

我們的團隊

R:謝懷德 醫師

R:何予甯 醫師

NP:楊堯郡 專科護理師





臨床場景Clinical Scenario

阿國,男性,45歲,身高165公分,體重100公斤,BMI:

36.73,近期診斷出高血壓、糖尿病、膽固醇過高情形。醫師建議他可以先從飲食控制及運動著手,他想知道,吃魚油及吃蛋,對於心血管疾病的效益。

經過半年**飲食控制**,阿國的抽血及體重皆無改善,他想知道自己適不適合**減重手術**,以及手術對於三高的控制是不是也有幫助。

希望醫師給他一點建議,以供判斷。

APPROACH TO MANAGEMENT

Circulation, 2017 Apr 11;135(15):e867-e884. doi: 10.1161/CIR.000000000000482. Epub 2017 Mar 13.

Omega-3 Polyunsaturated Fatty Acid (Fish Oil) Supplementation and the Prevention of Clinical Cardiovascular Disease: A Science Advisory From the American Heart Association.

Siscovick DS, Barringer TA, Fretts AM, Wu JH, Lichtenstein AH, Costello RB, Kris-Etherton PM, Jacobson TA, Engler MB, Alger HM, Appel LJ, Mozaffarian D; American Heart Association Nutrition Committee of the Council on Lifestyle and Cardiometabolic Health; Council on Epidemiology and Prevention; Council on Cardiovascular Disease in the Young; Council on Cardiovascular and Stroke Nursing; and Council on Clinical Cardiology.

Abstract

Multiple randomized controlled trials (RCTs) have assessed the effects of supplementation with eicosapentaenoic acid plus docosahexaenoic acid (omega-3 polyunsaturated fatty acids, commonly called fish oils) on the occurrence of clinical cardiovascular diseases. Although the effects of supplementation for the primary prevention of clinical cardiovascular events in the general population have not been examined, RCTs have assessed the role of supplementation in secondary prevention among patients with diabetes mellitus and prediabetes, patients at high risk of cardiovascular disease, and those with prevalent coronary heart disease. In this scientific advisory, we take a clinical approach and focus on common indications for omega-3 polyunsaturated fatty acid supplements related to the prevention of clinical cardiovascular events. We limited the scope of our review to large RCTs of supplementation with major clinical cardiovascular disease end points; meta-analyses were considered secondarily. We discuss the features of available RCTs and provide the rationale for our recommendations. We then use existing American Heart Association criteria to assess the strength of the recommendation and the level of evidence. On the basis of our review of the cumulative evidence from RCTs designed to assess the effect of omega-3 polyunsaturated fatty acid supplementation on clinical cardiovascular events, we update prior recommendations for patients with prevalent coronary heart disease, and we offer recommendations, when data are available, for patients with other clinical indications, including patients with diabetes mellitus and prediabetes and those with high risk of cardiovascular disease, stroke, heart failure, and atrial fibrillation.

KEYWORDS: AHA Scientific Statements; cardiovascular disease; fatty acids, omega-3; fish oils; prevention and control; randomized controlled trials



APPROACH TO MANAGEMENT

- Protein Protein should make up 10 to 35 percent of total caloric intake, as recommended by the United States Dietary Guidelines. Individuals should be counseled to eat a variety of healthy protein-rich foods, including fish, lean meat, poultry, eggs, beans, peas, soy products, and unsalted nuts and seeds.
- Protein-rich foods Individuals should be advised to take 5.5 ounces of protein-rich foods daily (approximately two to three servings) for a 2000-calorie diet, as recommended by the United States Dietary Guidelines (table 7).

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USDA recommended daily or weekly caloric intake of different food groups (USDA recommended average daily food intake)

Calorie level of pattern*	1000	1200	1400	1600	1800	2000		
Food group Daily amount of food from each group (vegetable and protein foods subgroup amounts are per week)								
Vegetables	1 c-eq	11/2 c-eq	11/2 c-eq	2 c-eq	21/2 c-eq	21/2 c-eq		
Dark-green vegetables (c-eq/week)	1/2	1	1	11/2	11/2	11/2		
Red and orange vegetables (c-eq/week)	21/2	3	3	4	51/2	51/2		
Legumes (beans and peas) (c-eq/week)	1/2	1/2	1/2	1	11/2	11/2		
Starchy vegetables (c-eq/week)	2	31/2	31/2	4	5	5		
Other vegetables (c-eq/week)	11/2	21/2	21/2	31/2	4	4		
Fruits	1 c-eq	1 c-eq	11/2 c-eq	11/2 c-eq	11/2 c-eq	2 c-eq		
Grains	3 oz-eq	4 oz-eq	5 oz-eq	5 oz-eq	6 oz-eq	6 oz-eq		
Whole grains (oz-eq/day)	11/2	2	21/2	3	3	3		
Refined grains (oz-eq/day)	11/2	2	21/2	2	3	3		
Dairy	2 c-eq	21/2 c-eq	21/2 c-eq	3 c-eq	3 c-eq	3 c-eq		
Protein foods	2 oz-eq	3 oz-eq	4 oz-eq	5 oz-eq	5 oz-eq	51/2 oz-eq		
Seafood (oz-eq/week)	3	4	6	8	8	8		
Meats, poultry, eggs (oz-eq/week)	10	14	19	23	23	26		
Nuts seeds, soy products (oz-eq/week)	2	2	3	4	4	5		
Oils	15 g	17 g	17 g	22 g	24 g	27 g		
imit on calories for other uses, calories (% of calories) $^{\S^{rac{1}{4}}}$	150 (15%)	100 (8%)	110 (8%)	130 (8%)	170 (9%)	270 (14%)		

