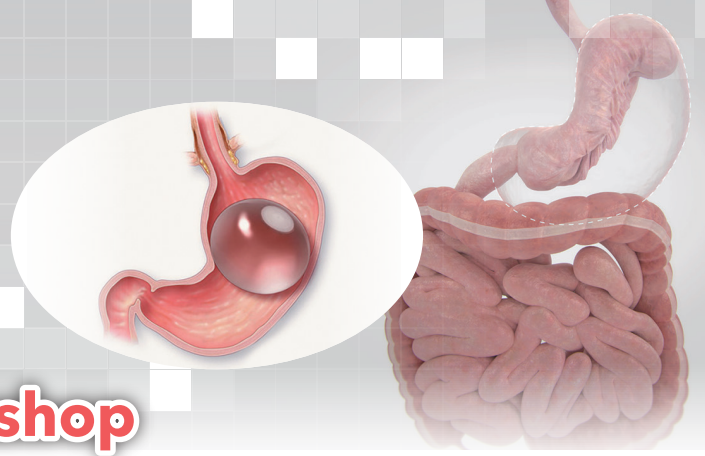
Percentage change bodyweight loss (95% CI)	Participants with bodyweight loss (%) (95% CI)	Quality of life score (95% CI)	Digestion symptom score (95% CI)	Discontinuation due to adverse events (%) (95% CI)	Total gastrointestinal adverse events (%) (95% CI)
11.8 (9.2-14.4)	81.2 (79.2-83.2)	0.48 (0.38-0.58)	0.07 (0.03-0.11)	2.0 (1.3-2.7)	5.8 (4.3-7.3)
8.1 (6.5-9.7)	61.2 (59.2-63.2)	0.38 (0.28-0.48)	0.23 (0.19-0.27)	2.0 (1.3-2.7)	4.2 (2.7-5.7)
3.9 (2.3-5.5)	31.2 (29.2-33.2)	0.28 (0.18-0.38)	0.48 (0.44-0.52)	1.3 (0.6-2.0)	2.7 (1.2-4.2)

Take home message

- 目前我國核准適用於肥胖治療的藥物且有長期療效之證據的有三種: Orlistat, Bupropion/Naltrexone(Contrave) 及 Liraglutide 3.0 mg (Saxenda)
- 目前坊間尚有如下非適應症性的藥品作為減重用藥, 包括消滯藥、麻黃素、抗憂鬱劑、利尿劑、降血糖藥、降血脂藥、甲状腺素、纖維等, 其主要用途及適應症, 並非衛生福利部核准用於減重, 因此, 利用上述等藥品於減重, 係屬於藥品「仿單核准適應症外的使用」。依衛生福利部 2002 年公告之「仿單核准適應症外的使用原則」不建議使用, 以共同保障病人用藥權益。
- 即使減重的需求與市場雖大, 長期使用減重藥物的安全性, 仍應被重視。
- 民眾務必使用合法處方藥物, 若私自購買仿單標示外使用藥物, 或逕自國外代購, 易忽視藥物安全性、副作用及交互作用; 若出現嚴重危害時, 無法取得藥毒救濟。

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Metabolic Therapies Workshop**



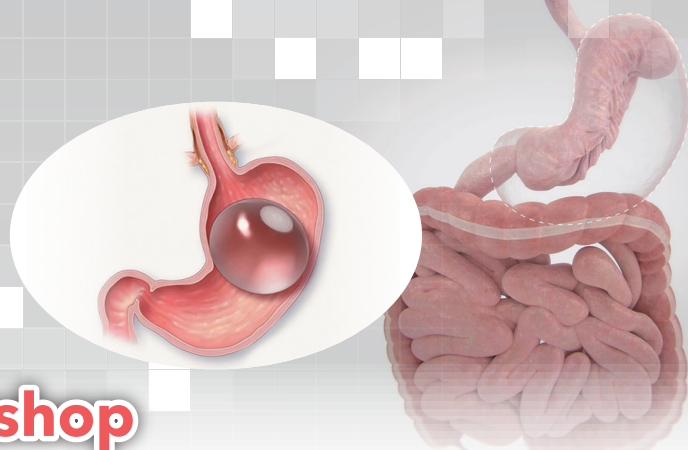
09:10-09:25

**Dietary approaches to obesity
management**

Speaker: 周佳慧 營養師

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Endoscopic Bariatric and Metabolic Therapies Workshop 1

Dietary approaches to obesity management

亞東紀念醫院 周佳慧營養師

▶ Outlines 2

1. Dietary recommends of obesity
2. Dietary recommends of post bariatric surgery
3. Nutritional care of bariatric surgery patients in FEMH Fit Center

▶ Outlines 3

1. Dietary recommends of obesity
2. Dietary recommends of post bariatric surgery
3. Nutritional care of bariatric surgery patients in FEMH Fit Center

Public Health England

Obesity harms health

Public Health England, 2022

▶ Treatment approaches to obesity 5

MeikeWiechert and Christina, 2021

▶ Dietary recommends of obesity 6

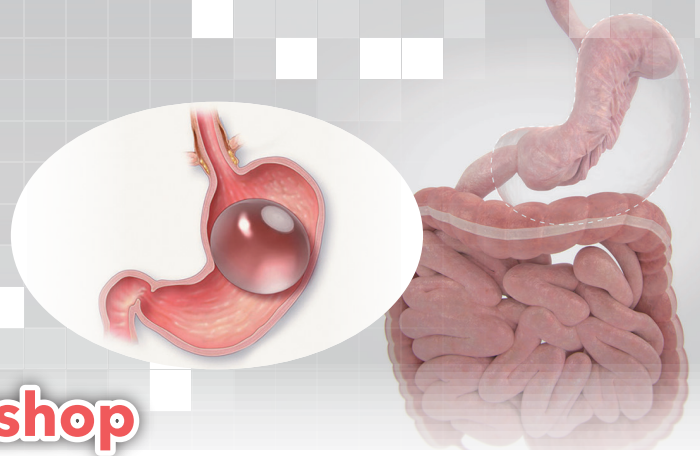
- Combining **reduced calorie intake** and **increased physical activity** for weight loss is more effective than a single approach, and diet-exercise in a lifestyle change approach is more effective.
- **Negative energy balance** is a necessary condition for weight loss. Generally, the principle of losing 0.5 kg/week, reduce caloric intake by 3500 kcal/week, that is, reduce calorie intake by at least 500 kcal/day.

Kirk et al., 2012

Lean & James, 1986

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7 Dietary recommends of obesity

- Specification of an energy intake target that is less than that required for energy balance, usually **1,200 to 1,500 kcal/d for women** and **1,500 to 1,800 kcal/d for men** (kilocalorie levels are usually adjusted for the individual's body weight and physical activity levels) Jensen et al., 2014
- Calorie reduction**
 - ↓ certain food intake (such as high sugar, low fiber or high fat)
 - Use meal replacements.
 - Negative energy balance can be achieved

Raynor & Champagne, 2016

8 Summary findings of dietary modifications for weight loss

Table 2
Summary findings of the studies on dietary modifications for weight loss in overweight and obese adults, published beyond the 2013 AHA/ACC/TOC guidelines

Dietary intervention	Summary of findings
Very low carbohydrate diets	Greater weight loss compared to a moderately energy restricted, and/or a low fat diet.
Low carbohydrate diets	Equal weight loss compared to an isocaloric diet with higher carbohydrate content.
High protein diets	No consistent evidence for a beneficial effect for weight loss and body composition of a high protein intake.
Intermittent fasting/severe energy restriction	No additional benefit on weight loss, compared to the continuous energy restriction.
Meal replacements	Greater weight loss, compared to conventional dietary plans.

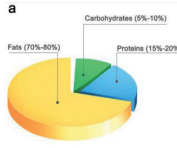
Mary et al., 2019

9 low carbohydrate diet

- Low- or very low-carbohydrate ketogenic diets have been popular in weight management. There is some evidence that these diets maybe associated with **increased satiety** and **decreased hunger** and **desire to eat**, with a **lower decrease** in the **satiety peptide YY** compared to low fat diets. Gibson et al., 2015
- It is possible that the beneficial effects of the low carbohydrate intake observed in most of these trials is the result of a profound **decrease in energy intake**, compared to the control diet, and the concomitant energy deficit that would inevitably produce a greater weight loss. Mary et al., 2019

10 The ketogenic diet

- The KD comprises a **high-fat component**, **very low carbohydrates**, and **adequate proteins**, and has been clinically used since the early 1920s to control seizures in patients with epilepsy, especially those who do not respond adequately to antiepileptic medication.



Diet	Carbohydrate:Protein:Fat Ratio	Notes
Classic KD (Long-chain triglycerides/LCT)	4:1 (0.1-1)	Fat (grams) to protein + carbohydrate (grams)
MCT KD (Medium-chain triglycerides)	30%-60%	Energy from MCT
MAD (Modified Atkins diet)	1:14.5:1	Ketogenic ratio
LGIT (Low glycemic index treatment)	<50	Glycemic indices for carbohydrates


Dowis & Banga, 2021

11 Ketogenic Diet & weight loss

- The interventional weight loss program based on a VLCK (very low-calorie-ketogenic) diet is most effective in **reducing body weight** and **improvement of glycemic control** than a **standard hypocaloric diet** with safety and good tolerance for T2DM patients. A Goday et al., 2016
- When conducted under the supervision of healthcare professionals, a VLCKD (Very low-calorie ketogenic diets) is an **effective and safe treatment for weight loss** in patients with obesity, including those affected by mild kidney failure. Adriano et al., 2020

12 The Mediterranean diet

- The Mediterranean diet**
 - Abundance of **plant-based foods**
 - Moderate intake of **fish and dairy**
 - Low intake of **red meat**
 - Use of **extra virgin olive oil** as the main source of dietary fat
- The **anti-inflammatory** and **anti-oxidant** property of the Mediterranean diet → to promote weight loss and improvement on comorbidities.
- Short term studies: superiority of the **Mediterranean diet over the high-protein diet** in inducing weight loss in obesity. Anuradha et al., 2022



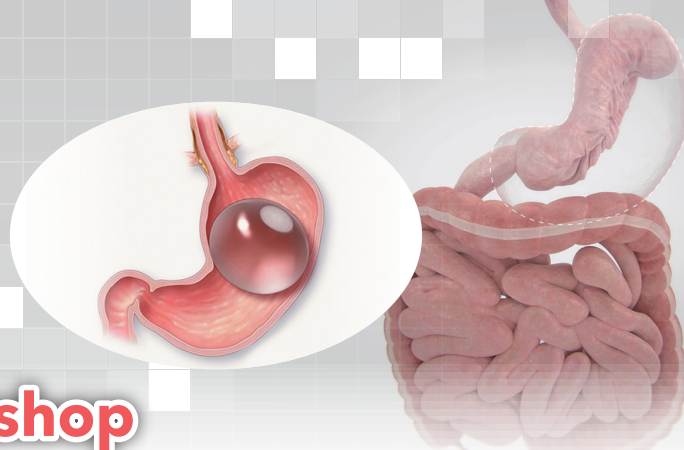
Diets close to the Mediterranean dietary pattern

- Benefits for weight reduction only in the context of a hypo-caloric diet.
- Evidence for other health-enhancing benefits.

Mary et al., 2019

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Meal replacements 13

- A total meal replacement intervention providing 800 kcal daily in obese individuals for 6.5 months led to a greater weight loss, compared to a prescribed low fat dietary plan with an energy restriction of 500–750 kcal.
- Because meal replacements have clear calories, are easy to carry, and eliminate the hassle of food selection and matching, compliance is high and the weight loss effect is remarkable.

Ard et al., 2019
Gibson et al., 2015

Outlines 14

- Dietary recommends of obesity
- Dietary recommends of post bariatric surgery
- Nutritional care of bariatric surgery patients in FEMH Fit Center

Dietary recommends of bariatric surgery 15

- If severely obese patients do not respond to a treatment plan that includes nutritional, exercise, and behavioral interventions plus anti-obesity drugs, bariatric surgery may be appropriate.
- Bariatric surgery**
 - Traditionally for the treatment of severe obesity (BMI ≥ 35 kg/m²)
 - Many studies in recent years have supported that bariatric surgery can be used for mild obesity (BMI > 30 kg/m² or BMI > 27 kg/m²), especially those with poorly controlled T2DM, overt hypoxic heart disease and other obesity-related diseases.

Anuradha et al., 2022
Phyllis and Donna, 2005

Mary et al., 2019
<https://www.hpa.gov.tw/Pages/EBook.aspx?nodeid=1788>

Multidisciplinary care team in endoscopic bariatric therapies 16

Table 2. Multidisciplinary care team and their role in endoscopic bariatric therapies.

Member	Role
Physician	<ul style="list-style-type: none"> Psychiatrist of a multidisciplinary team Determine weight and lifestyle Manage comorbidities and exclude secondary causes of obesity Contraindication for endoscopic bariatric therapy Surgeon for bariatric surgery
Dietician	<ul style="list-style-type: none"> Laying the foundation for dietary change Assessment of patient's diet Plan simple effective diet strategies Propose tailored dietary regime for weight loss before and after EBTs
Clinical psychologist	<ul style="list-style-type: none"> Mentally preparing the patient Identify psychosocial factors and barriers contributing to obesity Motivational interviewing and goal setting Managing expectations Cognitive restructuring Relapse prevention
Physical therapist	<ul style="list-style-type: none"> Integrating physical activity into healthy lifestyle Assessment of patient's physical condition Plan realistic and achievable goals Propose tailored exercise regime for weight loss before and after EBTs
Specialist nurse/ case manager	<ul style="list-style-type: none"> Keeping the patient involved Re-educate patient pre- and post-EBT Encourage tracking patient's progress Encourage communication between team members Schedule counseling sessions
Pharmacist	<ul style="list-style-type: none"> To work with physicians on optimizing pharmacological therapy for weight loss

Anuradha et al., 2022

Dietary recommends of bariatric surgery 17

- Proper diet selection after bariatric surgery involves more than the energy and macronutrient composition. Adequate vitamin and mineral composition of the diet is essential to ensure that surgery improves nutritional status.
- Malabsorption is present to some extent with most surgeries. Therefore, diet after surgery should be monitored closely for adequacy by a nutritionist.

Carter et al., 2021

<https://www.hpa.gov.tw/Pages/EBook.aspx?nodeid=1788>

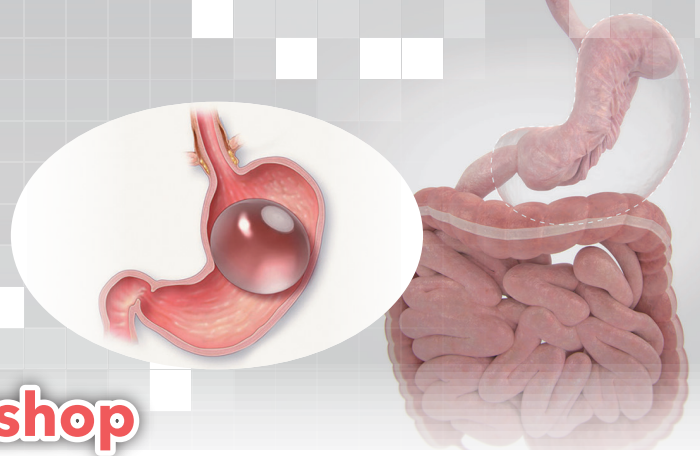
Dietary recommends of bariatric surgery 18

- Bariatric surgery with malabsorption, due to reduced food intake or limited absorption, which can easily lead to vitamins and minerals deficiencies, such as vitamin B1, B12, folic acid, A, D, E, K, Fe, Ca etc.
- Preoperative and postoperative nutritional assessments are recommended, preferably with biochemical tests, so as not to be ignored asymptotically.
- The frequency of postoperative nutritional assessments is recommended every 3 to 6 months for the first year and annually thereafter.

Mary et al., 2019
Bradley et al., 2016
Kruseman et al., 2010
Colles et al., 2008

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▶ Dietary recommends of bariatric surgery 19

- Initial **progressive dietary guidance**
clear liquid → full liquid → soft diet → solid foods
- Adequate protein intake
- Avoid dehydration
- Ensure vitamin/mineral supplementation
- To deal with **postoperative gastrointestinal symptoms**, such as diarrhea, bloating, vomiting, acid reflux (especially after **gastric sleeve resection** to eat too much or too quickly), dumping syndrome (especially after gastric bypass), food intolerance, dysphagia, constipation ... etc., and establishing healthy eating behaviors.

Nunes et al., 2020
<https://www.hpa.gov.tw/Pages/EBook.aspx?nodeid=1788>

▶ Post-operative attention 20

- Eat small and frequent meals, slow chew food more.
- Drink enough water** (≥ 1.5 L/day or 30 mL/kg/day)
→ eat solid liquids at the same time
→ avoid beverages 15 minutes before and 30 minutes after meals
- Protein intake is **60-80 g/day**, or **1.1-1.5 g/kg** of ideal body weight.
- Bariatric surgery often increases the risk of osteoporosis.
→ gastric acid secretion affects **CaCO₃ absorption**
→ **calcium citrate** supplementation with Vit-D type

Miranda-Peñarroya et al., 2022
Mechanick et al., 2020
Bradley et al., 2016
Canetti et al., 2009

▶ Post-operative attention 21

- After bariatric surgery, there is a high risk group of vitamin B12 deficiency.
→ the lack of gastric acid and intrinsic factors
→ release and absorption of B12 from food protein are affected

Colles et al., 2008

- Iron deficiency** is also common after **gastric sleeve resection** and gastric bypass surgery.
-Especially women of childbearing age should supplement **50-100 mg/d**.
-Consume with **fruit juice** (containing Vit-C) to improve absorption
-Avoid concomitant use with high calcium foods or supplements

Rudolph & Hilbert, 2013

▶ Post-operative attention 22

- Gastric bypass and biliopancreatic bypass surgery or duodenal transposition are prone to **lack of water-soluble B1**
→ Supplemented if persistent vomiting (2~3 times/week).

Anuradha et al., 2022

- Fat-soluble vitamin supplementation** is recommended due to malabsorption of fat after biliopancreatic bypass surgery or duodenal transposition surgery.

Canetti et al., 2009

▶ Post-operative attention 23

- Women who are planning to become **pregnant**
→supplementing enough **folic acid**
→vitamin A supplementation can consider safer β -carotene.

Kruseman et al., 2010

- The principle of **healthy and balanced diet** is the principle of **long-term** postoperative diet.
Patients should be informed that surgery may **reduce physiological hunger**, but it cannot prevent the temptation of external environment.

<https://www.hpa.gov.tw/Pages/EBook.aspx?nodeid=1788>

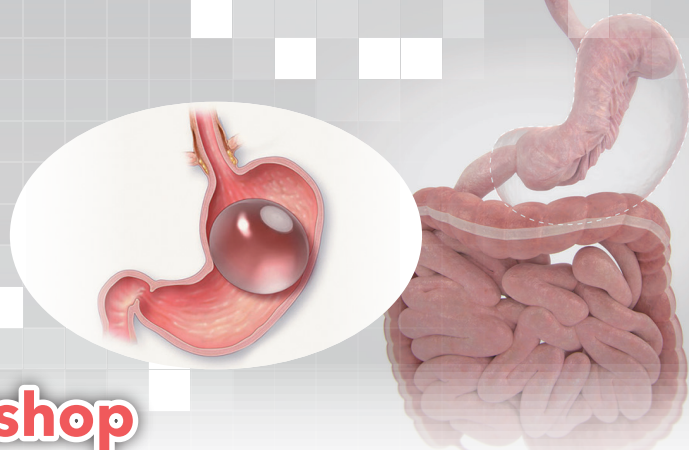
▶ 24

Figure 5. Example of the bariatric plate model based on macronutrient composition with breakfast and lunch options.