Height:165cm/Weight:100kg/BMI:36.73

INDICATIONS of Bariatric operations—

The patient阿國

Candidates for a bariatric surgical procedure include [19]:

- Adults with a BMI ≥40 kg/m² without comorbid illness [20-30].
- Adults with a BMI 35.0 to 39.9 kg/m² with at least one serious comorbidity, including but not limited to [31-48]:
 - Type 2 diabetes [49,50].
 - · Obstructive sleep apnea (OSA).
 - Hypertension.
 - Hyperlipidemia.
 - Obesity-hypoventilation syndrome (OHS).
 - · Pickwickian syndrome (combination of OSA and OHS).
 - · Nonalcoholic fatty liver disease (NAFLD).
 - Nonalcoholic steatohepatitis (NASH).
 - Pseudotumor cerebri.
 - Gastroesophageal reflux disease.
 - Asthma.
 - Venous stasis disease.
 - · Severe urinary incontinence.
 - Debilitating arthritis.
 - · Impaired quality of life.
 - Disqualification from other surgeries as a result of obesity (ie, surgeries for osteoarthritic disease, ventral hernias, or stress incontinence).

Medical outcomes following bariatric surgery

- Diabetes mellitus In addition to achieving weight loss, bariatric procedures result in marked improvement or resolution of many obesity-related health problems, such as type II diabetes.
- Bariatric surgical procedures, particularly RYGB, plus medical therapy, are effective interventions for treating type 2 diabetes. Improvement in metabolic control is often evident within days to weeks following RYGB, most likely reflecting an alteration in metabolism that is independent of weight loss.

Medical outcomes following bariatric surgery

- Hypertension Weight loss, whether by an intensive lifestyle-medical modification program or a bariatric operation, improves obesity-linked hypertension or contributes to remission. A randomized trial that included 120 obese patients (BMI 30.0 to 39.9) found that patients undergoing an RYGB (n = 60) plus intensive lifestyle medical management were able to achieve a similar reduction in systolic blood pressure at 12 months compared with patients managed with lifestyle medical modification alone (84 versus 79 percent).
- While intensive lifestyle modification resulting in weight loss appears beneficial for resolution of hypertension, this is unfortunately not feasible for all patients.

Medical outcomes following bariatric surgery

Dyslipidemia — Clinical studies have demonstrated improved lipid profiles following bariatric procedures. Perhaps the most extensively studied procedure is the RYGB. In a retrospective study that included 95 patients one year following RYGB, the mean total cholesterol levels decreased by 16 percent, triglyceride levels decreased by 63 percent, low-density lipoprotein cholesterol levels decreased by 31 percent, very-lowdensity lipoprotein cholesterol decreased by 74 percent, total cholesterol/high-density lipoprotein cholesterol risk ratio decreased by 60 percent, and high-density lipoprotein cholesterol levels increased by 39 percent.

檢索策略 先以" P&I" 搜尋·再依結果調整納入關鍵字和同義字

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研究 Studies

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The "55" levels of organisation of evidence from healthcare research

臨床問題 Asking 提出可以回答的臨床問題



Synonym 1 (MeSH term)



A 25 y/o male with traumatic liver injury

Obesity
Diabetes Mellitus

Obesity
Diabetes Mellitus

Surgical intervention
Bariatric Surgery

Bariatric Surgery

Bariatric Surgery

Lifestyle modification & No surgery

Lifestyle

Non-operative

0

Outcome

Outcome

Outcome



這是一個 《治療型 () 診斷型 () 預後型 () 傷害型問題

搜尋結果(Synonym 1)

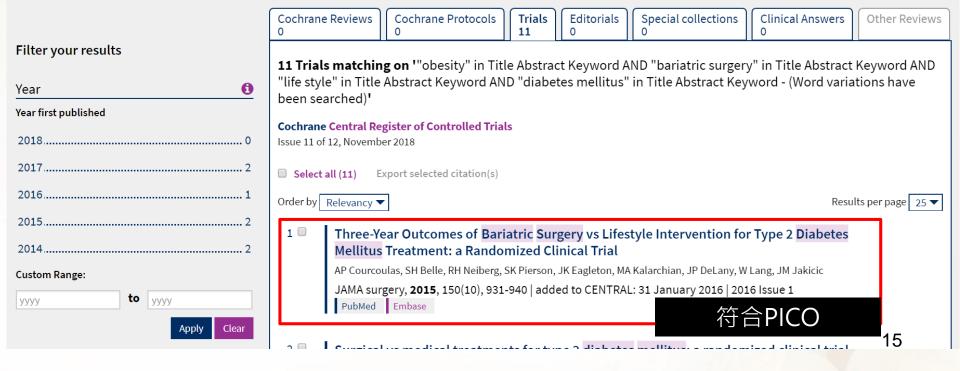
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Trip Liberating the literature	40	2
PublMed	51	3







≭ Clear all



9 Effects of diet and physical activity interventions on weight loss and cardiometabolic risk factors in severely obese adults: a randomized trial

BH Goodpaster, JP Delany, AD Otto, L Kuller, J Vockley, JE South-Paul, SB Thomas, J Brown, K McTigue, KC Hames, W Lang, JM Jakicic

JAMA, 2010, 304(16), 1795-1802 | added to CENTRAL: 31 January 2011 | 2011 Issue 1

PubMed

10 🗆 Roux-en-Y gastric bypass surgery or lifestyle with intensive medical management in patients with type 2 diabetes: feasibility and 1-year results of a randomized clinical trial

F Halperin, SA Ding, DC Simonson, J Panosian, A Goebel-Fabbri, M Wewalka, O Hamdy, M Abrahamson, K Clancy, K Foster, D Lautz, A Vernon, AB Goldfine

JAMA surgery, **2014**, 149(7), 716-726 | added to CENTRAL: 30 September 2014 | 2014 Issue 9

PubMed Embase

符合PICO

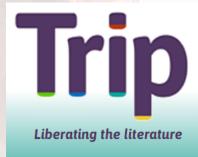
11 Osa in bariatric population; current evidence among asians

N Chirakalwasan

Respirology. Conference: 21st congress of the asian pacific society of respirology, APSR 2016. Thailand. Conference start: 20161112. Conference end: 20161115, 2016, 21, 12 | added to CENTRAL: 31 January 2017 | 2017 Issue 1

Embase





SEARCH	PICO	ADVANCED PRO	RECENT PRO
JEANCH	1100	ADVANCED	ILECTIVI

(Obesity Diabetes Mellitus)(Bariatric Surgery)(Life Style)

Q

Language Settings

40 results for (Obesity Diabetes Mellitus)(Bariatric Surgery)(Life Style) by date ▼

■ 1. ESC/ESH Management of Arterial Hypertension

European Society of Cardiology 2018

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 \triangle

2. Why doctors have a hard time talking about obesity

KevinMD blog 2017

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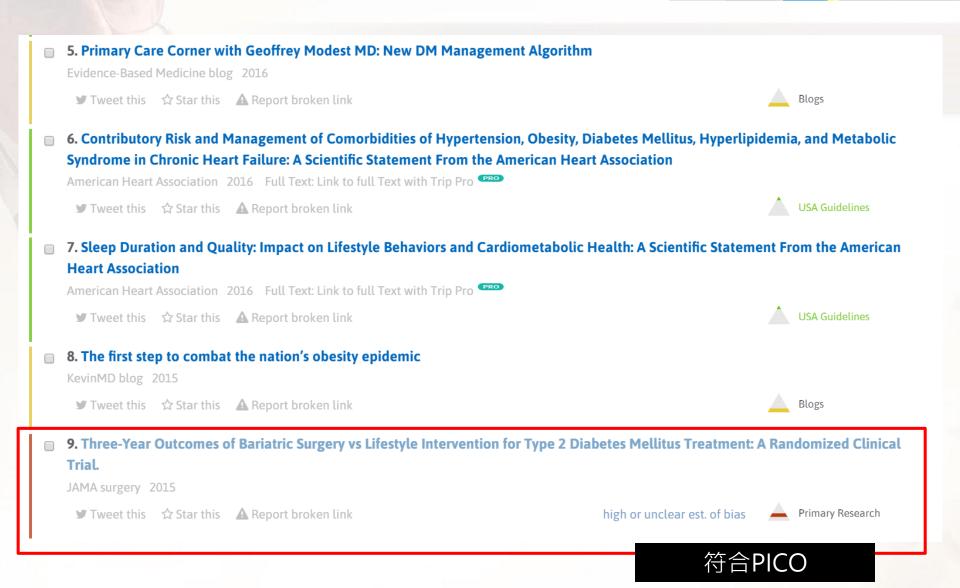
3. Primary Care Corner with Geoffrey Modest MD: Review of diabetes care guidelines 2017

Evidence-Based Medicine blog 2017

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4. Self-Care for the Prevention and Management of Cardiovascular Disease and Stroke







- Critical review of bariatric surgery, medically supervised diets, and behavioural interventions for
- 7. weight management in adults.

Beaulac J, Sandre D.

Perspect Public Health. 2017 May;137(3):162-172. doi: 10.1177/1757913916653425. Epub 2016 Jun 27. Review.

PMID: 27354536 Similar articles

- Durability of Addition of Roux-en-Y Gastric Bypass to Lifestyle Intervention and Medical
- 8. <u>Management in Achieving Primary Treatment Goals for Uncontrolled Type 2 Diabetes in Mild to Moderate Obesity: A Randomized Control Trial.</u>

Ikramuddin S, Korner J, Lee WJ, Bantle JP, Thomas AJ, Connett JE, Leslie DB, Inabnet WB 3rd, Wang Q, Jeffery RW, Chong K, Chuang LM, Jensen MD, Vella A, Ahmed L, Belani K, Olofson AE, Bainbridge HA, Billington CJ.

Diabetes Care. 2016 Sep;39(9):1510-8. doi: 10.2337/dc15-2481. Epub 2016 Jun 16.

PMID: 27311493 Free PMC Article

Similar articles

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- Improvements in glycemic control after gastric bypass occur despite persistent adipose tissue
- 9. inflammation.

Kratz M, Hagman DK, Kuzma JN, Foster-Schubert KE, Chan CP, Stewart S, van Yserloo B, Westbrook EO, Arterburn DE, Flum DR, Cummings DE.

Obesity (Silver Spring). 2016 Jul;24(7):1438-45. doi: 10.1002/oby.21524. Epub 2016 May 26.