Anuradha et al., 2022

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▶ Oral Nutritional Supplements 31

熱量控制

熱量	醣類	蛋白質	脂質	膳食纖維
333大卡	38.5公克	25.6公克	9.0公克	2.4公克

高蛋白補充

熱量	醣類	蛋白質	脂質
127大卡	7.8公克	20.8公克	1.4公克

▶ 衛教經驗分享 32

術後吃麻油龍膽石斑後，為何會腹脹不舒服？

手術後可以照常應酬喝酒嗎？

進展清流質飲食時可以喝雪碧嗎？

術後還可以吃蛋糕、喝含糖飲料嗎？

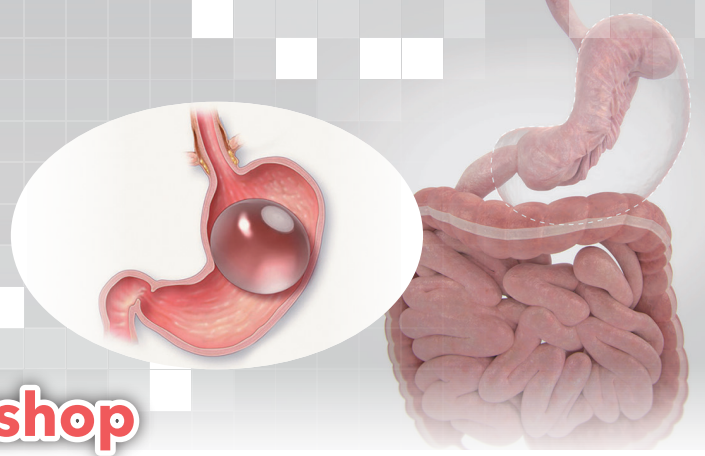
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33

Thanks for your attention!

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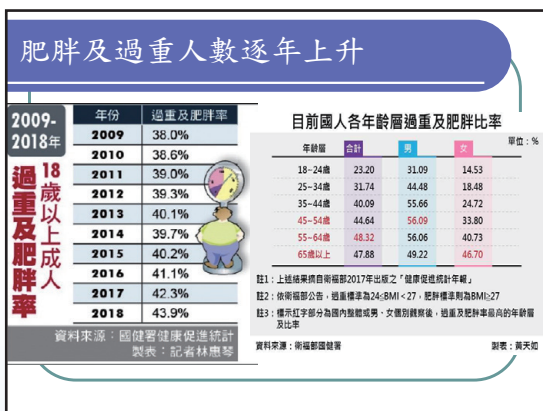
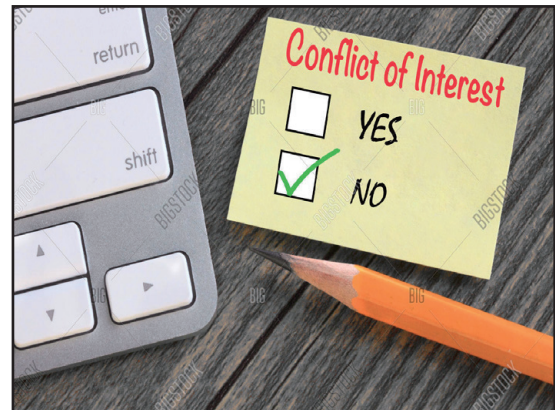
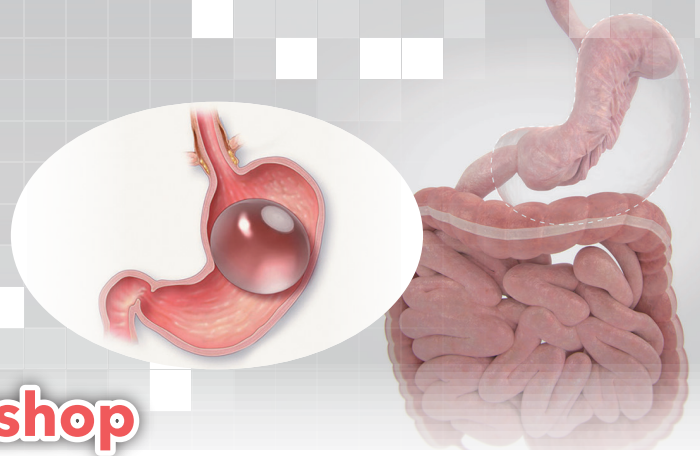
09:25-09:40

**History and rationale of EBMT and
MDT care**

Speaker: 高崧碩 主任

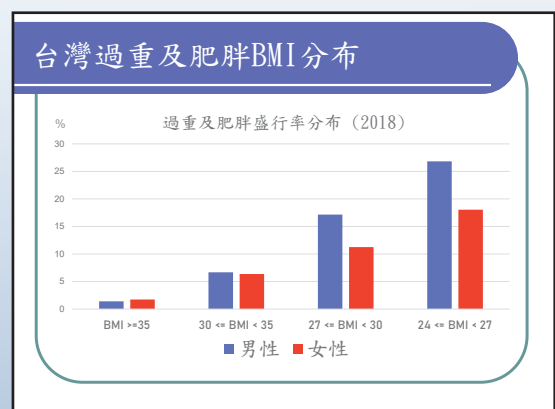
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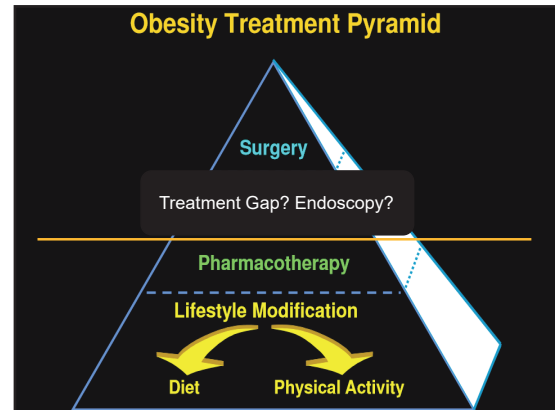
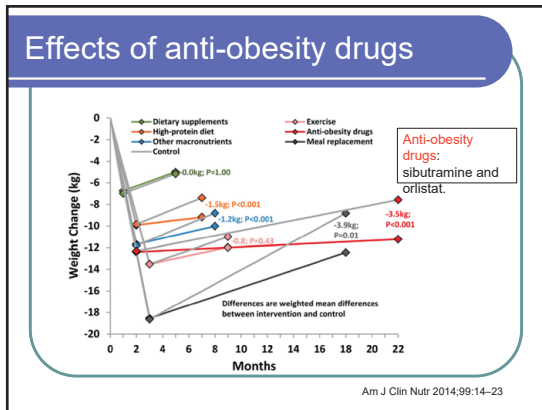
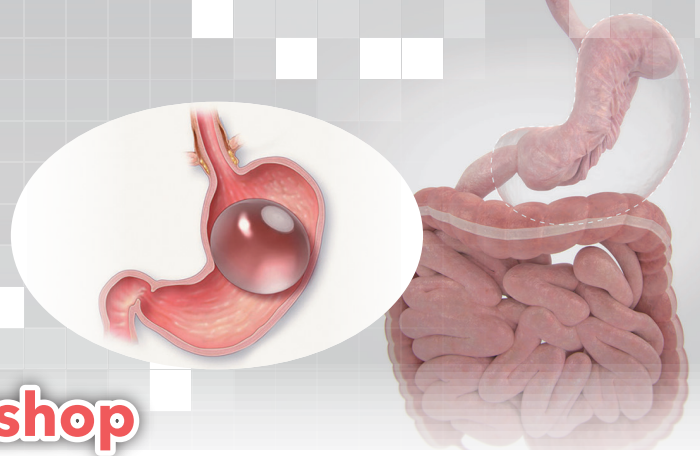
- ### Indications for bariatric surgery
- BMI ≥ 40 , or more than 100 pounds overweight.
 - OR
 - BMI ≥ 35 and at least one or more obesity-related comorbidities such as type II diabetes (T2DM), hypertension, sleep apnea and other respiratory disorders, non-alcoholic fatty liver disease, osteoarthritis, lipid abnormalities, gastrointestinal disorders, or heart disease.
 - Inability to achieve a healthy weight loss sustained for a period of time with prior weight loss efforts.
- Obes Surg 2014;24:42-55

- ### 外科減重手術
- 外科代謝減重醫學會及健保規範下
 - BMI > 37.5
 - OR
 - BMI > 32.5 且合併有**高危險併發症**，如：第二型糖尿病患者其糖化血色素經內科治療後仍7.5%、高血壓、呼吸中止症候群
 - 減重門診半年
 - 才符合外科**開刀**的資格



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The role of endoscopy in bariatric pts

- An important tool for **evaluation**, diagnosis, **management of complications**.

World J Gastroenterol 2014; 20(24): 7777-7784
Mini-invasive Surg 2020;4:47

The *wishes* for endoscopic therapies

- Less **invasive**
- Less **risky**
- Similar or better weight-loss **effect** compared with operation
- Good **durability**
- Easily **performed**
- Patient's **satisfaction**

Gastrointest Endosc. 2015 Sep;82(3):425-38

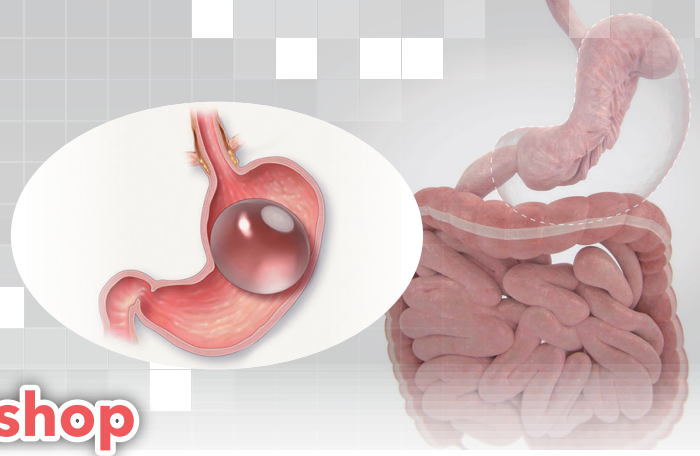
Choices of endoscopic bariatric & metabolic therapies

- Bioenteric Intra-gastric Balloon
- Aspiration therapy
- Endoluminal bypass liners
- Transpyloric shuttle Magnetic compression gastrojejunostomy
- Mucosal resurfacing
- Endoscopic sleeve gastroplasty

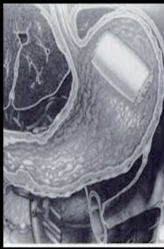
胃内水球 Bioenteric Intra-gastric Balloon

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Garren-Edwards Gastric Bubble



- First obesity device approved by the FDA, on September 17, 1985
- Cylinder-shaped elastomeric polyurethane balloon with a hollow central channel through which fluid/food could pass

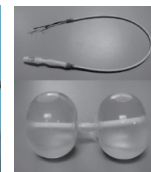
Mini-invasive Surg 2020;4:47



Different types of BIB



Orbera
450-700 ml



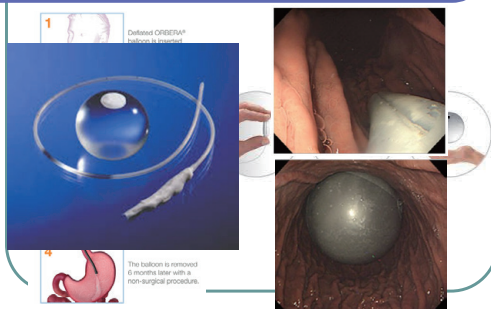
Reshape
Dual System



Obalon
<250 ml gas

Mini-invasive Surg 2020;4:47

Steps of insertion and removal



World J Gastroenterol. 2016;28:22(24): 5495-5504

General Concepts of BIB

- Approved for use in US in 2016 and in Taiwan in 2018
- Most involve endoscopic placement and removal
 - Requires lifestyle changes to be effective
 - Very low complication rates
- 47% delay in gastric emptying
- Removal after 6 months

Indications and Contraindications

Indications

- BMI
 - 27 ~ 35 kg/m² in Europe
 - 30 ~ 35 kg/m² in US
- Failed previous attempts at weight management
- Alternative or bridging intervention for operation

Contraindications

- Previous gastric surgery
- Large hiatal hernia
- UGI bleeding conditions
- Inflammatory GI disease
- Coagulation or liver disorder
- Psychiatric disorder
- Unwilling for lifestyle modification counseling
- Pregnancy

JLS. Jan-Mar 2016;20(1):e2015.00107

Efficacy of Orbera BIB

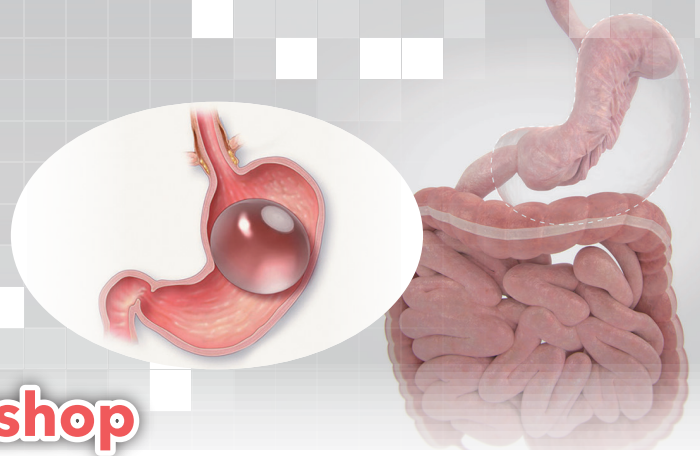
- Favorable weight-loss outcomes with statistical significance
- Over the control group
 - Mean difference in AWL: 7.88 kg
 - BMIL: 2.49 kg/m²
 - %EWL: 25.02%
 - %TWL of 1.62%.



Obesity Surgery (2020) 30:2743-2753

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Aspiration therapy

Concepts of Gastrostomy

- Percutaneous Endoscopic Gastrostomy tubes
 - Used for feeding in patients unable to eat
 - Used for removal of gastric fluid in patients with intestinal obstruction
- AspireAssist System (FDA approved in 2016)
 - Used for Aspiration Therapy: removal of a portion of gastric contents after a meal for weight loss

AspireAssist System (Aspire Bariatrics)

- Indications:
 - BMI of 35 to 55 kg/m² (US)
 - failed to lose weight with non-surgical alternatives.
- Placed using standard pull technique
- Aspirate gastric contents 20~30 mins after meals
- Remove 25~30% of calories

Gastrointest Endosc Clin N Am 2017;27:277-88

Effects of Aspiration therapy (1 year)

N = 137 v.s. N = 70

Am J Gastroenterol. 2017 Mar;112(3):447-457

Aspiration therapy ~ 4 years

Aspiration Therapy As a Tool to Treat Obesity: 1- to 4-Year Results in a 201-Patient Multi-Center Post-Market European Registry Study

	n/N	%TWL	%EWL	AWL (kg)
Year 1	155/173	18.2% ± 9.4%	46.3% ± 26.3%	22.7 ± 13.3
		95% CI 16.7%, 19.7%	95% CI 42.1%, 50.5%	95% CI 20.6, 24.8
Year 2	82/114	19.8% ± 11.3%	48.2% ± 28.2%	25.8 ± 17.3
		95% CI 17.3%, 22.3%	95% CI 42.0%, 54.4%	95% CI 22.0, 29.6
Year 3	24/42	21.3% ± 9.6%	50.3% ± 26.2%	29.1 ± 16.2
		95% CI 17.2%, 25.4%	95% CI 39.2%, 61.4%	95% CI 22.3, 35.9
Year 4	12/30	19.2% ± 13.1%	47.9% ± 36.2%	25.1 ± 19.1
		95% CI 10.9%, 27.5%	95% CI 24.9, 70.9	95% CI 13.0, 37.2

n is the size of the measured protocol population, N is the size of the available population, if no drop-outs or lost to follow-up

Obes Surg. 2018 Jul;28(7):1860-1868

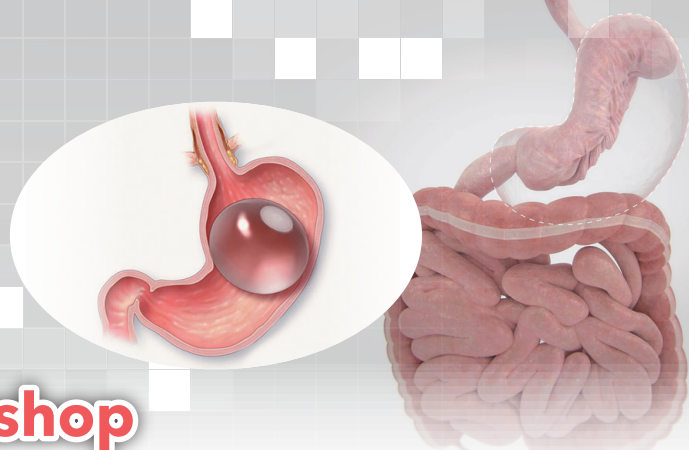
Adverse events of aspiration therapy

Adverse event	No. of participants (n/N)	No. of participants (n/N)	No. of patients (n/N)
Aspiration gastrostomy (AG)	65/201 (32.3%)	0	0
Aspiration gastrostomy (AG) with AspireAssist	42/213 (19.7%)	41	1
Aspiration gastrostomy (AG) without AspireAssist	23/213 (10.8%)	26	3
Intestinal obstruction	18/213 (8.5%)	2	2
Intestinal perforation	18/213 (8.5%)	15	2
Intestinal perforation (without AspireAssist)	18/213 (8.5%)	13	2
Intestinal perforation (with AspireAssist)	0/137 (0%)	0	0
Intestinal perforation (with AspireAssist)	7/82 (8.5%)	1	4
Intestinal perforation (with AspireAssist)	5/62 (8.1%)	4	2
Stomach perforation	1/62 (1.6%)	1	1
Stomach perforation	1/62 (1.6%)	1	1
Stomach perforation	1/62 (1.6%)	1	1
Stomach perforation	1/62 (1.6%)	1	1

Am J Gastroenterol. 2017 Mar;112(3):447-457

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Aspiration Therapy

It should be considered in cases of severe obesity as a **bridge therapy** to more effective weight loss procedures

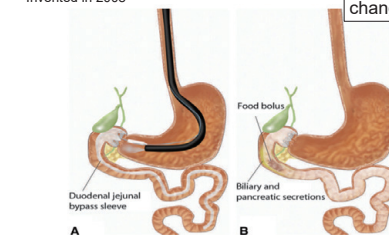


Obesity Surgery (2020) 30:2743–2753

Endoluminal bypass liners

Invented in 2008

mimics the anatomic changes of RYGB



Gastrointest Endosc. 2012 Jul;76(1):1-7

Endoluminal bypass liners

- Under **clinical trial** and yet to be FDA-approved
- **Nitinol** anchor, barbs, retrieval drawstring, impermeable fluoropolymer linear, 2 feet long
- Removal after 12 months



Obesity Surgery (2020) 30:2743–2753

Study Results

- A pilot study in 2008 (n=12)
 - 10/12 maintaining the device for 12 weeks
 - %excess weight loss: 23.6%
 - All 4 diabetic patients had normal fasting glucose levels
- Another study for follow-up 12 ~ 18 months (n=24/39)

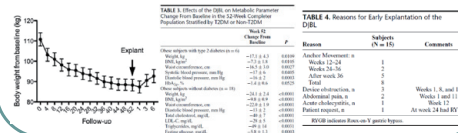


TABLE 3. Effect of the OBE on Metabolic Parameters Change from Baseline in the 12-Week Complete Resection Postoperatively (RYGB) in Non-Diabetic

Parameter	n	Baseline	12 Weeks	Z
Mean weight	12	110.0	85.0	0.0000
Mean BMI	12	40.0	32.0	0.0000
Mean waist circumference	12	110.0	85.0	0.0000
Mean systolic blood pressure	12	110.0	85.0	0.0000
Mean diastolic blood pressure	12	110.0	85.0	0.0000
Mean fasting glucose	12	110.0	85.0	0.0000
Mean HbA1c	12	110.0	85.0	0.0000
Mean triglycerides	12	110.0	85.0	0.0000
Mean total cholesterol	12	110.0	85.0	0.0000
Mean LDL cholesterol	12	110.0	85.0	0.0000
Mean HDL cholesterol	12	110.0	85.0	0.0000
Mean fasting insulin	12	110.0	85.0	0.0000
Mean HOMA-IR	12	110.0	85.0	0.0000
Mean C-peptide	12	110.0	85.0	0.0000
Mean proinsulin	12	110.0	85.0	0.0000
Mean insulin resistance	12	110.0	85.0	0.0000
Mean beta cell function	12	110.0	85.0	0.0000

TABLE 4. Reasons for Early Exploitation of the OBE

Reason	Subjects (N=11)	Comments
Anchor Movement	1	
Weeks 12-24	1	
Week 24-36	2	
End	8	
Device obstruction	1	Weeks 1, 8, and 39
Abnormal pain	2	Weeks 1 and 11
Anchor obstruction	1	Week 12
Patient request	1	At week 24 had RYGB

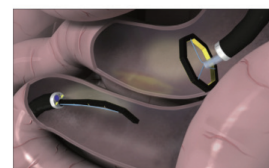
Surg Obes Relat Dis 2008;4:55-9
Ann Surg 2012;255:1080-5

Uncertainty

- Higher than anticipated incidence of spontaneous **hepatic abscesses** detected in the treatment group especially when sleeves in place > 3 months.
- Study put on enrollment hold by DSMB, FDA notified and could not come to agreement with GI Dynamics on mediation of this complication.
- Unclear how the FDA will rule on the complication data.

Surg Obes Relat Dis. 2016 Jun;12(5):e47-e50

Magnetic Anastomosis System



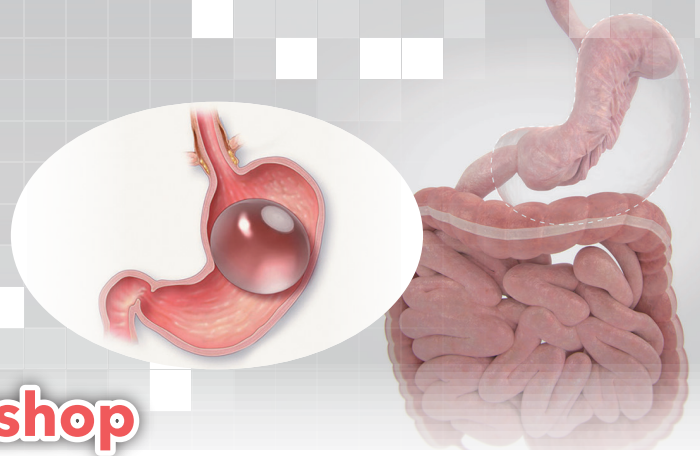
Invented in 2011

Figure 1. Deployment of the octagonal self-forming magnet device with the deployment tool. The magnet device incorporates an exoskeleton that directs self-assembly. The device can be delivered in a linear configuration using an endoscope working channel, at which time the device self-assembles into an octagonal ring when fully deployed.

Gastrointest Endosc 2017;86:904-12.

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Magnetic Anastomosis System

- The small bowel is accessed by colonoscopy and enteroscopy.
- The magnets are deployed in the jejunum and ileum
- **Reduction** in postprandial insulin and glucose levels and **increase** in peptide YY levels and GLP-1
- Mechanism: partial flow diversion

Gastrointest Endosc 2017;86:904-12.

Magnetic Anastomosis System

Weight Loss - 12 Months

Month	N	% Excess Wgt Loss	% Total Wgt Loss
Month 1	10	14.5	5.7
Month 2	10	19.5	7.4
Month 3	10	21.7	8.2
Month 6	10	28.3	10.6
Month 9	10	35.8	13.1
Month 12	10	40.2	14.6

Figure 4. Percent excess weight loss and total weight loss from baseline to month 12.

Gastrointest Endosc 2017;86:904-12.

Magnetic Anastomosis System

HbA1c Reduction - 12 Months

Time Point	Diabetics (%)	Pre-Diabetics (%)
Baseline	7.8	6.1
2 Weeks	7.4	6.0
2 Month	6.5	5.4
3 Month	6.1	5.4
6 Month	6.0	5.2
9 Month	6.1	5.4
12 Month	5.9	5.1

Gastrointest Endosc 2017;86:904-12.

Magnetic Anastomosis System

	Mild, n (%)	Moderate, n (%)	Severe, n (%)
Gastrointestinal disorders			
Abdominal distension	3 (30)	0 (0)	0 (0)
Abdominal pain*	9 (90)	1 (10)	0 (0)
Constipation	1 (10)	1 (10)	0 (0)
Diarrhea	5 (50)	5 (50)	0 (0)
Nausea	10 (100)	0 (0)	0 (0)
Vomiting	2 (20)	0 (0)	0 (0)
Investigations			
Vitamin D decreased	2 (20)	0 (0)	0 (0)
Metabolism and nutrition disorders (total events)			
Iron deficiency	3 (30)	1 (10)	0 (0)
Magnesium deficiency	0 (0)	2 (20)	0 (0)
Vitamin B ₁₂ deficiency	1 (10)	3 (30)	0 (0)
Vitamin D deficiency	1 (10)	1 (10)	0 (0)

*Pain at the tracer site coded as abdominal pain.

Gastrointest Endosc 2017;86:904-12.

Mucosal resurfacing for diabetes

Mucosal resurfacing for diabetes

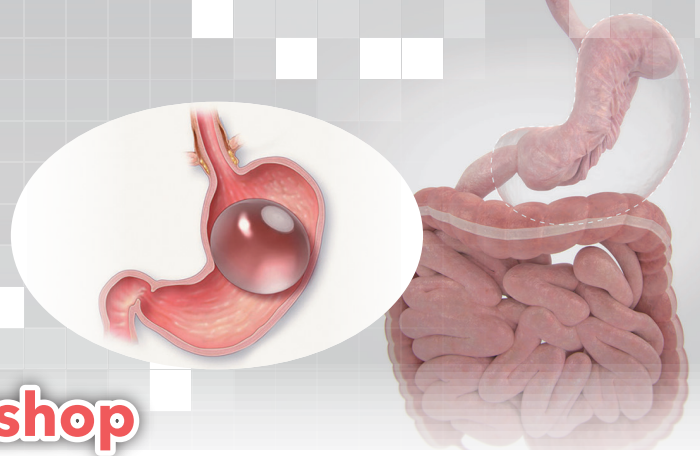
- Procedures:
 - Sizing balloon → Submucosal saline injection → thermal ablation
 - Site: from 1 cm distal to ampullar Vater to ligament of Treitz

Figure 3—The duodenal mucosa prior to DMR (A), immediately after hydrothermal ablation (B), and 1 month after the procedure (C) as seen during follow-up endoscopy.

Diabetes Care 2016;39:2254-61

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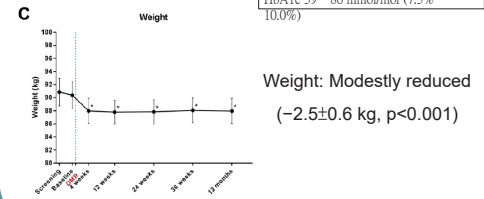
Hypothesis

- It is hypothesized that mucosal remodeling may reset duodenal enteroendocrine cells that have become diseased.
- This restores signaling and amplifies the incretin effect
- Human trials were conducted in 2014.

Endoscopic duodenal mucosal resurfacing for the treatment of type 2 diabetes mellitus: one year results from the first international, open-label, prospective, multicentre study

N = 36 Patients (BMI 24–40) with T2D on stable oral glucose-lowering drug

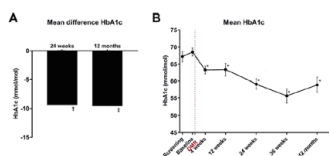
HbA1c 59 – 86 mmol/mol (7.5% – 10.0%)



Gut 2020;69:295–303

Endoscopic duodenal mucosal resurfacing for the treatment of type 2 diabetes mellitus: one year results from the first international, open-label, prospective, multicentre study

HbA1c reduction at week 24
(-10 ± 2 mmol/mol ($-0.9\% \pm 0.2\%$))



Gut 2020;69:295–303

Adverse Events of Resurfacing

Table 2 Summary of adverse events during study 12 months follow-up period (intention-to-treat population, n=66)	
Total number of adverse events (in 4246 patient-years)	189 (in 96% of patients)
Total DMR-related adverse events* (in 4246 patient-years)	172 (in 87% of patients)
GI symptoms	19
Such as symptoms occurring before DMR or mild abdominal symptoms weeks after DMR	
General symptoms	63
Such as fatigue, back pain, headache, pruritus, cough	
Metabolic symptoms	21
Such as hypoglycaemia and hyperglycaemia	
28	
Infections	28
Such as cystitis, common cold, cellulitis	
DMR-related adverse events* (in 2446 patients)	54 (in 52% of patients)
GI symptoms	46
Such as diarrhoea, abdominal pain, nausea and oropharyngeal pain	
General symptoms	11
Such as malaise, fatigue, musculoskeletal pain and rash	
Metabolic symptoms	3
Such as hypoglycaemia and hyperglycaemia	
Severity of DMR-related adverse events†	54 (81%)
Mild	44 (81%)
Moderate	10 (19%)
Severe	0 (0%)
Total number of serious adverse events (in 4246 patient-years)	6 (in 9% of patients)

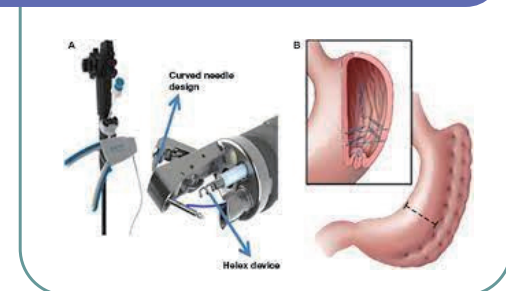
*Relationship to DMR was assessed as to terms of not, possible, probably and definitely based on the temporal association with DMR and the possibility of other aetiologies. †Mild: discomfort but no disruption of daily activity; Moderate: discomfort sufficient to affect daily activity; Severe: inability to perform daily activity.

Gut 2020;69:295–303

FDA approval for study

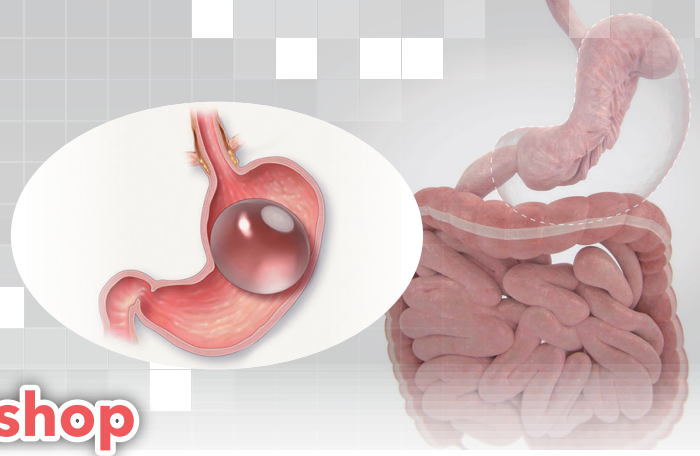
- The FDA granted breakthrough device designation for a first-in-class duodenal mucosal resurfacing intervention for adults with insulin-treated type 2 diabetes, according to an industry press release.
- Fractyl gets FDA approval for Revita DMR IDE study to treat diabetes

Endoscopic sleeve gastropasty



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Endoscopic Sleeve Gastroplasty

Introduced in 2013 and modified till now

OBES SURG (2021) 31:70-78

Endoscopic Sleeve Gastroplasty

- TFDA approval in 2020/10

Procedure	Ref	Coefficient	95% confidence	p value
ESG	Ref	-0.139	0.022	0.219
LAGB	-0.117	-0.246	0.013	0.075
Age	0.009	-0.003	0.006	0.027
Gender	Ref			
Female	Ref			
Male	0.004	-0.006	0.108	0.939
ASA class	0.071	-0.215	0.337	0.118

1. ↓ ghrelin without ↑ GLP-1 or PYY levels.
2. delay gastric emptying and increase satiation

J Gastrointest Surg (2018) 22:267-273

EBMT mimicking or not mimicking surgery

Clinical Gastroenterology and Hepatology 2017;15:619-630

The wishes for endoscopic therapies

- Less **invasive**
- Less **risky**
- Similar or better weight-loss **effect** compared with operation
- Good **durability**
- Easily **performed**
- Patient's **satisfaction**

Gastrointest Endosc. 2015 Sep;82(3):425-38

Endoscopic bariatric and metabolic therapies	Indications	Placement duration	Reversible	Repeatable	Advantages	Disadvantages	Approximate total weight loss (TWL)
Endoscopic Sleeve Gastroplasty (ESG)	Class I obesity (BMI 30-35 kg/m ²) with high obesity-related comorbidity Class II obesity (BMI 35.0-39.9 kg/m ²)	6-12 months	Yes	Yes	• Early placed and removed • Widely adopted globally	• Feasibility • Durability • Weight regain	5-15%
Aspiration Therapy (AspireAssist)	Class II and III obesity (BMI 35.0-55.0 kg/m ²)	24 months	Yes	Yes	• Similar to RYGB • Safe placement • Approved for high-risk patients	• Potential for significant gastrointestinal issues • Morbidity	15-25%
Oral Inhibitor of Gastric Acid Secretion (OIGAS)	Class I obesity (BMI 30-35 kg/m ²) Class II obesity (BMI 35.0-39.9 kg/m ²)	Permanent	Yes	No	• Full-thickness technique • Durability	• Procedural complexity	15-25%
Endoscopic Intra-Gastric Bypass (EIGB)	Class I obesity (BMI 30-35 kg/m ²) Class II obesity (BMI 35.0-39.9 kg/m ²)	12 months	Yes	Yes	• Weight loss and satiety • Significant decrease in HbA _{1c}	• Feasibility • Concerns regarding hepatic steatosis • Minimal abdominal weight loss • Fluoroscopy needed • More data required	10-15%
Endoscopic Duodenal Bypass (EDB)	Class I obesity (BMI 30-35 kg/m ²) Class II obesity (BMI 35.0-39.9 kg/m ²) Patients with poorly controlled type 2 Diabetes Mellitus (HbA _{1c} > 7.5%) based on the standard	NA	No	Yes	• Restore insulin sensitivity and promote weight loss	• Requires less than 10-15% dem. endoscopic resection • Morbidity • More data required	10-15%

Digestive Endoscopy 2021;33: 321-334

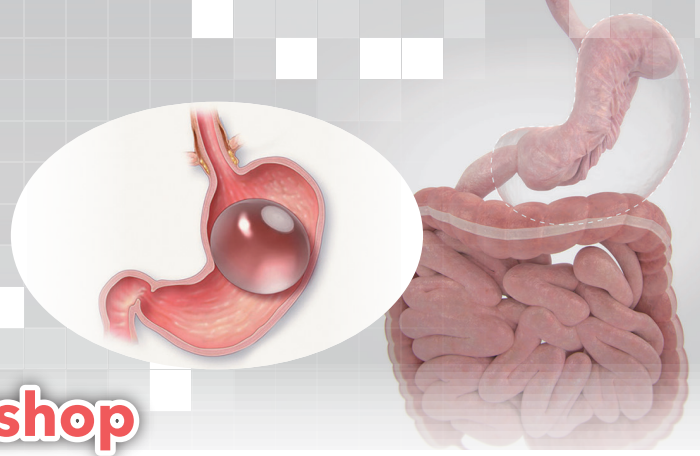
Multidisciplinary team ~ 多專科團隊

- Traditional diagnosis and treatment model
 - Relatively simple and less effective
- The technical aspects of EBTs have been well explained
- The nutritional management surrounding EBTs and the effectiveness of multidisciplinary team for maximizing weight loss will be described.

Am J Transl Res. 2021 Apr 15;13(4):2571-2580

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bariatric MDT

- Suggested core members
 - obesity physician (Endocrine, FM, GI man)
 - specialist surgeon
 - dietitian
 - psychologist
 - anesthetist
- There is no standardized approach to patients after bariatric endoscopy treatment

Obesity, Bariatric and Metabolic Surgery pp 1-8

Bariatric MDT

- The backbone for success of any bariatric program
 - nutritional intervention
 - physical activity planning
 - behavior changes
 - overcoming psychological barriers

Role of each member in MDT

Table 2. Multidisciplinary case team and their role in endoscopic bariatric therapies.

Member	Role
Physician	<ul style="list-style-type: none"> • Synthesis of a multidisciplinary team • Discuss weight and lifestyle • Manage comorbidities and exclude secondary causes of obesity • Gastroenterologist for endoscopic bariatric therapy • Surgeon for bariatric surgery
	<ul style="list-style-type: none"> • Laying the foundation for dietary change
Dietician	<ul style="list-style-type: none"> • Assessment of patient's diet • Plan simple effective diet strategies • Propose tailored dietary regime for weight loss before and after EBTs
Clinical psychologist	<ul style="list-style-type: none"> • Mentally preparing the patient • Identify psychosocial factors and barriers contributing to obesity • Motivational interviewing and goal setting • Managing expectations • Cognitive restructuring • Relapse prevention
	<ul style="list-style-type: none"> • Integrating physical activity into healthy lifestyle
Physical therapist	<ul style="list-style-type: none"> • Assessment of patient's physical condition • Plan realistic and achievable goals • Propose tailored exercise regime for weight loss before and after EBTs
Specialist nurse/care manager	<ul style="list-style-type: none"> • Keeping the patient involved
	<ul style="list-style-type: none"> • To educate patient pre- and post EBT • To assist in tracking patient's progress • To assist communication between team members • Scheduled counselling sessions
Pharmacist	<ul style="list-style-type: none"> • To work with physicians on optimizing pharmacological therapy for weight loss

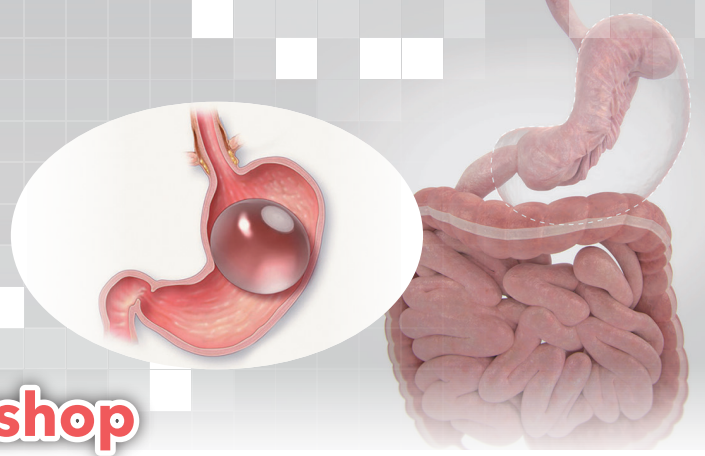
Nutrients 2022, 14, 3450.