PMID: 27228052 Free PMC Article

Similar articles

Three-Year Outcomes of Bariatric Surgery vs Lifestyle Intervention for Type 2 Diabetes Mellitus

Treatment: A Randomized Clinical Trial.

Courcoulas AP, Belle SH, Neiberg RH, Pierson SK, Eagleton JK, Kalarchian MA, DeLany JP, Lang W, Jakicic JM.

JAMA Surg. 2015 Oct;150(10):931-40. doi: 10.1001/jamasurg.2015.1534.

PMID: 26132586 Free PMC Article

Similar articles



- Obesity and diabetes in an aging population: time to rethink definitions and management?
- ^{16.} Rothberg AE, Halter JB.

Clin Geriatr Med. 2015 Feb;31(1):1-15, vii. doi: 10.1016/j.cger.2014.08.016. Epub 2014 Oct 16. Review.

PMID: 25453297 Similar articles

- Clinical trial demonstrates exercise following bariatric surgery improves insulin sensitivity.
- 17. Coen PM, Tanner CJ, Helbling NL, Dubis GS, Hames KC, Xie H, Eid GM, Stefanovic-Racic M, Toledo FG, Jakicic JM, Houmard JA, Goodpaster BH.

J Clin Invest. 2015 Jan;125(1):248-57. doi: 10.1172/JCI78016. Epub 2014 Dec 1.

PMID: 25437877 Free PMC Article

Similar articles

- Obesity and type 1 diabetes mellitus management.
- Chillarón JJ, Benaiges D, Mañé L, Pedro-Botet J, Flores Le-Roux JA. Minerva Endocrinol. 2015 Mar;40(1):53-60. Epub 2014 Nov 21. Review.

PMID: 25413942 Similar articles

嚴格評讀 critical appraisal

Clinical and Patient-Centered Outcomes in Obese Patients With Type 2 Diabetes 3 Years After Randomization to Roux-en-Y Gastric Bypass Surgery Versus Intensive Lifestyle Management: The SLIMM-T2D Study

Donald C. Simonson¹n, Florencia Halperin¹, Kathleen Foster², Ashley Vernon³ and Allison B. Goldfine²

+ Author Affiliations

Corresponding author: Donald C. Simonson, dsimonso@hsph.harvard.edu.

Diabetes Care 2018 Apr; 41(4): 670-679. https://doi.org/10.2337/dc17-0487





這篇文獻「納入理由」



最符合臨床問題



() 最佳的研究設計

April 2018, Randomised controlled trial, RCT





有全文可供評讀

評讀工具 Critical Appraisal tools

Medical outcomes following bariatric surgery

- 使用 CASP Systematic Review Checklist (目前最新 31.05.13版,共10題)
- · 並以VIP進行評讀
 - · Validity 效度 研究方法評析以判斷結果之可信與否
 - Importance 重要性 結果差異的重要性及對臨床的意義
 - Practicability 實用性 可否用來照顧我的病人

1. Did the review address a clearly focused question?

This paper: Yes **✓** No □ Unclear □

· Yes,依據標題及摘要,問了一個清楚、明確的臨床問題,並符合PICO、最新發表年份

Abstract

OBJECTIVE To compare the effect of Roux-en-Y gastric bypass (RYGB) surgery versus intensive medical diabetes and weight management (IMWM) on clinical and patient-reported outcomes in obese patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS We prospectively randomized 38 obese patients with type 2 diabetes (15 male and 23 female, with mean \pm SD weight 104 \pm 16 kg, BMI 36.3 \pm 3.4 kg/m², age 52 \pm 6 years, and HbA_{1c} 8.5 \pm 1.3% [69 \pm 14 mmol/mol]) to laparoscopic RYGB (n = 19) or IMWM (n = 19). Changes in weight, HbA_{1c}, cardiovascular risk factors (UKPDS risk engine), and self-reported health status (the 36-Item Short-Form [SF-36] survey, Impact of Weight on Quality of Life [IWQOL] instrument, and Problem Areas in Diabetes Survey [PAID]) were assessed.

Validity

2. Did the authors look for the right type of papers?

This paper: Yes **√** No □ Unclear □

· Yes,搜尋文獻皆與PICO一致,有隨機分派,並且有在 Results of Participants清楚說明納入及排除條件

Abstract

ive

Validity

OBJECTIVE To compare the effect of Roux-en-Y gastric bypass (RYGB) surgery versus intensive medical diabetes and weight management (IMWM) on clinical and patient-reported outcomes in obese patients with type 2 diabetes.

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3. Were all of the patients who entered the trial properly accounted for at its conclusion?

This paper: Yes ✓ No □ **Unclear** □

· Yes,使用Intention-To-Treat (ITT) analysis分析方式

Statistical Analyses

The primary outcome was achievement of glycemic goal, defined as fasting plasma glucose levels <126 mg/dL and HbA $_{1c}$ <6.5% (48 mmol/mol) at 1 year of follow-up, regardless of whether patients were using pharmacological interventions. Longer time interval observational follow-up was conducted to assess durability of effects and emergent differences. The primary analysis was intention to treat and involved all randomly assigned patients who received at least one postrandomization assessment. Follow-up was prespecified to be censored at the time of bariatric surgery for those who were randomized to medical intervention but subsequently underwent surgery. Sample size was estimated assuming that RYGB would result in resolution of hyperglycemia in 80% of the patients and medical management in 20%. Twenty participants per group provided 97% power to detect a significant difference between groups with α = 0.05. Baseline results are presented as mean \pm SD and outcome data as mean (95% CI) or median (interquartile range).