Thank you for your attendance



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Metabolic Therapies Workshop**

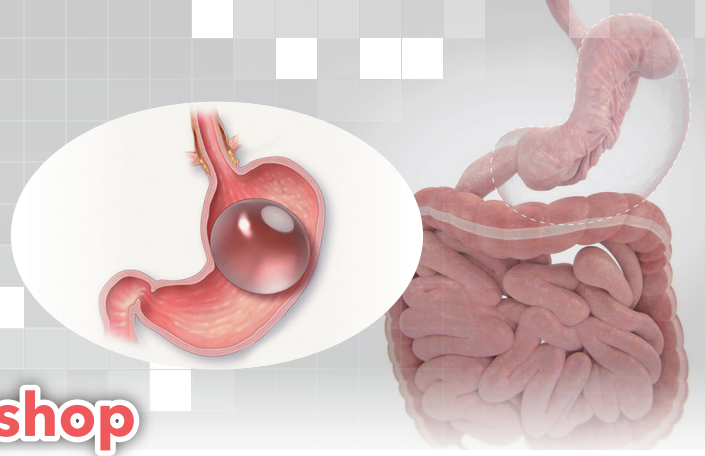


09:55-10:55

Moderator: 陳建華 主任 (慈濟)
曾屏輝 教授

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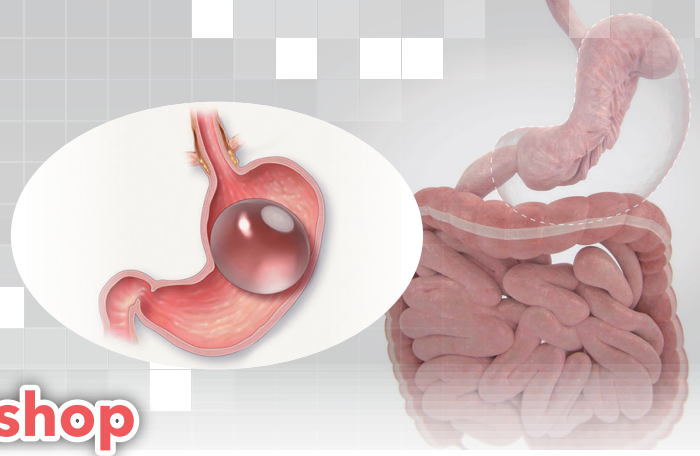
09:55-10:10

**Intragastric balloon and injection of
botulinum toxin A for obesity
management: pros and cons**

Speaker: 戴啟明 部長

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義大醫療財團法人
E-DA HEALTHCARE GROUP

Intra-gastric balloon and injection of botulinum toxin A for obesity management: pros and cons

Chi-Ming Tai (戴啟明), MD, PhD
義大醫院 胃腸肝膽科

真實存在關心您健康的好鄰居

Treatment Recommendations for Obesity on the Basis of AHA/ACC/TOS Obesity Guideline

Treatment	BMI category (kg/m ²)				
	25-26.9	27-29.9	30-34.9	35-39.9	>40
Lifestyle: diet, physical activity, behavior therapy	With comorbidities	With comorbidities	+	+	+
Pharmacotherapy		With comorbidities	+	+	+
Endoscopic bariatric therapies	Based on BMI and comorbidities		+	+	As bridge therapy
Bariatric and metabolic surgeries				With comorbidities	+

Clin Gastroenterol Hepatol. 2017;15(5):631-649.e10, Circulation. 2014;129(25 Suppl 2):S102-38, Clin Nutr. 2017;36(4):917-938.

Treatment Recommendations for Obesity on the Basis of AHA/ACC/TOS Obesity Guideline

Treatment	BMI category (kg/m ²)				
	25-26.9	27-29.9	30-34.9	35-39.9	>40
Lifestyle: diet, physical activity, behavior therapy					
Pharmacotherapy					
Endoscopic bariatric therapies	IGB	BTA	ESG	+	As bridge therapy
Bariatric and metabolic surgeries				With comorbidities	+

✓ Obese patients who fail to achieve adequate weight loss after lifestyle modification and pharmacotherapy
 ✓ These BMI thresholds should be reduced by 2.5kg/m² for Asian patients

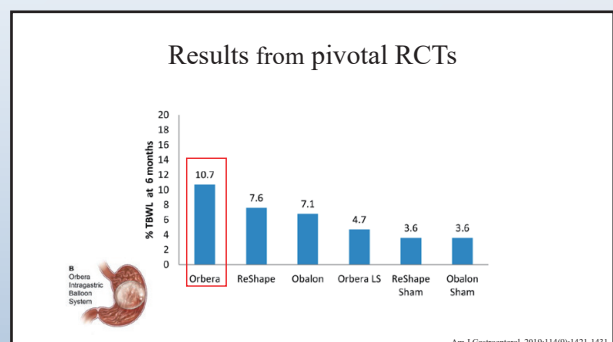
Clin Gastroenterol Hepatol. 2017;15(5):631-649.e10, Circulation. 2014;129(25 Suppl 2):S102-38, Clin Nutr. 2017;36(4):917-938.

- Outlines**
- ✓ Intra-gastric balloon (IGB)
 - ✓ Intra-gastric botulinum toxin A (BTA) injection

Summary of IGB characteristics

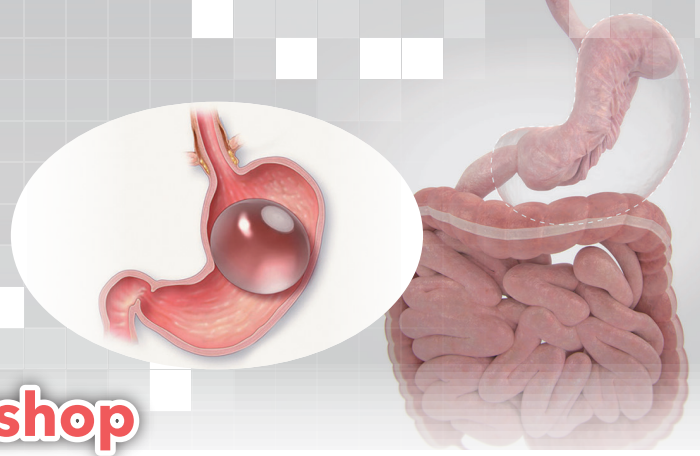
Balloon type	FDA/CE approved			CE approved		
	Orbera	ReShape Duo	Obalon	Heliosphere	Spatz FGIA	Elipse
Manufacturer	Apollo Endosurgery	ReShape Medical	Obalon Therapeutics	Helioscope Medical Implants	Spatz FGIA	Allurion Technologies
Filled with	Saline	Saline	Nitrogen gas	Air	Saline	Liquid
Capacity (mL)	400-700	450 × 2	250 × 3	900-1000	300-900	550
Number of balloons	1	2	Up to 3	1	1	1
Insertion	Endoscopy	Endoscopy	Swallowed	Endoscopy	Endoscopy	Swallowed
Removal	Endoscopy	Endoscopy	Endoscopy	Endoscopy	Endoscopy	Natural passage
Duration	6	6	6	12	4	4
Adjustable	No	No	No	No	Yes	No

FDA: Food and Drug Administration
 CE: European Community
World J Gastrointest Endosc. 2021;13:238-259 Gastroenterology 2017;152:1791-1801



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Orbera IGB

approved for use in Europe in 1997; FDA in 2015

- ✓ 400-700ml (500 ml)
- ✓ NS-methylene blue
- ✓ 輕度麻醉: propofol
- ✓ 不需住院

「胃內水球術」:

- 在胃鏡的觀察下，將一個矽膠材質的扁氣球，從嘴巴置入胃部，之後再打進約500cc的生理食鹽水(亦即在胃部放一個500cc的水球)
- 目的在於藉由這種填充胃部，產生飽食感降低食物攝取量的方式來達到減重的效果
- 此水球可放置六個月，之後要取出，以防止水球滲漏。

ASGE Technology Committee. Gastrointest Endosc. 2012;76:1-7

IGB extraction

- ✓ Clear liquid diet before removal
- ✓ IVG
- ✓ Overtube:
 - Prevent aspiration
 - Prevents IGB from getting stuck in the upper esophageal sphincter
- ✓ Needle aspirator, grasper

Troubleshooting: Partial deflation of IGB

- ✓ Early withdrawal of the aspirator
- ✓ Balloon leak

Biopsy forceps!

Weight loss through each month

第一周處理急性併發症: 噁心, 嘔吐, 胃酸逆流

積極衛教, 且配合長期飲食和行為監控調整計畫, 以長期維持減重成效

Phelan et al. 2010
Totter et al. 2001

The weight loss with IGBs is most steep within the first 3 months.

Gastrointest Endosc. 2015;81:1330-6

Effectiveness of IGB treatment for obese patients: one-year follow-up after balloon removal (E-Da experience)

- ✓ April 2009 – June 2011, 28 obese patients.
- ✓ Female: 23 (72.1 %). Age: 31.5 (20–55) years
- ✓ One-year follow-up after balloon removal
- ✓ 16 patients with BMI <32, 12 patients with BMI ≥32
- ✓ Responders (n=20): lost more than 20% of excess weight
- ✓ Adherence to dietitian counseling was significantly better in responders than in non-responders (85 vs. 25 %, respectively; P<0.01)

Characteristics	Baseline (n=28)	At time of BIB removal (n=28)	P-value
BMI (kg/m ²), mean (SD)	32.4 (3.7)	28.5 (3.7)	< 0.01
WC (cm), mean (SD)	101.9 (8.9)	90.6 (9.3)	< 0.01
SBP (mm Hg), mean (SD)	136.8 (14.3)	125.9 (11.5)	< 0.01
DHP (mm Hg), mean (SD)	84.0 (13.4)	76.1 (9.8)	< 0.01
Glucose (mg/dL), median (range)	92.5 (83.0-209.0)	91.0 (76.0-117.0)	< 0.01
AST level (IU/L), median (range)	33.0 (16.0-170.0)	23.0 (13.0-110.0)	< 0.01
ALT level (IU/L), median (range)	49.0 (15.0-196.0)	22.0 (6.0-99.0)	< 0.01
Triglyceride (mg/dL), median (range)	149.0 (45.0-241.0)	88.5 (38.0-197.0)	< 0.01
Cholesterol (mg/dL), median (range)	200.0 (124.0-350.0)	186 (109.0-257.0)	0.13
HDL-cholesterol (mg/dL), median (range)	45.0 (31.0-62.0)	52.0 (31.0-92.0)	0.01
LDL-cholesterol (mg/dL), median (range)	119.5 (52.0-245.0)	114.0 (42.0-184.0)	0.03
Metabolic syndrome, n (%)	18 (64.3)	9 (32.1)	0.01

Tai CM, et al. Obes Surg. 2013;23:2068-74

Comparison of effectiveness of IGB in patients with BMI <32 and BMI ≥32

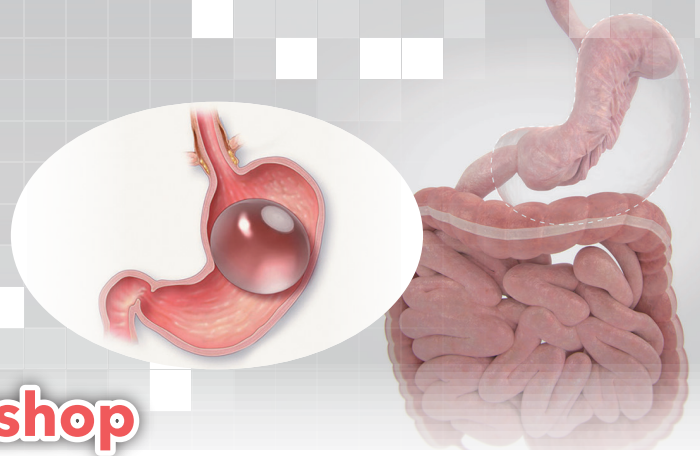
	Total (n=28)	BMI <32 (n=16)	BMI ≥32 (n=12)	P-value
BMI reduction at time of BIB removal, median (range)	3.7 (0.1-9.4)	3.1 (0.1-7.7)	4.3 (1.1-9.4)	0.14
BWL at time of BIB removal, median (range)	9.5 (0.1-25.5)	7.9 (0.1-18.1)	10.5 (2.4-25.5)	0.16
% FWL at time of BIB removal, median (range)	40.1 (0.94-132.3)	44.7 (0.94-132.3)	34.4 (7.07-66.3)	0.71
Responders at time of BIB removal, n (%)	20 (71.4)	11 (68.8)	9 (75%)	1.0
Responders 1 year after BIB removal, n (%)	12 (42.9)	10 (62.5)	2 (16.7)	0.02
BMI reduction in responders 1 year after BIB removal, median (range)	2.1 (1.0-6.7)	2.08 (1.1-4.5)	2.3 (1.0-6.7)	0.7
BWL in responders 1 year after BIB removal, median (range)	5.9 (2.8-18.3)	6.1 (2.8-11.3)	5.6 (2.8-18.3)	0.81
% FWL in responders 1 year after BIB removal, median (range)	27.2 (11.1-94.3)	29.7 (21.0-94.3)	17.1 (11.1-47.6)	0.14

- ✓ IGB placement can achieve significant weight loss and improvement of co-morbidities in obese patients.
- ✓ Better adherence to dietitian counseling is associated with better response.
- ✓ Patients with BMI <32 maintain better weight loss at 1 year after IGB removal.

Tai CM, et al. Obes Surg. 2013;23:2068-74

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Meta-analysis by ASGE
% EWL at 12 months (6 months after balloon removal) with Orbera IGB

Study name	Intragastric balloon study	Patients in each study	%EWL
Shah 2006	Obese	10,000	25.47%
Woo 2006	Obese	10,000	21.50%
Guo 2006	Obese	10,000	15.50%
Guo 2007	Obese	10,000	13.90%
Costa 2009	Obese	10,000	20.10%
Chen 2010	Obese	10,000	13.90%
Chen 2011	Obese	10,000	13.90%
Chen 2012	Obese	10,000	13.90%
Chen 2013	Obese	10,000	13.90%
Chen 2014	Obese	10,000	13.90%
Chen 2015	Obese	10,000	13.90%
Chen 2016	Obese	10,000	13.90%
Chen 2017	Obese	10,000	13.90%
Chen 2018	Obese	10,000	13.90%
Chen 2019	Obese	10,000	13.90%
Chen 2020	Obese	10,000	13.90%
Chen 2021	Obese	10,000	13.90%
Chen 2022	Obese	10,000	13.90%
Chen 2023	Obese	10,000	13.90%
Chen 2024	Obese	10,000	13.90%
Chen 2025	Obese	10,000	13.90%
Chen 2026	Obese	10,000	13.90%
Chen 2027	Obese	10,000	13.90%
Chen 2028	Obese	10,000	13.90%
Chen 2029	Obese	10,000	13.90%
Chen 2030	Obese	10,000	13.90%

EWL: excess weight loss, 過多體重

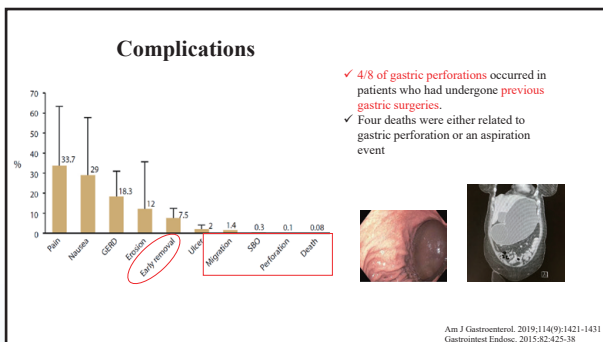
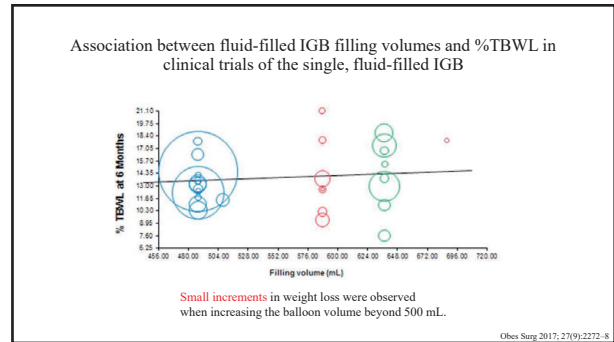
500 intragastric balloons: what happens 5 years thereafter?