4. Were patients, health workers and study personnel 'blind' to treatment?

This paper: Yes □ No Unclear □

· No,此研究介入為手術,無法做到double-blind或 triple-blind

5. Were the groups similar at the start of the trial?

This paper: Yes ✓ No □ Unclear □

· Yes,此研究兩組病患的基本特質是相似的

Table 1—Continued									
	Baseline *		1 year		2 years		3 years		
	RY GB	IMWM	RY GB	IMWM	RYGB	IMWM	RYGB	IMWM	P
10-year UKPDS risk scores									
CHD, %	9.8 ± 9.6	10.8 ± 6.9	-4.1 (-5.7, -2.5)	0.5 (-1.1, 2.0)	-2.6 (-4.3, -0.8)	-0.7 (-2.6, 1.2)	-2.5 (-4.3, -0.7)	0.1 (-2.0, 2.1)	0.00
Fatal CHD, %	6.5 ± 7.7	6.9 ± 4.9	-3.0 (-4.3, -1.7)	0.4 (-0.9, 1.8)	-1.8 (-3.3, -0.3)	0.1 (-1.5, 1.7)	-1.5 (-3.2, 0.2)	1.1 (-0.8, 2.9)	0.0
Stroke, %	4.0 ± 4.1	4.0 ± 2.3	-0.2 (-0.6, 0.2)	0.6 (0.2, 1.0)	0.6 (0.1, 1.1)	1.2 (0.6, 1.8)	1.4 (0.8, 2.0)	2.2 (1.5, 2.9)	0.0
Fatal stroke, %	0.6 ± 0.6	0.5 ± 0.3	-0.1 (-0.2, 0.0)	0.1 (0.0, 0.2)	0.0 (-0.2, 0.1)	0.2 (0.0, 0.4)	0.2 (0.0, 0.3)	0.5 (0.3, 0.7)	0.0
aboratory measurements									
HbA _{1c} , %	8.24 ± 1.42	8.78 ± 1.02	-1.97 (-2.52, -1.41)	-0.09 (-0.66, 0.47)	-1.91 (-2.49, -1.33)	-0.32 (-0.99, 0.35)	-1.79 (-2.38, -1.20)	-0.39(-1.06, 0.28)	<0.0
HbA _{Lo} mmol/mol	66.6 ± 15.5	72.5 ± 11.1	-21.5 (-27.5, -15.4)	-1.0 (-7.2, 5.1)	-20.9 (-27.2, -14.5)	-3.5 (-10.8, 3.8)	-19.6 (-26.0, -13.1)	-4.3 (-11.6, 3.1)	<0.0
Fasting plasma glucose, mg/dL	132 ± 50	162 ± 54	-47 (-62, -32)	-3 (-19, 13)	-47 (-64, -31)	-11 (-30, 8)	-46 (-62, -29)	-9 (-29, 10)	<0.0
Total cholesterol, mg/dL	154 ± 34	162 ± 39	-4 (-18, 10)	7 (-7, 22)	7 (-8, 24)	-16 (-35, 3)	5 (-12, 33)	-12 (-33, 9)	0.0
Direct LDL cholesterol, mg/dL	88 ± 28	99 ± 29	-6 (-18, 6)	9 (-4, 21)	5 (-9, 19)	-15 (-32, 2)	3 (-13, 19)	-11(-30,8)	0.0
HDL cholesteral, mg/dL	44 ± 10	39 ± 10	10 (7, 13)	0 (-3, 4)	12 (7, 16)	-1 (-6, 5)	15 (10, 21)	2 (-4, 9)	<0.0
Triglycerides, mg/dL	120 ± 66	156 ± 76	-46 (-61, -30)	-6 (-23, 10)	-42 (-58, -25)	6 (-13, 26)	-39 (-55, -22)	-22 (-42, -2)	<0.
Creatinine, mg/dL	0.71 ± 0.14	0.86 ± 0.21	-0.06 (-0.10, -0.02)	0.00 (-0.04, 0.04)	-0.06 (-0.11, -0.01)	0.07 (0.01, 0.13)	0.03 (-0.03, 0.10)	0.05 (-0.02, 0.12)	0.0
Urine albumin/creatinine,									
μg/mg ⁸	3 (0-7)	3 (0-10)	4 (2-7)	3.5 (0-4)	5 (2.5-15)	6.5 (4-17)	6 (3-9)	6.5 (0-8)	0.8
Hematocrit, %	36.8 ± 3.3	40.2 ± 4.3	-2.4 (-3.6, -1.2)	0.4 (-0.9, 1.6)	-3.0 (-4.4, -1.7)	1.3 (-0.4, 2.9)	-2.6 (-4.2, -1.0)	1.0 (-0.8, 2.9)	<0
White blood count, ×10°/mL	6.8 ± 2.1	6.5 ± 1.8	-0.9 (-1.4, -0.4)	0.1 (-0.5, 0.6)	-1.1 (-1.7, -0.5)	0.1 (-0.6, 0.9)	-0.9 (-1.6, -0.2)	0.4 (-0.4, 1.2)	< 0.
ALT, IU/L	32 ± 16	27 ± 12	-10 (-14, -7)	-5 (-9, -1)	-13 (-18, -9)	-9 (-14, -4)	-15 (-19, -10)	-7 (-12, -1)	0.0
AST, IU/L	31 ± 22	23 ± 13	-6 (-9, -2)	-4 (-7, 0)	-7(-11, -4)	-8 (-12, -4)	-8 (-12, -5)	-6 (-11, -2)	0.7

ALT, alanine aminotransferase; AST, aspartate aminotransferase. *Baseline data are mean ± SD, n (%), or median (interquartile range), unless otherwise stated. ^aHispanic subjects may be any race. ^bP values represent comparison of proportions at 3 years (RYGB vs. IMWM) by Fisher exact test. ^cPrimary end point, defined as proportion with HbA_{3c} < 6.5% and fasting plasma glucose <1.26 mg/dL with or without additionable of the self-ine values and self-ine values, unless otherwise noted. ^aGroup × time interaction also significant at P < 0.05. ^bP value represents group × time interaction; group effect was not significant. ^aMedian and interquartile range provided due to skewed distribution. ^bBy Kruskal-Wallis test for nonparametric data.

6. Aside from the experimental intervention, were the groups treated equally? 除了實驗介入外,實驗及對照組是否接受一樣的治療?

Participants randomized to the medical arm of the study enrolled in the Why WAIT program, which is designed for clinical practice6 and run quarterly at the Joslin Diabetes Center for groups of 10 to 15 patients. Why WAIT's multidisciplinary approach includes an endocrinologist (O.H.), registered dietician, exercise physiologist, mental health provider (A.G.-F.), and certified diabetes nurse educator. Two-hour weekly group sessions are conducted during a 12-week initiation phase. Patients receive individual medication adjustments and participate in supervised group exercise and support/didactic sessions. Key aspects of Why WAIT include (1) weekly medication adjustments; (2) structured modified dietary intervention with hypocaloric (1500-1800 kcal) diet with carbohydrates (40%-45%), protein (20%-30%), and saturated fat intake reduced to less than 7%,7 with the 6 initial weeks including breakfast and lunch meal replacement (Boost Glucose Control; Nestle Health Science; nutrient content per 237 mL [8 fl oz] including calories, 190; protein, 16 g; carbohydrate, 16 g; fiber, 3 g; and fat, 7g), 2 snacks, and structured dinner menus; (3) up to 300 minutes per week of graded, balanced, and individualized exercise, with emphasis on strength training; (4) cognitive behavioral intervention; and (5) group education. A maintenance phase of individual monthly counseling follows for the remainder of the year. Additional information describing the Why This paper: Yes \square No \square Unclear \square

The RYGB procedure was performed at Brigham and Women's Hospital. All surgical patients were given routine antibiotic and venous thromboembolism prophylaxis and standardized anesthesia per routine hospital protocols. The RYGB procedure involved a 75-cm antecolic, antegastric Roux limb created with a 50-cm biliopancreatic limb. A 15- to 20-mL gastric pouch was created along the lesser curve of the stomach, and the lesser omentum was divided at that level. A gastrojejunostomy was constructed using a linear cutter stapler, and the gastroenterotomy was closed using a running polyglactin 910 suture (Vicryl 2.0; Ethicon Inc). Provocative leak tests were performed, including "blue dye" and "bubble" tests.

ANS:無法分別,本文章分別敘述手術組以及飲食控制組的介入處置,然除此之外未提及其餘處置是否在觀察下一樣。



7. How large was the treatment effect?

治療效果有多少?

What outcome were measured?

Metabolic Outcomes

Metabolic assessments were performed at baseline and repeated at 10% of initial body weight loss to obtain measurements at a comparable level of weight loss in both groups. If 10% weight loss did not occur by 3 months, metabolic assessments were performed at that time. Metabolic visits were also conducted at 12, 18, 24, and 36 months to obtain a timebased comparison. Assessments included weight, height, waist circumference, seated blood pressure using an automated device (BP742; Omron Healthcare), and medication doses. Clinical laboratory tests (performed by Quest Diagnostics) included HbA_{1c}, fasting plasma glucose, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, microalbuminuria, renal function, liver function, and hematology. Body composition was assessed by bioelectrical impedance (TBF-215; Tanita Corporation). A 6-min walk test was performed. The UK Prospective Diabetes Study (UKPDS) Risk Engine was used to calculate risk of fatal and nonfatal cardiovascular events and stroke (14).

This paper: Yes ✓ No □ Unclear □

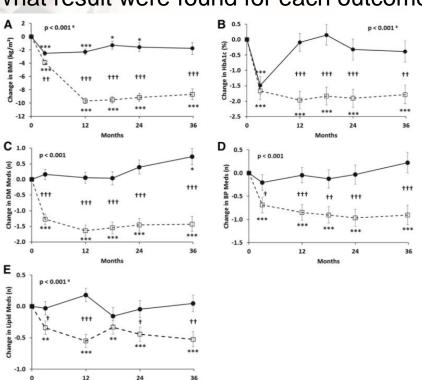
Patient-Reported Outcomes

Self-reported health outcomes were determined using the following validated instruments: 1) the 36-Item Short-Form (SF-36) survey, a generic health status instrument comprising two component scores (physical health and mental health) and eight scales (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, roleemotional, and mental health) (15); 2) Impact of Weight on Quality of Life (IWQOL)-Lite, a 31-item disease-specific quality of life instrument comprising five scales (physical function, self-esteem, sexual life, public distress, and work), for which higher scores indicate greater impact (5); and 3) Problem Areas in Diabetes Survey (PAID), a 20-item questionnaire that assesses difficulty with diabetes selfmanagement, emotional distress, eating behaviors, and other issues related to diabetes management, for which a higher score indicates more problems (16).