Variables of 500 patients	1 year interval	12 months after	24 months after
Baseline weight (kg) [SD]	126.94 (26.73)	100.00 (26.70)	100.00 (26.70)
Final weight (kg) [SD]	100.00 (26.70)	112.59 (26.27)	118.05 (26.42)
Weight loss (kg) [SD]	26.94 (26.73)	16.35 (17.37)	18.85 (19.89)
Baseline BMI (kg/m ²) [SD]	40.68 (8.66)	35.74 (7.94)	35.74 (7.94)
Final BMI (kg/m ²) [SD]	35.74 (7.94)	38.82 (7.71)	40.02 (7.52)
BMI reduction (kg/m ²) [SD]	6.93 (3.98)	6.86 (3.48)	6.93 (3.98)
Baseline EW [SD]	63.81 (25.89)	38.66 (23.83)	38.66 (23.83)
Final EW [SD]	38.66 (23.83)	47.16 (21.96)	51.42 (23.99)
EW reduction [SD]	25.15 (16.74)	16.51 (17.37)	16.51 (17.37)
% EW [SD]	41.58 (18.77)	37.71 (13.40)	17.11 (8.40)

Variables of 193 patients 5 years after

Variables of 193 patients	Baseline	5 years after
Baseline weight (kg) [SD]	125.61 (26.70)	106.36 (27.27)
Final weight (kg) [SD]	106.36 (27.27)	118.25 (29.45)
Weight loss (kg) [SD]	19.25 (19.30)	7.88 (14.11)
Baseline BMI (kg/m ²) [SD]	41.20 (8.21)	37.87 (7.57)
Final BMI (kg/m ²) [SD]	37.87 (7.57)	40.81 (8.20)
BMI reduction (kg/m ²) [SD]	7.33 (3.63)	2.91 (3.52)
Baseline EW [SD]	66.76 (21.12)	48.76 (21.12)
Final EW [SD]	48.76 (21.12)	53.59 (21.73)
EW reduction [SD]	18.00 (19.56)	1.26 (8.41)
% EW [SD]	49.87 (13.93)	13.87 (8.54)

✓ Half of the patients maintained >20% excess weight loss at 1 year after IGB removal
✓ A quarter of patients kept this weight loss at 5 years



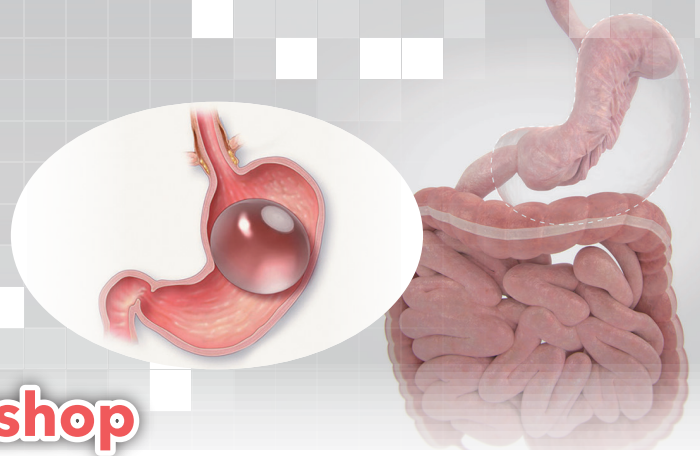
- ✓適應症
 - BMI介於27至32間，同時有肥胖合併症，飲食和運動減重依然無法達成或維持減重成效的病患。
 - 不想接受減重手術之病態性肥胖病患。
- ✓特質
 - 減重動機: 結婚、交友、健康... (被動型的患者效果差)
 - 避免給患者裝水球就有效的觀念
 - Binging eating disorder: 合併精神科治療

- 禁忌症**
- ✓嚴重胃腸道的發炎疾病，包括：嚴重食道炎、胃或十二指腸潰瘍、癌症、或克隆氏症之類的特殊發炎疾病。
 - ✓可能的上胃腸道出血情況，例如：食道或胃靜脈曲張、先天或後天腸道微血管擴張、或胃腸道的其他先天異常(例如：閉鎖或狹窄)。
 - ✓嚴重裂孔疝氣(Hiatal Hernia >5cm)。
 - ✓食道或咽喉(例如狹窄或憩室)結構異常。
 - ✓過去曾經接受胃或腸手術。
 - ✓服用阿司匹林抗發炎藥物、抗凝血劑或其他胃腸問題而未受到醫療監督的病患。
 - ✓所有其他可能會提高內視鏡檢查危險性的醫療行為。
 - ✓懷孕或哺乳的婦女
- Am J Gastroenterol. 2019;114(9):1421-1431

- Outlines**
- ✓Intragastric balloon (IGB)
 - ✓Intragastric botulinum toxin A (BTA) injection

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Mechanisms

- Delay the gastric emptying and improve satiety by causing a temporary paralysis at the injection site
- Its effect is lost gradually over the first 3 to 6 months, and there is no permanent damage

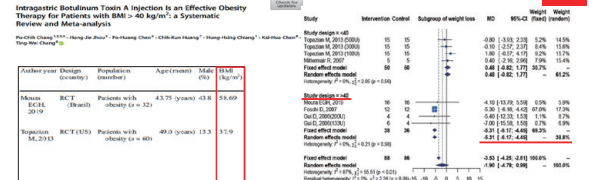
Procedures

- Inject 30ml of botulinum type A (Botox; Allergan, Irvine, CA) containing 300 units in 0.9% normal saline through a 25-gauge needle
- Inject 10ml each on antrum, body, and fundus through submucosal injection

J Clin Med. 2022;11(12):3325

Intragastric Botulinum Toxin A Injection is an Effective Obesity Therapy for Patients with BMI > 40 kg/m²: a Systematic Review and Meta-analysis



n=140

Obs Surg. 2020;30(10):4081-4090

- Intragastric BTA injection was **no superior** to saline in absolute weight loss or BMI change
- Significantly **lengthened** the gastric emptying time
- Absolute weight loss** was significantly higher among the patients with baseline BMI more than 40 kg/m² (MD, -5.31; 95% CI, -6.17 to -4.45)

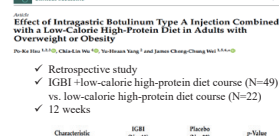
Meta-analysis of Botulinum Toxin A for Weight Loss: A Systematic Review and Meta-analysis of Randomized Controlled Trials

Study	Intervention	n	Age (mean ± SD)	Male %	Baseline weight (kg)	95% CI
Gu 2006	BTA 100 U	8	46.1 ± 12	50%	108 ± 33.3	49.4 ± 7.1
	BTA 200 U	4	43 ± 9	75%	117 ± 30.7	49.3 ± 5.3
	Saline	4	34 ± 11	50%	119 ± 22.7	46.5 ± 7.2
Fuoch 2007	BTA 200 U	12	45.6 ± 12.1	17%	116 ± 35.3	45.6 ± 4.9
	Saline	12	42.5 ± 12.8	23%	103 ± 8	46 ± 5.8
Momoni 2007	BTA 100 U	5	43.6 ± 11.5	20%	103 ± 3.3	50.4 ± 1.3
	Saline	5	43.6 ± 11.5	20%	103 ± 3.3	50.4 ± 1.3
Tsai 2011	BTA 100 U	15	45 range	13%	105.3 range	37.9 range
	Saline	15	45 range	13%	105.3 range	37.9 range
de Moraes 2019	BTA 100 U	18	43.8 ± 10.5	44%	105.1 ± 29.9	51.7 ± 5.4
	Saline	18	43.8 ± 10.5	44%	105.1 ± 29.9	51.7 ± 5.4
Shahrestani 2021	BTA 200 U	18	45.6 ± 10.2	30%	137.1 ± 20.7	47.1 ± 7.1
	Saline	24	45.1 ± 8.6	19%	136 ± 17.1	49.9 ± 4.9

- 6 RCTs with 192 participants
- Dose of BTA:
 - 100 to 200 U
 - 200 U was the most commonly used dose
- Intragastric puncture sites:
 - antrum only in three studies
 - antrum plus other sites in the other studies.
- No difference in the absolute weight loss between intragastric BTA injection and control.
- Subgroup analysis showed a significantly decreased absolute weight loss:
 - BTA injection dose ≥ 200 U (MD, 2.04 kg)
 - Multiple injection regions in the stomach combined with diet control (MD, 4.44 kg)

J Gastroenterol Hepatol. 2022;37(6):983-992

Effect of Intragastric Botulinum Type A Injection Combined with a Low-Calorie High-Protein Diet in Adults with Overweight or Obesity



Retrospective study

IGBI + low-calorie high-protein diet course (N=49) vs. low-calorie high-protein diet course (N=22)

12 weeks

	IGBI	Placebo	p-Value
Age (mean)	39.1 (27-42.6)	39 (27-50.3)	0.807
Female sex (%)	67 (27)	50 (22)	0.80
Height (cm)	172.2 (167-177)	172.2 (165-183)	0.28
BMI (kg/m ²)	26.3 (24.3-31.6)	26.3 (24.6-31.6)	0.63
	29.3		

At adverse event

Adverse Event	IGBI (n=49)	Placebo (n=22)
Time to any adverse event, weeks	1 (0-2)	1 (0)
Any adverse event, no (%)	2 (4.1)	2 (9.1)
Specific adverse events, no (%)	0	0
Reported adverse event, no (%)	0	0
Nausea	2 (4.1)	0
Bloating	1 (2.0)	0
Diarrhea	1 (2.0)	0
Constipation	0	2 (9.1)
Neurotoxicity	2 (4.1)	0
Urinary disorder	1 (2.0)	0
Abdominal pain	1 (2.0)	0

Reasons for good result:

- Higher dose of BTA
- Multiple site injection

J Clin Med. 2022;11(12):3325

Efficacy of Intragastric Balloon Placement and Botulinum Toxin Injection in Bariatric Endoscopy

	Median (Min-Max)			P
	Intragastric Balloon (N=40) med (min-max)	Intragastric Balloon (N=42) med (min-max)	Intragastric Botulinum Toxin (N=39) med (min-max)	
Weight (Before-obt)	82.5 (4-149)	111 (21-189)	113 (21-172)	<0.001
Average weight loss	4.9 kg (3.2-7)	10.2 kg (10.8-11)	13.62 kg (13.2-14)	<0.001
BMI (Before-obt)	31.6 (15.5-51.9)	37.9 (31.5-49.9)	41.9 (35.5-50.6)	<0.001
Average BMI Loss	1.82 kg/m ² (1.52-2)	3.72 kg/m ² (3.08-5)	5.1 kg/m ² (3.3-7)	<0.001
% TBMV	5.2	11.1	13.2	<0.001
Weight	91 (76-112)	94.5 (74-126)	106 (79-129)	0.018
Before				
After	86 (72-126)	84 (68-109)	88 (69-107)	
P	<0.001	<0.001	<0.001	
BMI	34.2 (28.1-46.2)	35.4 (29.4-47.4)	37.2 (29-48)	0.001
Before				
After	32.65 (28.8-44.1)	31.43 (26.1-37.3)	32.8 (28.42-5)	
P	<0.001	<0.001	<0.001	

6 months

Early removal: 5 in group 2 and 6 in group 3

Surg Laparosc Endosc Percutan Tech. 2020;30(6):508-503

Conclusions

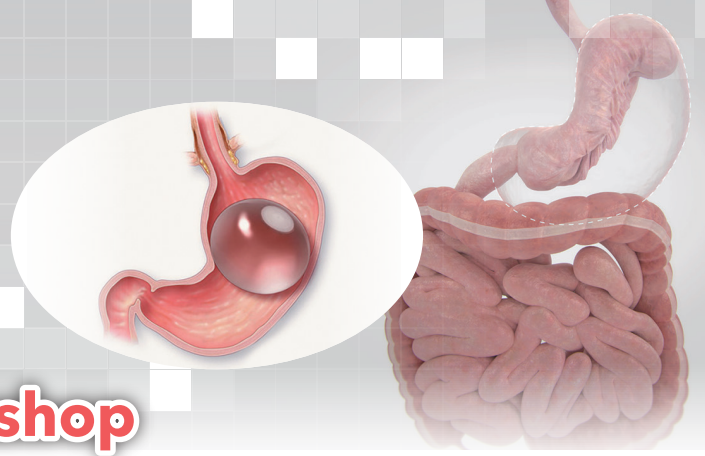
- IGBs are safe and effective weight loss tools that lead to improvements in physical and mental health.
- Better results of intragastric injection of BTA in Asian (or overweight/obese class I) ?
- To optimize the effect of the EBMTs, they should be used in conjunction with a multi-disciplinary program.
- Management of obesity has evolved to a model of chronic disease management.

Combination therapy:

an initial weight loss strategy including **short-term devices** such as IGBs, followed by an aggressive weight-maintenance phase using **long-term pharmacotherapy and lifestyle changes**.

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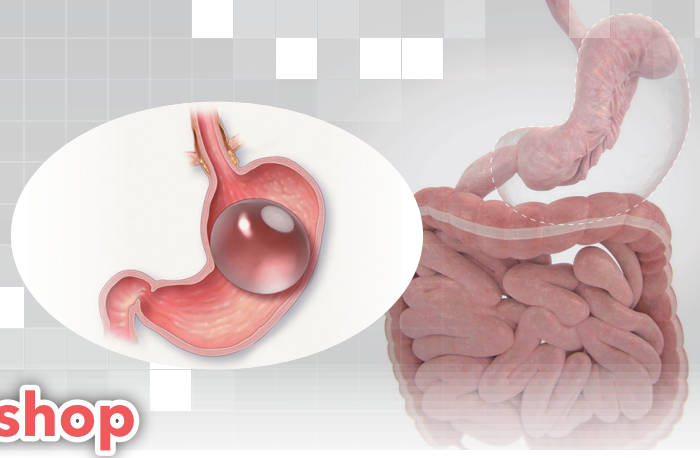
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**Endoscopic sleeve gastropasty for
obesity management: pros and cons**

Speaker: 鍾承軒 主任

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Endoscopic Bariatric and Metabolic Therapies Workshop



台灣消化系內視鏡醫學專科
1st Endoscopic Bariatric and Metabolic Therapies Workshop

Endoscopic Sleeve Gastroplasty for Obesity Management: Pros and Cons

Chen-Shuan, CHUNG (鍾承軒) MD, MSc

Division of Gastroenterology & Hepatology,
Department of Internal Medicine;
Ultrasonography and Endoscopy Center
Far Eastern Memorial Hospital, New Taipei City, Taiwan
(亞東紀念醫院)
Dec 11, 2022

Outlines

- Endoscopic sleeve gastroplasty (ESG): ready for the prime time ?
- Basic procedures of ESG

Prevalence of obese adult population (BMI ≥ 24)

Global data

Grading	WHO (for Asian)	Taiwan HPA
Underweight	< 18.5 (18.5)	< 18.5
Healthy weight	18.5-24.9 (18.5-22.9)	18.5-23.9
Overweight	25-29.9 (23-24.9)	24-26.9
Pre-obese	— (25-29.9)	
Class I	30-34.9	27-30 (程度)
Class II	35-39.9	30-35 (中度)
Class III	≥ 40	≥ 35 (重度)

Health Promotion Administration, Taiwan 2020; WHO 2021

Obesity-associated health disturbances

- MALIGNANCY**
 - Breast cancer
 - Colorectal cancer
 - Esophageal adenocarcinoma
 - Gastric cancer
 - Pancreatic cancer
 - Liver cancer
 - Gallbladder cancer
 - Ovarian / endometrial ca
 - Thyroid cancer
 - Multiple myeloma
- SKIN**
 - Psoriasis
 - Striae
- MENTAL**
 - Attention deficit diseases
 - Depression / Anxiety
 - Panic disorders
- COAGULATION**
 - Deep vein thrombosis
 - Lung embolism
- CARDIOPULMONARY**
 - Atherosclerotic / CAD
 - Hypertension
 - Atrial fibrillation
 - Heart failure
 - Sleep apnea
 - Asthma / COPD
- UROGENITAL**
 - UTI
 - Incontinence
- HEPATOBIILIARY**
 - Gallstone
 - NAFLD / NASH / Cirrhosis
- METABOLIC**
 - DM
 - Dyslipidemia
 - Gout
- MUSCULOSKELETAL**
 - Osteoarthritis
 - Fatigue / back pain
 - Physical impaired
- REPRODUCTION**
 - Polycystic ovarian syndrome
 - Hypogonadism / Male infertility

Step-up therapeutic approach for obesity

2-5%: Diet / Exercise / Behavioral intervention

5-10%: Anti-obesity medication

10-20%: Endoscopic bariatric and metabolic therapies

20-40%: Surgery

Current Obesity Reports 2021;10:396-408; Endocr Rev. 2022;43:507-557; Curr Obes Rep. 2021. PMID: 34297346

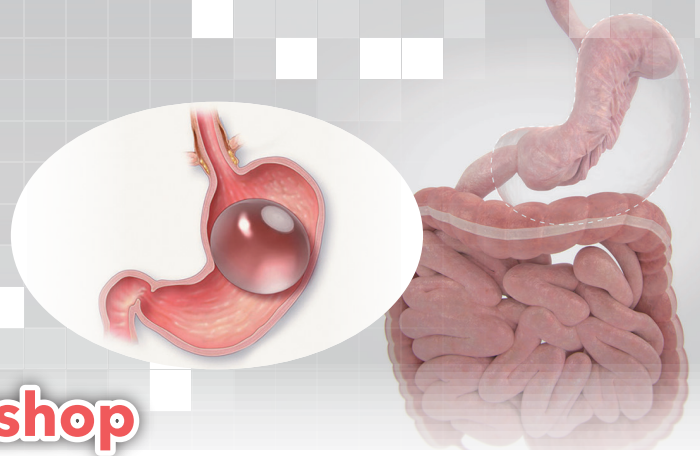
Endoscopic bariatric and metabolic therapies

- Gastric approach**
 - Intragastric botox injection
 - Intragastric balloon (IGB)
 - Endoscopic sleeve gastroplasty (ESG)
 - Aspiration therapy
 - Primary obesity surgery endoluminal (POSE)
- Intestinal approach**
 - Endoluminal magnetic jejunal diversion
 - Duodenal-jejunal bypass liner
 - Transoral outlet reduction (TORE) of GJA after RYGB
 - Duodenal mucosal resurfacing (DMR)

Tseng-Shan Ad et al. Ther Adv Gastroenterol. 2020; Vol. 13: 1-11; Doi: 10.1177/1756284820951103

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Endoscopic sleeve gastropasty (ESG)

Indications

- No age or BMI limit
- Minimum recommended BMI >27 kg/m²
- Ideal indication with grade I (I-II) obesity BMI 30-35 kg/m²

Contraindications

Patient factors

- History of surgery involving esophagus, stomach, duodenum or bariatric surgery
- Alcoholism, pregnant, drug addiction, uncontrolled psychiatric disorders, unwilling/allergic to PPI

Bleeding tendency

- Coagulopathy disorders, decompensated cirrhosis, unable to discontinued medication with bleeding tendency

Adverse events

- Perforation
- Stenosis
- Stricture
- Esophageal obstruction
- Esophageal perforation
- Esophageal varices
- Esophageal diverticulum
- Esophageal cancer
- Esophageal atresia
- Esophageal fistula
- Esophageal stricture
- Esophageal stenosis
- Esophageal perforation
- Esophageal varices
- Esophageal diverticulum
- Esophageal cancer
- Esophageal atresia
- Esophageal fistula
- Esophageal stricture
- Esophageal stenosis

ESG is safe and effective for weight reduction

Neto MG et al. Obesity Surgery (2021) 31:76-78 Brunaldi VO, et al. Curr Opin Rep. 2021 Sep;16(3):286-300.

ESG is effective and safe for weight reduction

• Meta-analysis of 8 original studies (1,772 patients), 2016-2019

Pooled proportion	1-month	3-month	6-month	12-month	18-24-month
TBWL	8.77%	11.28%	15.14%	16.50%	17.15%
BMI reduction	3.05%	3.86%	5.65%	6.14%	6.56%
EWL	32.42%	47.07%	57.71%	61.83%	66.92%

Adverse events

- Mortality: 0%
- Pain or nausea requiring hospitalization: 1.08%
- Upper GI bleeding: 0.56%
- Peri-gastric leak or collection: 0.48%
- Pulmonary embolism: 0.06%
- Pneumoperitoneum: 0.06%

Hedjoudje A et al. Clinical Gastroenterology and Hepatology 2020; 18:1043-1053

ESG is a safe and effective treatment option for patients with NAFLD and obesity

• In this single-center prospective study, consecutive adult patients (n=26) with NAFLD who underwent ESG between November 2018 and May 2019 were included.

TBW (kg) P<0.001 (11.3% to 18.07%)

Hepatic steatosis index P<0.001

Non-alcoholic fatty liver disease score P<0.001

BMI (kg/m2) P<0.001

FIB-4 index P<0.001

AST-to-PLT ratio P<0.001

Jagtap N et al. Indian Journal of Gastroenterology (November -December 2021) 40(6):572-578

ESG is superior to lifestyle modification for class 1 and 2 obesity ~ multicenter ESG randomized interventional trial (MERIT) ~

Class III obesity 21-45 y/o (nine US centers)

Lifestyle modification + ESG (n=89) vs Lifestyle modification alone (n=124)

Primary / Secondary endpoints: EWL / Metabolic comorbidities at 52 wks.

Comorbidity	ESG (n=89)	Lifestyle (n=124)
DM (P<0.005)	52%	93%
HTN (P<0.05)	6%	44%
Hyperlipidemia	27%	49%
Metabolic syndrome (P<0.001)	83%	95%

EWL (P<0.001): 49.2% vs 3.2%

TWL (P<0.001): 13.6% vs 0.8%

Barnham et al. Lancet 2022 Aug 6;400(10350):441-451

Addition of liraglutide to ESG results in superior efficacy

• Retrospective study of prospectively collected data from patients undergoing ESG at 3 outpatient clinics in Brazil between November 2017 and July 2018

• Liraglutide was offered to all patients 5 months after ESG.

• Patients with liraglutide (ESG-L) were matched 1:1 to patients who declined it (ESG).