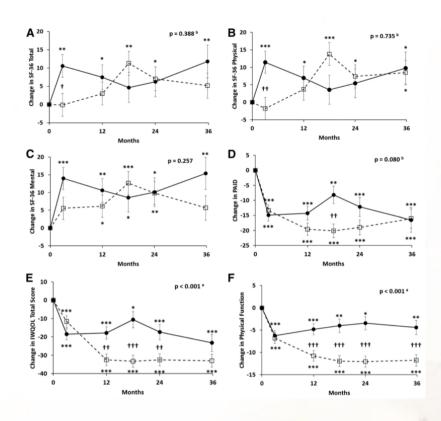
7. How large was the treatment effect?

治療效果有多少?

What result were found for each outcome?



Is the primary outcome clearly specified? This paper: Yes
✓ No □ Unclear □



ANS:

7. How large was the treatment effect?

治療效果有多少?

Is the primary outcome clearly specified? This paper: Yes ✓ No □ Unclear □ What result were found for each outcome?

Duration of diabetes, years	10.6 ± 6.6	10.2 ± 6.1							
					Clinical en	d points, n (%) ^b			
Study-defined diabetes resolution ^c			11 (58)	3 (16)	7 (37)	0 (0)	8 (42)	0 (0)	0.005
Meeting ADA treatment goals									
HbA _{1c} <7.0% (<53 mmol/mol)			15 (79)	5 (26)	13 (68)	5 (26)	11 (58)	2 (11)	0.013
Direct LDL cholesterol <100 mg/dL			15 (79)	9 (47)	10 (53)	8 (42)	8 (42)	6 (32)	0.300
Systolic blood pressure <130 mmHg			16 (84)	11 (58)	14 (74)	5 (26)	8 (42)	6 (32)	0.30
Meeting all three goals			11 (58)	1 (5)	7 (37)	3 (16)	2 (11)	1 (5)	0.29
Normoglycemia									
HbA _{1c} <6.0% (<42 mmol/mol)			6 (32)	0 (0)	4 (21)	0 (0)	2 (11)	0 (0)	0.10
Fasting plasma glucose <100 mg/dL			14 (74)	3 (16)	8 (42)	2 (11)	7 (37)	3 (16)	0.21
Meeting both criteria			6 (32)	0 (0)	3 (16)	0 (0)	1 (5)	0 (0)	0.18
			Changes in clinical, metabolic, and laboratory measures, mean (95% CI) ^d						
Medications									
Antidiabetes	2.3 ± 1.0	1.8 ± 0.8	-1.6 (-2.0, -1.3)	0.1 (-0.3, 0.4)	-1.4 (-1.8, -1.1)	0.4 (0.0, 0.8)	-1.4 (-1.9, -1.0)	0.7 (0.2, 1.2)	< 0.00
Antihypertensive	1.6 ± 1.0	1.2 ± 1.0	-0.8 (-1.2, -0.5)	0.0 (-0.4, 0.3)	-1.0 (-1.3, -0.6)	0.0 (-0.4, 0.4)	-0.9 (-1.3, -0.5)	0.2 (-0.2, 0.7)	< 0.00
Lipid lowering	0.9 ± 0.5	0.8 ± 0.5	-0.6 (-0.8, -0.3)	0.2 (0.0, 0.4)	-0.4 (-0.7, -0.2)	0.0 (-0.3, 0.2)	-0.5 (-0.8, -0.3)	0.0 (-0.2, 0.3)	< 0.00
Weight, kg	104.6 ± 15.5	102.7 ± 17.0	-27.9 (-30.2, -25.6)	-6.9 (-9.3, -4.6)	-26.3 (-29.6, -22.9)	-4.8 (-8.6, -1.0)	-24.9 (-29.5, -20.4)	-5.2 (-10.3, -0.2)	< 0.00
BMI, kg/m²	36.0 ± 3.5	36.5 ± 3.4	-9.7 (-10.5, -8.8)	-2.3 (-3.1, -1.4)	-9.2 (-10.3, -8.0)	-1.6 (-2.9, -0.2)	-8.7 (-10.3, -7.1)	-1.8 (-3.5, 0.0)	< 0.00
Body composition									
Fat mass, kg	45.5 ± 9.4	42.6 ± 9.8	-22.6 (-25.0, -20.2)	-6.0 (-8.6, -3.4)	-21.4 (-24.6, -18.2)	-3.0 (-6.7, 0.7)	-19.9 (-24.0, -15.8)	-4.1 (-8.8, 0.6)	< 0.00
Lean mass, kg	59.2 ± 14.1	60.1 ± 10.8	-5.2 (-6.7, -3.6)	-1.3 (-2.9, 0.3)	-5.2 (-6.9, -3.5)	-1.9 (-3.8, 0.1)	-5.8 (-7.8, -3.8)	-1.3 (-3.5, 1.0)	0.003
Waist circumference, cm	117.8 ± 14.9	114.1 ± 12.2	-26.9 (-30.5, -23.4)	-6.4 (-10.1, -2.6)	-27.4 (-32.1, -22.6)	-5.4 (-10.9, 0.1)	-24.8 (-31.0, -18.6)	-1.0 (-8.2, 6.2)	< 0.00
Blood pressure									
Systolic, mmHg	132.8 ± 10.5	126.3 ± 14.7	-13.1 (-19.0, -7.1)	-1.6 (-7.9, 4.8)	-10.7 (-17.5, -3.8)	4.2 (-4.1, 12.4)	-0.3 (-8.3, 7.8)	9.7 (0.3, 19.1)	0.01
Diastolic, mmHg	81.7 ± 7.4	76.6 ± 8.8	-5.3 (-8.6, -2.0)	-2.4 (-5.9, 1.1)	-4.3 (-7.8, -0.7)	0.6 (-3.7, 4.9)	2.0 (-2.0, 5.9)	-1.2 (-5.8, 3.5)	< 0.00
Physical fitness				,		,			
Distance walked in 6 min, m	464 ± 56	467 ± 56	13 (-11, 37)	25 (0, 50)	34 (5, 62)	32 (-1, 65)	33 (-1, 68)	37 (-4, 79)	0.54
Heart rate recovery									
at 1 min, bpm	92.2 ± 15.2	87.5 ± 12.0	-10.7 (-15.4, -6.1)	0.9 (-4.0, 5.9)	-5.7 (-11.3, -0.2)	2.7 (-4.0, 9.4)	-7.0 (-13.6, -0.4)	1.4 (-6.9, 9.7)	0.00