• Primary outcome: %TBWL and %EWL 7 months after liraglutide (12 months after ESG).

Variable	ESG (n=26)	ESG-L (n=26)	P val
TBWL (%)	20.51	24.72	<0.001
EBWL (%)	69.94	84.33	<0.001
BMI loss, kg/m²	7.31	8.88	<0.001
Visceral fat (%)	10.54	7.85	<0.001
HbA1C (%)	5.40	5.09	0.013

Badurdeen D et al. Gastrointest Endosc. 2021 Jun;93(6):1316-1324.e1

ESG with more significant and sustained weight loss than IGB

• A total of 28 studies were included in the final meta-analysis.

• Only 1 study directly compared ESG to IGB, 9 studies evaluated ESG alone, while 18 studies evaluated IGB

Variable	ESG (n=1,979)	IGB (n=3,025)
Age mean (years)	42.23 (95% CI 40.66-44.39)	39.06 (95% CI 37.49-40.62)
Males (%)	23.52 (95% CI 16.67-30.62)	21.34 (95% CI 16.64-26.99)
BMI	36.08 (95% CI 35.66-37.09)	41.70 (95% CI 34.59-44.88)
%TWL		
4 months	15.34 (95% CI 14.33-16.33)	12.14 (95% CI 10.37-13.93)
12 months	17.51 (95% CI 16.44-18.58)	10.35 (95% CI 8.36-12.32)
18-24 months	17.85 (95% CI 15.85-19.86)	06.89 (95% CI 0.76-10.01)
%EWL		
4 months	55.48 (95% CI 50.28-60.69)	34.83 (95% CI 30.07-39.60)
12 months	48.51 (95% CI 44.39-52.64)	26.45 (95% CI 21.40-31.91)
18-24 months	66.77 (95% CI 57.54-76.00)	23.88 (95% CI 17.41-30.33)

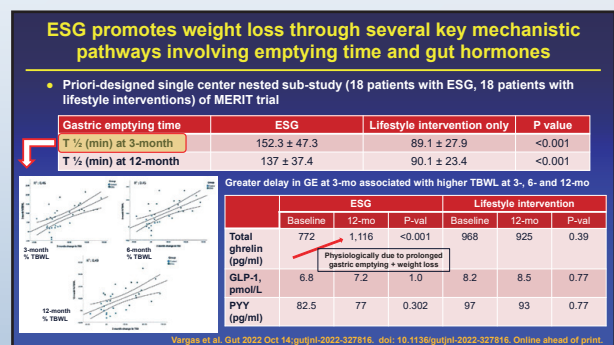
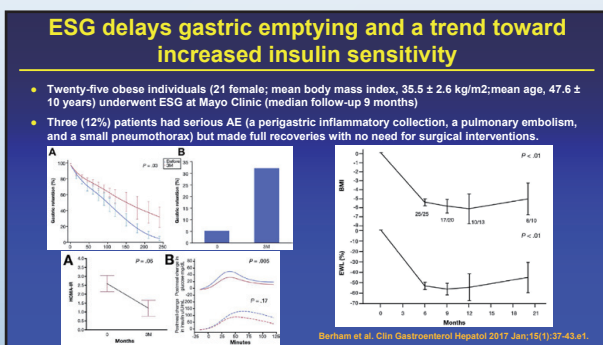
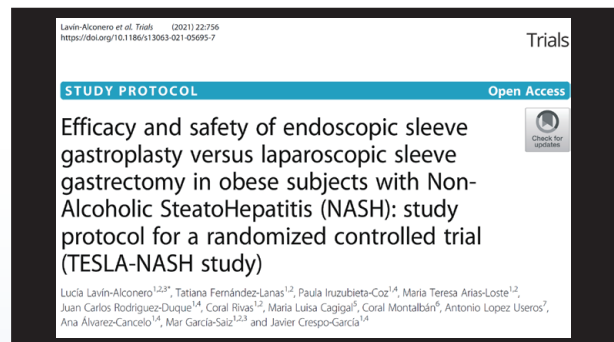
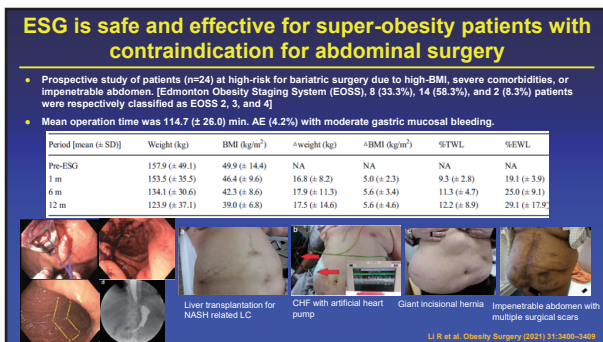
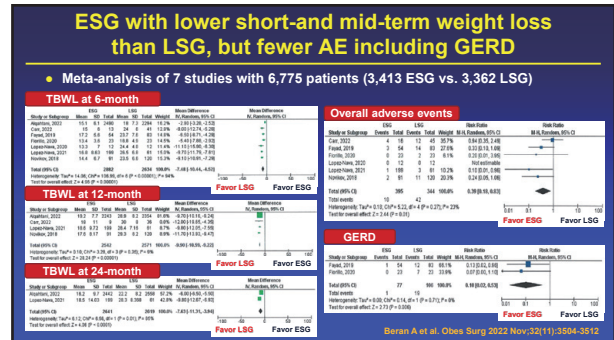
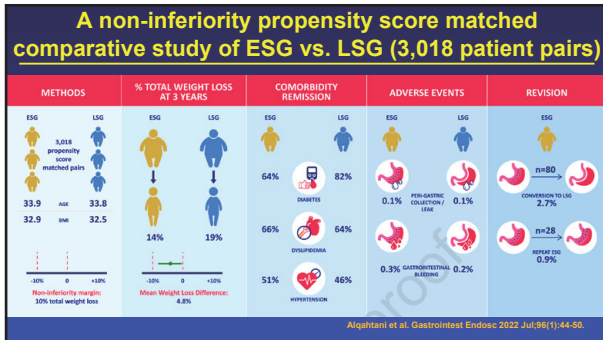
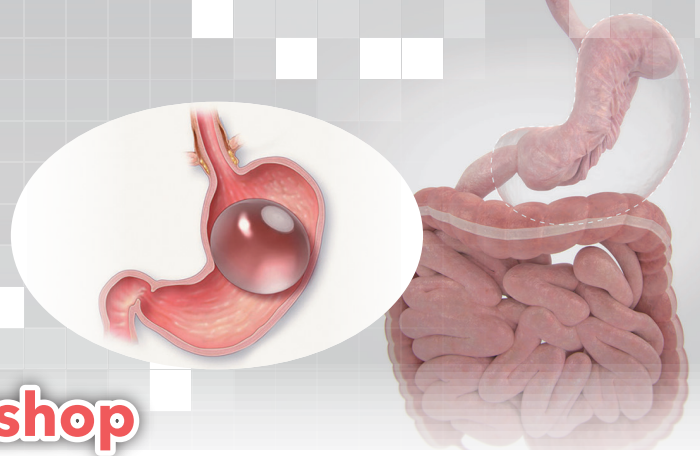
Adverse events

Weight regain

Singh et al. Obesity Surgery (2020) 30:3910-3929

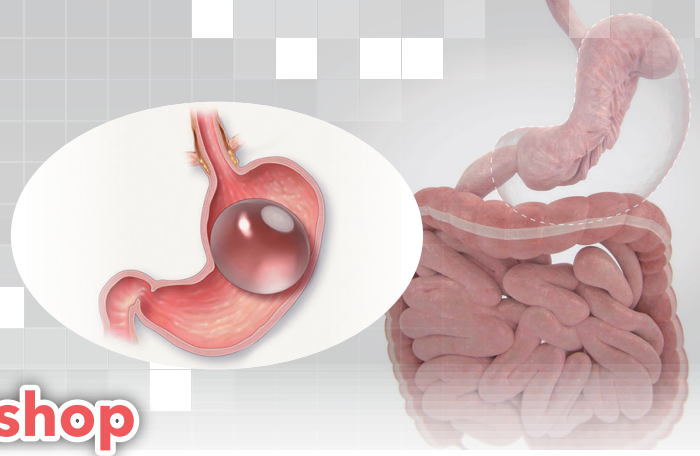
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Outlines

- Endoscopic sleeve gastropasty (ESG): ready for the prime time ?
- Basic procedures of ESG

Preparation of overstitch endoscopic suturing system

(Brazilian consensus agreement)

- ETGA (100%), supine or left decubitus position, prophylactic antibiotics (97.4%), DVT prophylaxis (compression device or heparin) (82.5%)
- Double channel (OverStitch) or single channel endoscope (OverStitch Sx)
- CO₂ insufflation (100%), Overtube (88.0%), APC (85.1% without marking)

Needle driver (handle) / end cap

Suture cinch

Anchor exchange

Tissue helix

Suture-anchor

Neto MG et al. Obesity Surgery (2021) 31:79-78

Position of suturing system under endoscopic view

ESG procedures

Marking: ant and post wall, angle to 2cm below EGJ, sparing antrum/proximal fundus

Suturing: standard "U" shape; helix below leading suture when ant-to-post, and above leading suture when post-to-ant direction; leading suture below trailing suture

Closing anchor whenever moving without intention to suturing

2-4cm interval of suture; Bite when alignment tube invisible

ESG procedures

Cinch: dropping anchor after 6-8 stitches in "U" shape then pulling trailing suture (do not forcefully but pull-and-loose intermittently) and minimizing CO₂ insufflation

On average, 4-6 sutures are used in each case.

Suture pattern

- Brazilian consensus: most (77.5%) used suture pattern is the square/rectangle (Barham/Galvao).

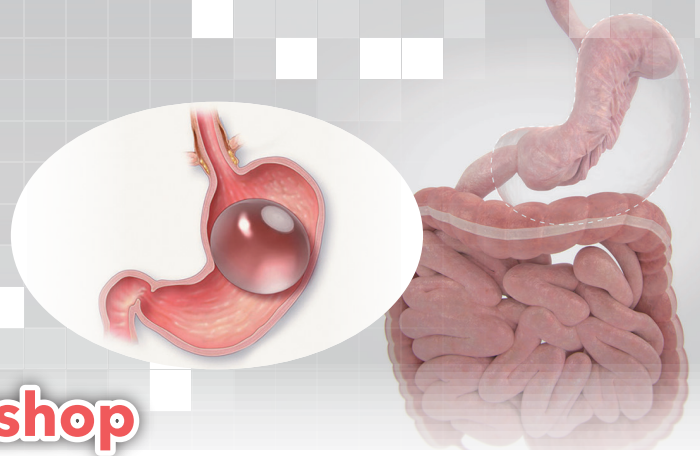
"U" PATTERN

SQUARE / RECTANGLE PATTERN

Neto MG et al. Obesity Surgery (2021) 31:79-78

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Suture pattern does not influence outcomes of ESG

- Retrospective and comparative review of 5 years of prospectively collected data (n=88) at two hospitals in Barcelona, Spain

Suture pattern	%EBWL	%TBWL
Transverse bilinear (TbP)	20.4%	18.9%
Longitudinal (Lp)	45.4%	14.9%
Transverse monilinear (TmP)	18.3%	14.4%

• No differences in %TBWL, but there were in %EWL (43.7 ± 20.4%, 59.8 ± 18.9% and 45.4 ± 14.9% in TbP, Lp and TmP patterns, respectively) (P = 0.034).
 • No differences in number of sutures (mean 5.2 ± 0.73, r = 4 – 7) or stitches (mean 27.4 ± 5.59, r = 18 – 50) applied.
 • 43 of 72 (59.7%) major comorbidities were resolved.
 • No serious AEs were noted with any pattern.

Expinet-Coll et al. *Endosc Int Open* 2022 Oct 31(10):E1348-E1358

Suture pattern does not influence outcomes of ESG

- Single-blind, single-center, prospective randomized controlled trial (each group n=16)
- Age 18 to 65 years, obesity class I or II (BMI 30–40 kg/m²)

A: pattern "band"
Creating a pouch at upper body, mimicking gastric band to increase fundus distensibility

B: pattern "volume reduction"
Longitudinal suture on anterior wall

C: pattern "dams"
Making bridges (dams) in gastric body

TBWL

EBWL

The three groups did not differ in terms of adverse events, mean gastric emptying time or in terms of satiety tests at the end of the follow-up.

	Group A	Group B	Group C	P-value
Nausea, mean (SD)	1.21 (0.81)	2.20 (2.46)	1.88 (2.33)	0.868
Vomiting, mean (SD)	1.27 (0.83)	1.94 (3.36)	0.94 (2.37)	0.463
Cramps, mean (SD)	4.68 (2.39)	4.21 (2.47)	3.83 (3.33)	0.617

Guillotakis P et al. *Endosc Int Open* 2022 Sep 14(10):E1245-E1249

Suturing the gastric fundus does not confer benefit

- Two-center (USA) retrospective analysis of 247 patients who underwent ESG with (ESG-FS) or without (ESG-NFS) fundal suturing
- Primary outcome: %EWL at 3, 6, and 12 months post-ESG
- Secondary outcomes: SAE rate and procedure duration

	ESG-NFS	ESG-FS	P value
EWL (%) at 3-mo	38.4	31.2	0.001
EWL (%) at 6-mo	54.7	37.7	<0.001
EWL (%) at 12-mo	65.3	40.6	<0.001
SAE (%)	2.0	2.6	>0.99
Procedure time (min)	59.1	93.0	<0.001
Suture number	5.7	8.4	<0.001

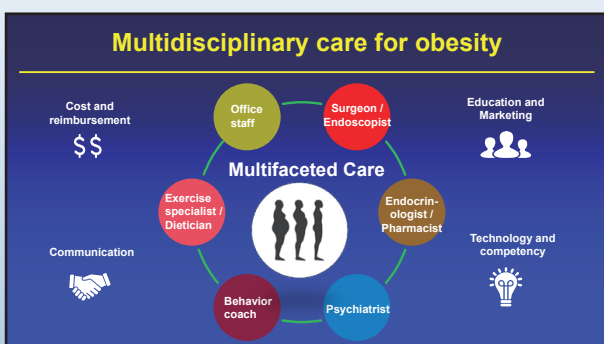
Hypothesis: Preserving adaptive relaxation function of fundus => Delayed gastric emptying time, without increasing intragastric pressure after eating

Farras J et al. *Endoscopy* 2021 Jul 53(7):727-731

Post-procedural care

Includes a flowchart for patient care and a detailed dietary plan (1:1 稀碎) with food images and instructions.

FTI Center, Far Eastern Memorial Hospital, Negi A, et al. *Nutrients*. 2022; PMID: 36014656

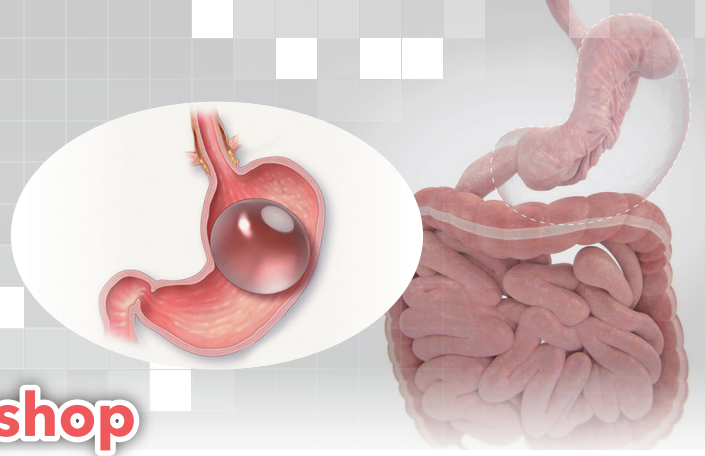


Takeaway messages

- Trained endoscopists can use suturing device to facilitate weight loss by reducing stomach volume through ESG in adult patients with obesity with BMI 30 – 50 kg/m² who have not been able to lose weight, or maintain weight loss, through more conservative measures. (U.S. FDA July 12, 2022)
- ESG is non-inferior to or with lower short- and mid-term weight loss than LSG, but fewer adverse events including GERD.
- Among endoscopic bariatric and metabolic therapies, ESG is the most promising procedure in terms of efficacy and safety. However, long-term data and randomized controlled trials in comparison with other bariatric procedures are warranted.

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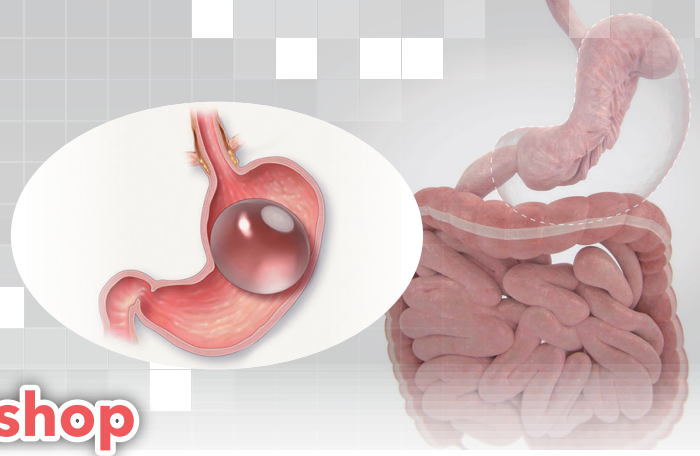
10:25-10:40

**Bariatric surgeries: indications and
outcomes**

Speaker: 陳盛世 主任

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Chen Sheng Shih
Director of bariatric surgery of Kaohsiung Veterans General Hospital

METABOLIC AND BARIATRIC SURGERY

Treatment of Obesity

- How to choose appropriate procedure for metabolic surgery –(definitions and current indications for obesity and metabolic surgery)
- Tips, tricks and complication of surgery

Prevalence

- Obesity is one of the major public health problems for modern world
- Obesity and obesity related chronic diseases including, cardiovascular disease, diabetes, metabolic syndrome, and many cancers are increasing globally.
- 1980 and 2013 showed that, obesity-related deaths are three times more than fatalities related to malnutrition and starvation

Ng M et al. Global, regional, and national prevalence of overweight and obesity in children and adults during 1980-2013: a systematic analysis for the Global Burden of Disease Study 2013

- WHO- in 2016 identified -39% of adult men and women (aged +18) with a BMI >25 kg/m² were “overweight”. Further 11% of men and 15% of women with BMI >30 kg/m² were “obese”.
- 18% of children and adolescents were overweight or obese
- more than 10% of the whole world population -now introduced as “Globesity”

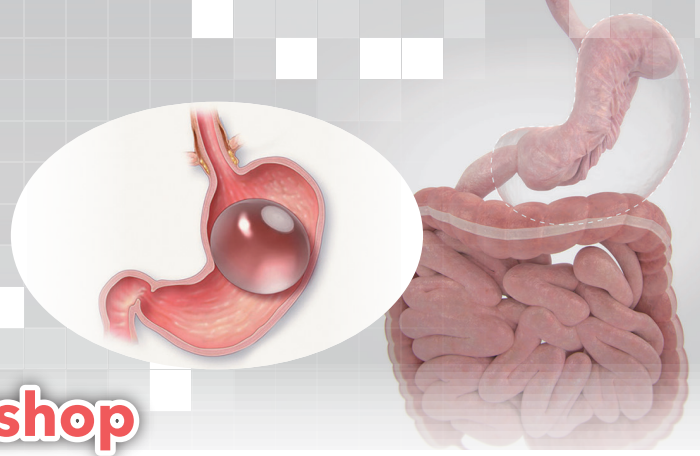
Vasileva LV, Marchev AS, Georgiev MI. Causes and solutions to “globesity”: The new fat(s)it alarming global epidemic. Food Chem Toxicol 2018.

Introduction

- 1950s, the jejunoileal bypass (JIB) surgery, the earliest method of Obesity and Metabolic Surgery, an effective treatment for weight loss and dyslipidemia-serious metabolic post-JIB side effects-failure
- An experimental evaluation of the nutritional importance of proximal and distal small intestine. Ann Surg 1954
- 1966, Dr. Mason introduced the first gastric bypass operation-to different complications- change to standart Roux-En-Y
- Mason EE, Ito C. Gastric bypass in obesity. Surg Clin North Am 1967

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- Current concepts of Bariatric and Metabolic Surgery operations and recent metabolic studies -the mechanisms of these operations seem to extend beyond the magnitude of weight loss.
- different hormonal pathways-for the early metabolic improvements, especially weight-independent glucose-lowering effects of Bariatric and Metabolic Surgery

Madadi S. Mechanisms of changes in glucose metabolism and bodyweight after bariatric surgery. Lancet Diabetes Endocrinol 2014

- Current accepted operations -promise maximum weight loss and metabolic regulatory effects with minimum complication rates.
- Current guidelines support the use of metabolic surgery in individuals with mild obesity and uncontrolled Type 2 Diabetes Mellitus (T2DM)

Rubino F, Nathan DM, Eckel RH, et al. Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations. Diabetes Care 2016

Benefit of bariatric and metabolic surgery

- 1. Diabetes Mellitus -remission or improved
Obesity is a major independent risk factor for developing type 2 diabetes, and more than 90% of type 2 diabetics are overweight or obese, female,male(93 fold, 42fold)

UCLA Center for Obesity and Metabolic Health

- 2. Fatty liver disease
(NAFLD) is one of the most common causes of chronic liver disease worldwide, and morbid obesity is strongly associated with its development.
- NAFLD is subdivided into nonalcoholic fatty liver (NAFL), hepatic steatosis without inflammation, and nonalcoholic steatohepatitis (NASH),
- general approach to the overweight or obese patient with NAFLD or NASH is lifestyle modification and weight loss

UCLA Center for Obesity and Metabolic Health

- Hypertension and Hyperlipidemia
- normalization of hypertension in 30-50% of patients with medication and reduced need of antihypertensive treatment in a further 20-30% of patients.
- resolution of dyslipidemia in about 60%
- 50% reduction of heart attack risk and more than 50% reduction of stroke risk.

UCLA Center for Obesity and Metabolic Health

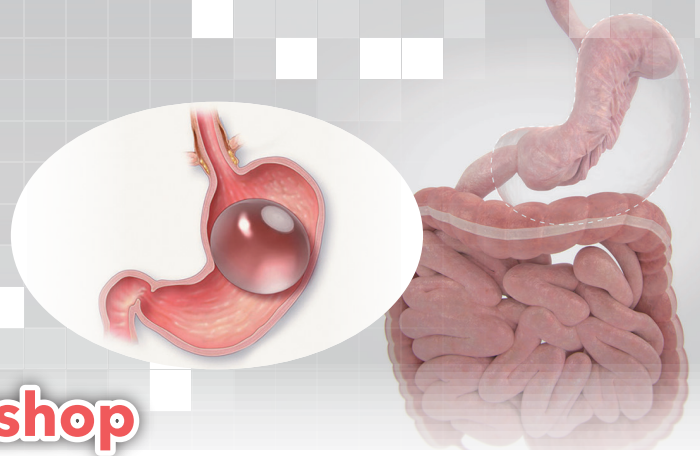
- Joint Pain and Osteoarthritis (OA)
- The Knee osteoarthritis risk was 0.1% for BMI < 20, but 13.6% for BMI > 36. For every 5kg weight gain, there is a commensurate 36% increased risk for developing OA.

Center for Obesity and Metabolic Health

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- Mortality
- prospective study from the United States revealed an increased risk of death with being either overweight (20 to 50 percent increase in those between 26.5 to 29.9) or obese (two- to over threefold increase in those ≥ 30).

• UCLA Center for Obesity and Metabolic Health

- Obstructive Sleep Apnea
- A 10 percent increase in weight was associated with a six fold increase in risk of incident OSA, 70-80 % resolution or improvement
- Obesity Associated Cancer
- nearly 80% reduction of cancer incidence after bariatric surgery.

• UCLA Center for Obesity and Metabolic Health

- Polycystic Ovary Syndrome and Infertility
- 30 percent to 70 percent of obese women of reproductive age and is associated with irregular period, excessive hair and a high risk of infertility.
- 47.0% of patients who were unable to become pregnant preoperatively were successful after bariatric surgery

• UCLA Center for Obesity and Metabolic Health

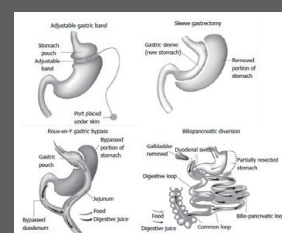
Obesity-Asia Pacific

New proposed classification of BMI in Asia Pacific region		
CATEGORY	BMI (kg/m ²)	COMORBIDITY RISK
Under-weight	< 18.50	Low (but increased risk of other clinical problems)
Normal	18.50 – 22.99	Average
Over-weight	23.00 – 24.99	Increased
Obese I	25.00 – 29.99	Moderate
Obese II	≥ 30	Severe

* The Asia Pacific International Resemblance Obesity and its Treatment (EASO 2008) WHO Obesity Global Action Plan International Association for the Study of Obesity (IASO) & International Obesity Task Force

Methods of surgery

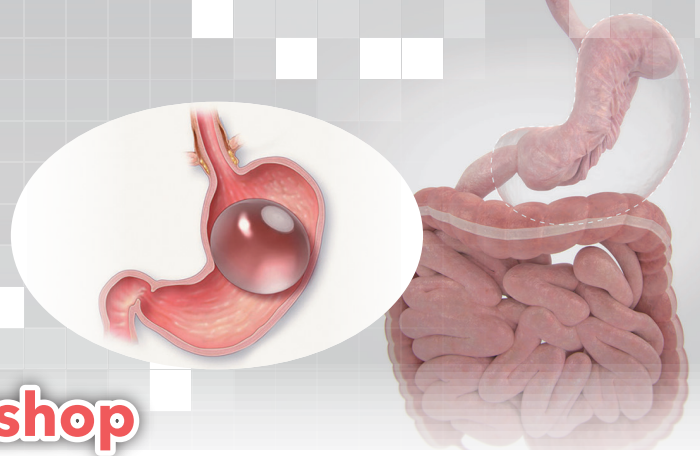
- 1.restrictive:
- Lap band, sleeve gastrectomy
- 2.restrictive+malabsorption
- Roux-en-Y gastric bypass ,biliopancreatic diversion ,mini-gastric bypass(OAGB ,SADI-S)
- 3.malabsorption-duodenal switch



Bariatric surgery and long term nutritional issues, world journal of diabetes 2017

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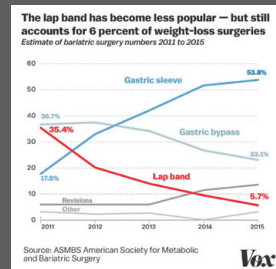
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Prevalence

- 2013 survey of (IFSO), the total number of bariatric procedures performed worldwide was 468,609
- RYGB-45%, SG-35%

Prevalence



Estimate of Bariatric Surgery Numbers, 2011-2020

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Sleeve	28,124	57,090	75,359	99,781	105,448	125,318	135,401	154,976	152,413	122,056
RYGB	57,986	64,875	61,218	51,724	45,276	40,316	40,074	42,945	45,744	41,289
Band	55,932	34,946	25,000	18,335	11,172	7,310	6,318	2,660	2,375	2,283
BPO-DS	1,422	1,730	1,790	772	1,176	1,236	1,588	2,123	2,272	3,550
Revision	9,480	10,380	10,740	22,195	20,656	30,077	32,238	38,971	42,881	22,022
SAH	—	—	—	—	—	—	—	—	—	4,883
OMG	—	—	—	—	—	—	—	—	—	5,338
Other	5,056	3,979	4,833	193	6,272	5,865	5,606	5,847	6,060	5,221
ENO	—	—	—	—	—	—	—	—	—	1,500
Balloons	—	—	—	—	700	5,744	6,280	5,042	4,655	2,800
Total	158,000	171,000	179,000	193,000	196,700	215,696	228,005	252,564	256,000	198,051

The ASBMS total bariatric procedure numbers are based on the best estimation from available data (BOLD ACS/NESQAIP, National Inpatient Sample Data and outpatient estimations).

Operation selection for bariatric and metabolic surgery

- Choice of surgery depends –
 1. patient's status weight loss
 2. metabolic control
 3. patient's preferences
 4. surgeon's expertise
 5. facilities
- None of the different approaches for obesity and metabolic surgery has gained superiority over another.

Definitions and current indications for obesity and metabolic surgery 2021

Past indications

- Obesity surgery guidelines throughout the years – change over time
- 1978(NIH)- high serious complications- age limit 50 years old
- 1991(NIH)- Vertical banded gastroplasty(VBG), Gastric bypass are recommended

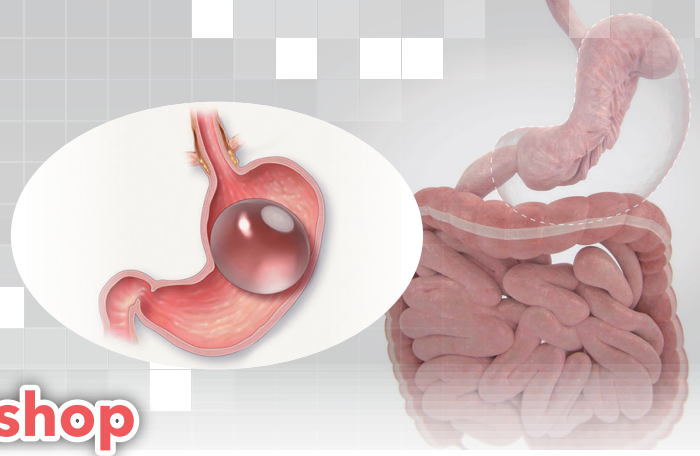
Table 2 Obesity and metabolic surgery indications changed by years

Indications	Consensus in 1991 NIH	Consensus in 2004 ASBS	Current ASBMS Qualifications for our
Age	No age limit	No age limit	18 to 60 Note: successful and safe bariatric surgery has been performed in patients in their 70s and in adolescents Patients aged above 60 should be considered individually
BMI	>40 or >35 with specific co-morbidities	>40 or >35 with co-morbidities	>40 or >35 with co-morbidities
Co-morbidities	Obstructive sleep apnea syndrome Pickwickian syndrome Obesity related cardiomyopathy Severe diabetes mellitus Obesity-induced physical problems interfering with lifestyle, i.e., disabling arthropathy	Obstructive sleep apnea syndrome Pickwickian syndrome Obesity related cardiomyopathy Severe diabetes mellitus Obesity-induced physical problems interfering with lifestyle, i.e., disabling arthropathy (severe joint disease)	Obstructive sleep apnea syndrome a other respiratory disorders – Heart disease Type 2 diabetes mellitus Osteoarthritis

Fried M, Yumuk V, Oppart JM, et al. Interdisciplinary European guidelines on metabolic and bariatric surgery. Obes Surg 2014

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Drug image to repository. Double click to magnify further.		
	Severely reducing quality of life	Severely reducing quality of life
Genetic factors	-	Severely reducing quality of life Hypertension Non-alcoholic fatty liver disease Lipid abnormalities Gastrointestinal Disorders Consideration to reducing the BMI by 2.5 for patients have Asian genetic background
Adolescents	Not sufficiently studied	BMI $\geq 35 \text{ kg/m}^2$ or higher with major comorbidities (such as Type 2 diabetes, moderate or severe sleep apnea, pancreatic cancer, or severe fatty liver disease) BMI $\geq 33 \text{ kg/m}^2$ or higher with other less severe comorbidities (such as high blood pressure, high cholesterol, mild or moderate sleep apnea)
Recommended Operation Types	<ul style="list-style-type: none"> Vertical Banded Gastroplasty (VBG) Gastric Bypass 	<ul style="list-style-type: none"> Gastric bypass Laparoscopic adjustable Gastric Banding Vertical Banded Gastroplasty (VBG) Biliopancreatic diversion and duodenal switch Sleeve Gastrectomy Laparoscopic adjustable Gastric Banding Biliopancreatic diversion and duodenal switch
Lower BMI-Class	This BMI change requires obesity (BMI ≥ 30) additional data and long-term risk-benefit analyses	Certain data demonstrate that bariatric surgery can ameliorate obesity comorbidities (e.g., type 2 diabetes) in patients with a BMI $< 35 \text{ kg/m}^2$ T2 DM (Patients with BMI ≥ 30 and $< 35 \text{ kg/m}^2$ may be considered for surgery to T2 DM remission)

ASMBS/IFSO NEW Guidelines for BMS(2022)

- Major updates to 1991 NIH Guidelines for bariatric surgery
- Metabolic and Bariatric surgery (MBS) is recommended for individuals with BMI $\geq 35 \text{ kg/m}^2$, regardless of presence, absence, or severity of comorbidities.
- MBS should be considered for individuals with metabolic disease and BMI 30-34.9 kg/m^2
- BMI thresholds should be adjusted in the Asian population such that BMI $\geq 25 \text{ kg/m}^2$ suggests clinical obesity, and individuals with BMI $\geq 27.5 \text{ kg/m}^2$ should be offered MBS

The contraindications for Bariatric Surgery

- Absence of medical management;
- Non-stabilized psychotic disorders;
- Severe depression and/or personality disorders;
- Alcohol abuse and/or drug addiction;

The contraindications for Bariatric Surgery

- A life threatening disease in the short-term;
- Patients who are not able to care for themselves;
- Secondary diabetes and T2DM with positive antibodies (anti-GAD or ICA) or having less than 1 ng/mL c-peptide level or unresponsive to mixed meal challenge are contraindicated for bariatric surgery.

Tips, tricks and complication of surgery

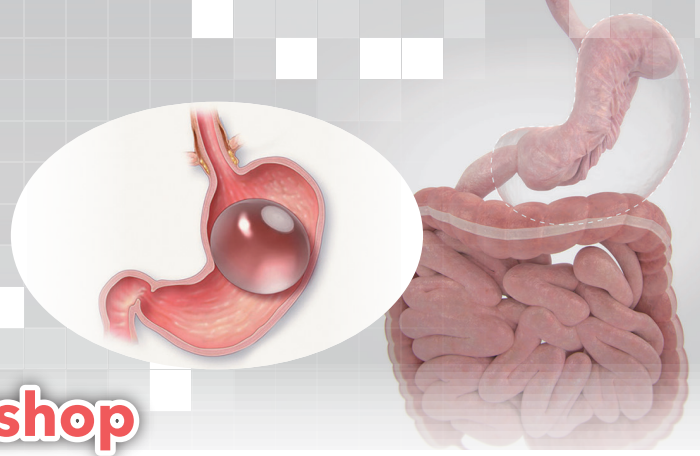
- Sleeve gastrectomy
- Roux-en-Y (RYGB)

Sleeve gastrectomy

- fewer major complications within the first month of the post-operative period
- ASMBS defines SG as a recognizable primary surgical procedure for patients who was planned a staged approach.
- restrictive operation -an increased post-operative intraluminal pressure
- strong evidence that SG is shown to increase post-operative reflux or *de novo* reflux
- Howard DD et al. Gastroesophageal reflux after sleeve gastrectomy in morbidly obese patients. Surg Obes Relat Dis 2011

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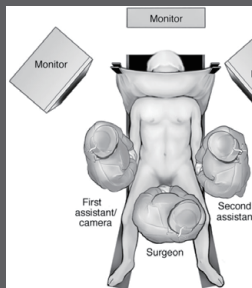
- considering indications of surgery, reflux is not a strong contraindication however, one should know that with current data in patients with reflux disease that was diagnosed preoperatively, the operation of choice should be the RYGB procedure. RYGB is shown to be effective on resolving GER symptoms

Woodman G, Cywes R, Billy H, et al. Effect of adjustable gastric banding on changes in gastroesophageal reflux disease (GERD) and quality of life. *Curr Med Res Opin* 2012

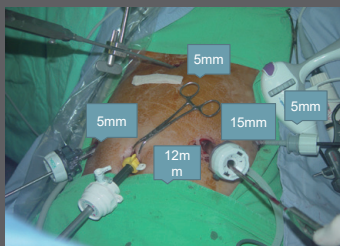
- long-term results (body weight regain) - major decrease of %EWL that could result in weight regain (from starting %EWL of 80% to 50–60% in 5 years)
- 20% remission rate of diabetes, within 5 years
- RYGB, the remission rate of DM and long term EWL success is slightly better.

Hoyuela C. Five-year outcomes of laparoscopic sleeve gastrectomy as a primary procedure for morbid obesity: A prospective study. *World J Gastrointest Surg* 2017

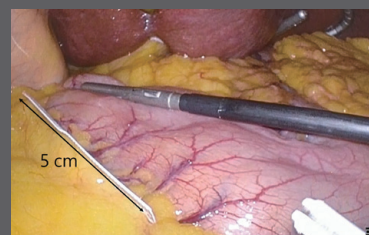
French position



- pneumoperitoneum via the optical trocar technique
- Five trocars, 12mm, 15mm, 5mm x III

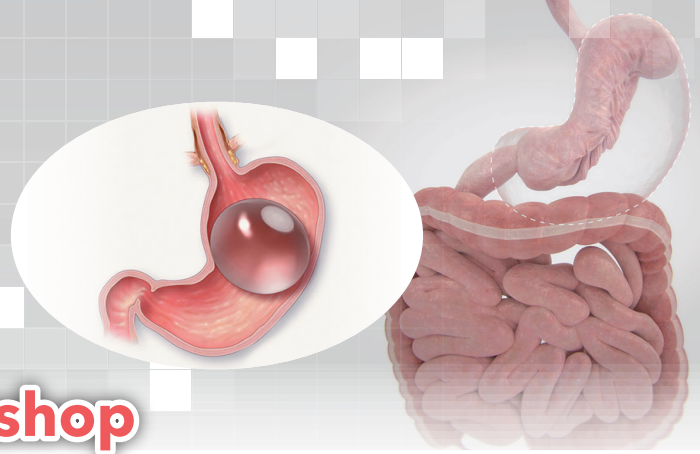


Distance from pylorus at least 5cm

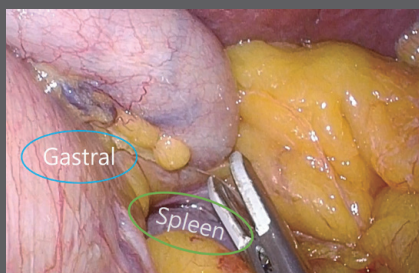
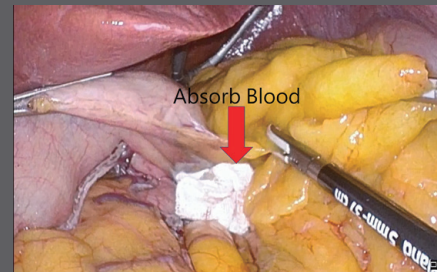
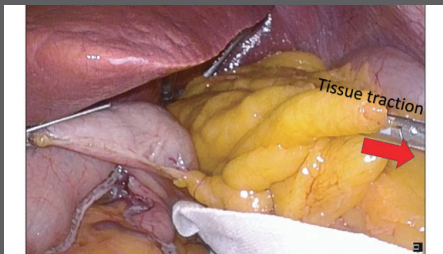
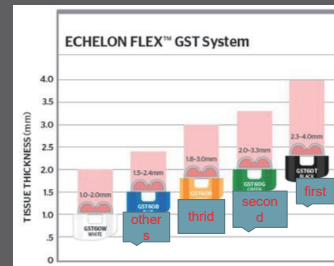
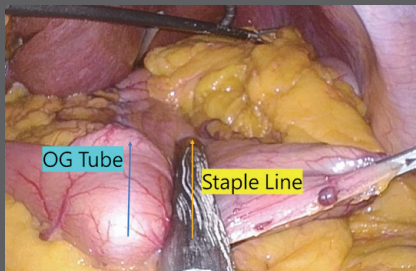


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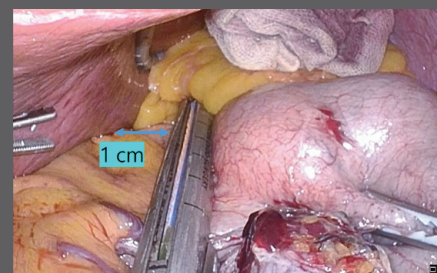
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38 French OG tube , just create 3cm gastrocolic ligament

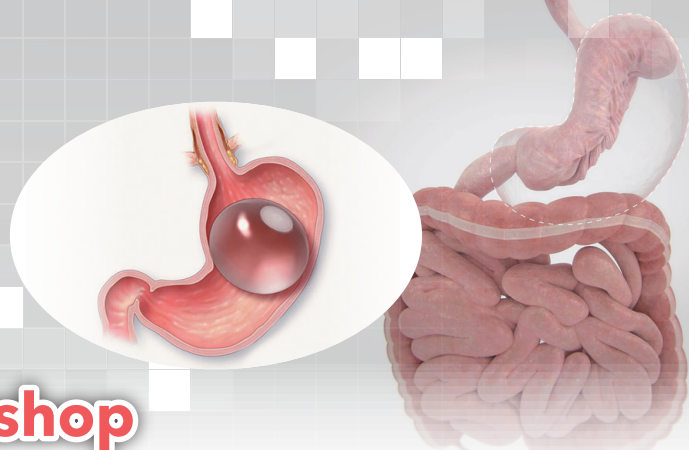


Away from EC junction 1cm



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Late complication of surgery

- Complications of bariatric surgery that occur after 30 days include cholelithiasis, nutritional deficiencies, and neurologic and psychiatric complications

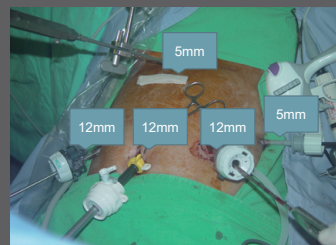
Early complication rate

- anastomotic leak rate was 1.15%
- myocardial infarction rate was 0.37%;
- pulmonary embolism rate was 1.17%.
- mortality rate following anastomotic leak was 0.12%, myocardial infarction - 0.37%
- pulmonary embolism was 0.18%

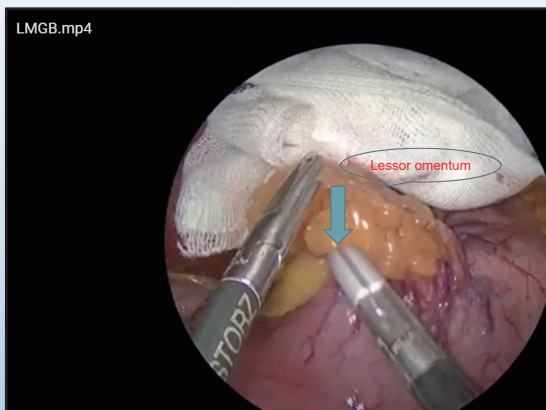
S.H. Chang Early major complications after bariatric surgery in the USA, 2003–2014: a systematic review and meta-analysis 2017

RYGB

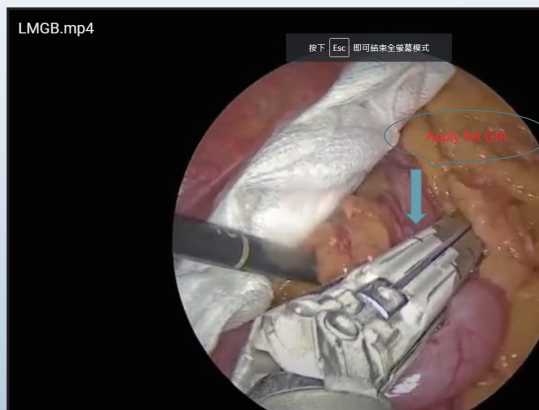
- small pouch of about 30–40 mL from the proximal stomach
- attaches this pouch to jejunum that is called a roux limb



LMGB.mp4

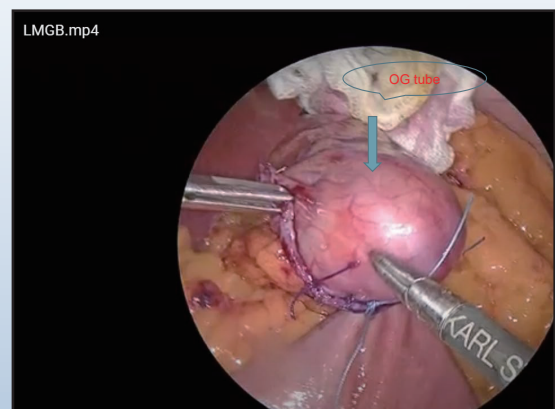
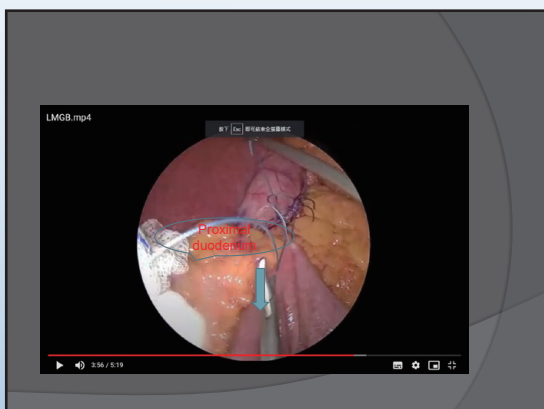
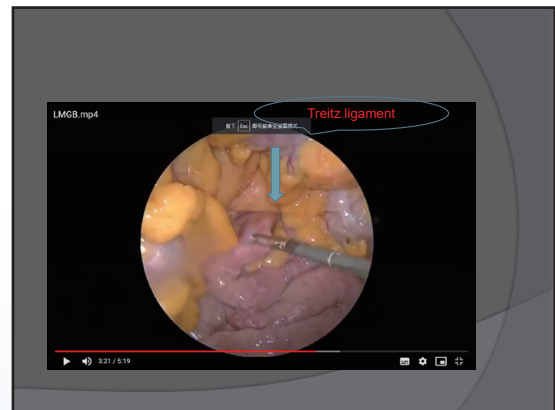
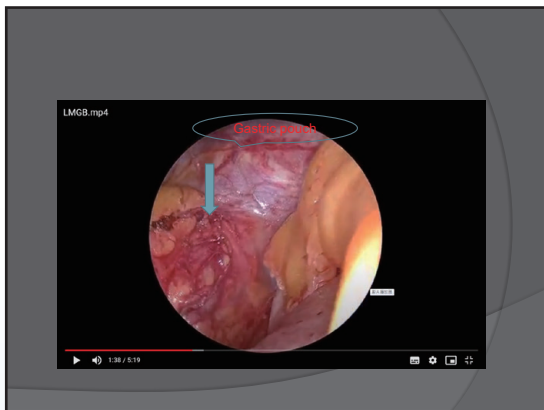
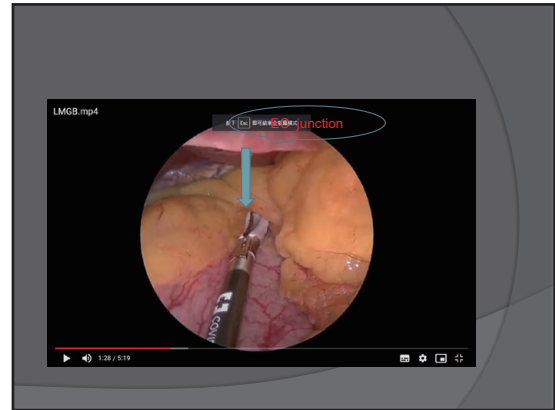
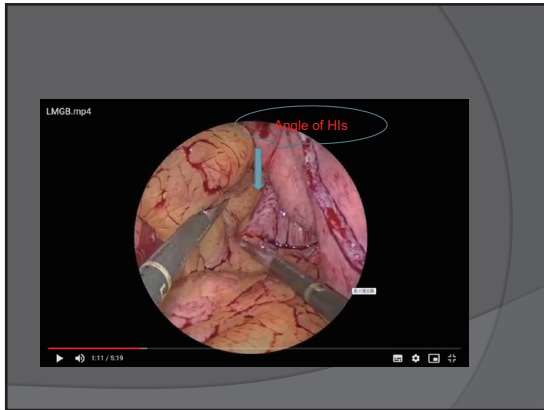
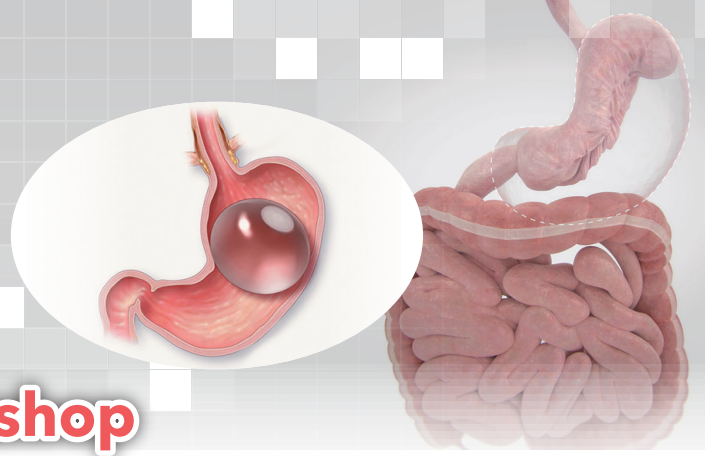


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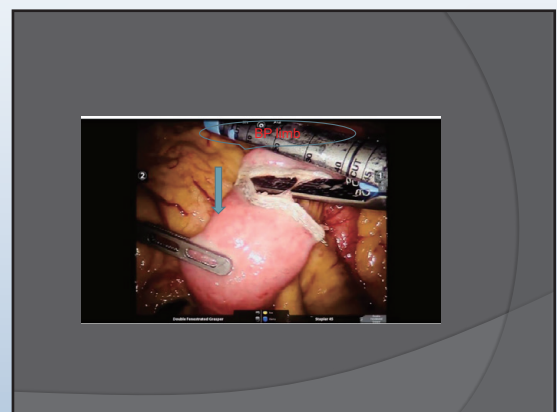
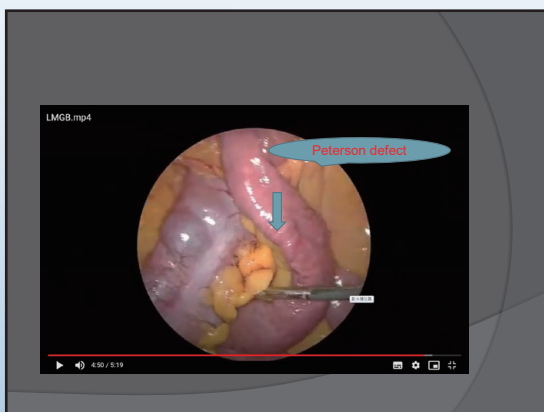
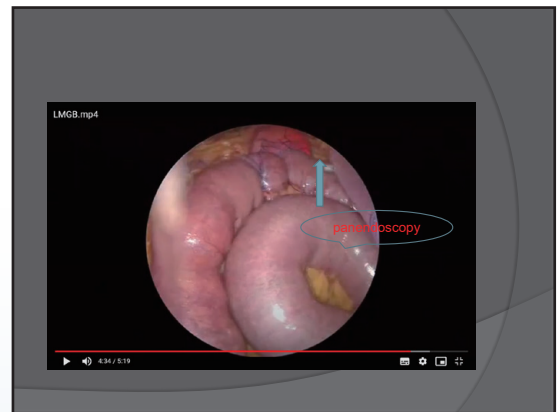
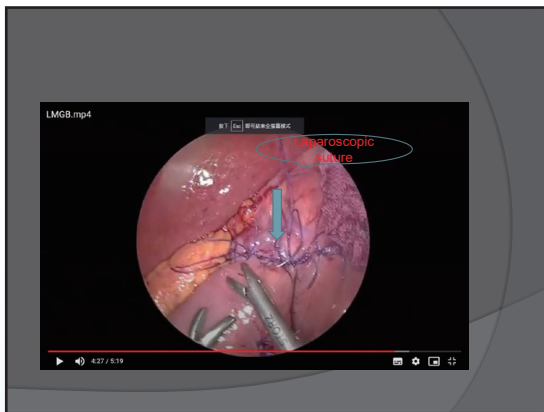
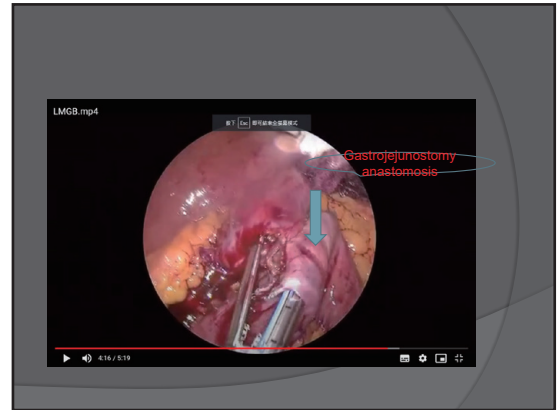
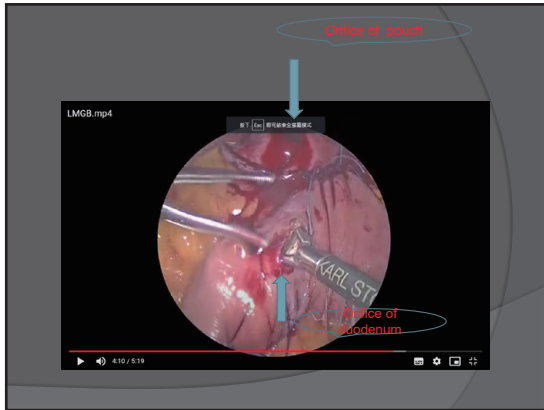
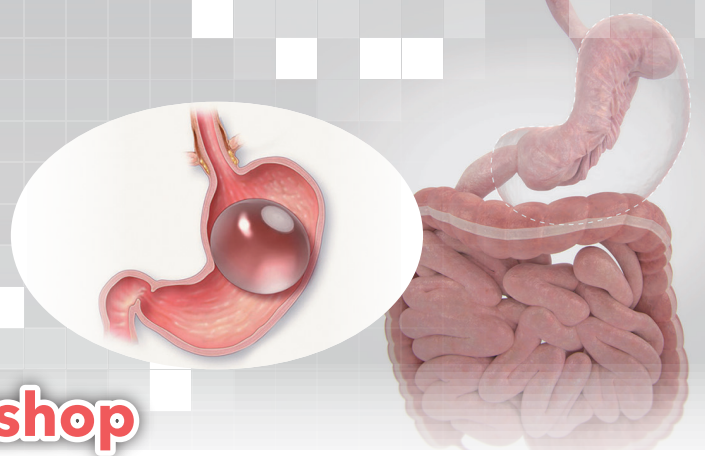
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Endoscopic Bariatric and Metabolic Therapies Workshop



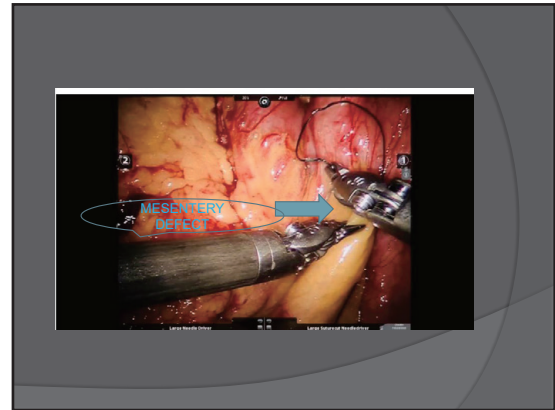
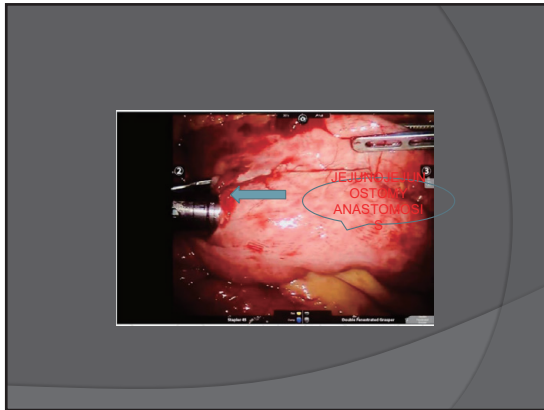
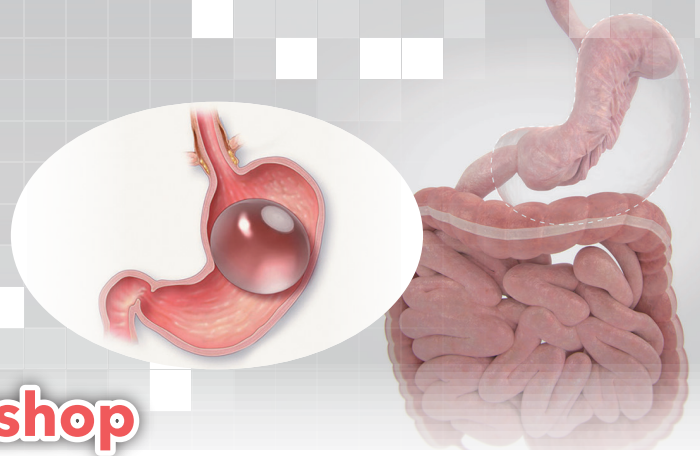
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Early complication

- Anastomotic leak (1-3%)
- Pulmonary embolism, DVT (< 1%)
- Wound infection (more common with open approach)
- Gastrointestinal hemorrhage, bleeding (0.5-2%)
- Respiratory insufficiency, pneumonia
- Acute distention of the distal stomach

Alan A Saber, What are early complications of Roux-en-Y gastric bypass bariatric surgery?2021

Late complication

- Stomal stenosis, most common (20%)
- Bowel obstruction, small bowel obstruction (1%)
- Internal hernia
- Cholelithiasis
- Micronutrient deficiencies
- Marginal ulcer
- Staple line disruption
- Ventral hernia formation

Alan A Saber, What are early complications of Roux-en-Y gastric bypass bariatric surgery?2021



Thanks for your attention !



台灣消化系內視鏡醫學會
The Digestive Endoscopy Society of Taiwan