Continued on p. 674

8. How precise was the estimate of the treatment effect?

This paper: Yes ✓ No □ Unclear □

Yes

RESULTS

After 3 years, the RYGB group had greater weight loss (mean -24.9 kg [95% CI -29.5, -20.4] vs. -5.2 [-10.3, -0.2]; P < 0.001) and lowering of HbA_{1c} (-1.79% [-2.38, -1.20] vs. -0.39% [-1.06, 0.28] [-19.6 mmol/mol [95% CI -26.0, -13.1] vs. -4.3 {-11.6, 3.1}]; P < 0.001) compared with the IMWM group. Changes in cardiometabolic risk for coronary heart disease and stroke were all more favorable in RYGB versus IMWM (P < 0.05 to P < 0.01). IWQOL improved more after RYGB (P < 0.001), primarily due to subscales of physical function, self-esteem, and work performance. SF-36 and PAID scores improved in both groups, with no difference between treatments. A structural equation model demonstrated that improvement in overall quality of life was more strongly associated with weight loss than with improved HbA_{1c} and was manifest by greater improvements in IWQOL than with either SF-36 or PAID.

9. Can the results be applied to the local population, or in your context?

This paper: Yes ☐ No ☐ Unclear ☐

	Base	eline*
	RYGB	IMWM
N	19	19
Age, years	50.7 ± 7.6	52.6 ± 4.3
Sex Male Female	6 (32) 13 (68)	9 (47) 10 (53)
Race/ethnicity White African American Asian Hispanic ^a	14 (74) 3 (16) 1 (5) 1 (5)	10 (53) 8 (42) 0 (0) 1 (5)
$BMI < 35 \text{ kg/m}^2$	6 (32)	7 (37)
Duration of diabetes, years	$\textbf{10.6} \pm \textbf{6.6}$	10.2 ± 6.1

10. Were all clinically important outcomes considered?

Metabolic Outcomes

Metabolic assessments were performed at baseline and repeated at 10% of initial body weight loss to obtain measurements at a comparable level of weight loss in both groups. If 10% weight loss did not occur by 3 months, metabolic assessments were performed at that time. Metabolic visits were also conducted at 12, 18, 24, and 36 months to obtain a timebased comparison. Assessments included weight, height, waist circumference, seated blood pressure using an automated device (BP742; Omron Healthcare), and medication doses. Clinical laboratory tests (performed by Quest Diagnostics) included HbA_{1c}, fasting plasma glucose, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, microalbuminuria, renal function, liver function, and hematology. Body composition was assessed by bioelectrical impedance (TBF-215; Tanita Corporation). A 6-min walk test was performed. The UK Prospective Diabetes Study (UKPDS) Risk Engine was used to calculate risk of fatal and nonfatal cardiovascular events and stroke (14).

This paper: Yes No 🗆

No □ Unclear □

Patient-Reported Outcomes

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健保點數

次全或半胃切除術及胃空腸吻合術 Roux-en-Y型-無迷走神經切除

17414點

阿國先生符合減重手術的標準。

BMI>35 且合併有肥胖併發症

- >血壓增高:收縮壓≥130mmHg/舒張壓≥85mmHg
- >空腹血糖值升高≥110mg/dl
- >三酸甘油脂升高≥150mg/dl

【減重手術健保給付標準】

台灣健保對於減重手術治療的給付主要是根據美國國家衛生研究院在1991年所公布的標準,

須符合下列條件:

- BMI≥40,或BMI≥35且合併有肥胖相關併發症。
- 年齡介於18~55歳。
- 經半年以上的內科減重治療失敗。
- 無內分泌系統異常或其他會造成肥胖的疾病。
- 無藥物濫用或精神疾病。
- 無重大器官功能異常並能接受外科手術風險。

臨床問題 Clinical Problems

經過與阿國先生討論後,阿國提問:

接受減重手術治療,對我三高及糖尿病的病情控制是不有幫助?

臨床回覆:

關於阿國先生提出的問題,根據我們從最新實證醫學的方法求證,結果所述接受減重術會比嚴格飲食控制在血糖控制、血脂及血壓等方面都會改善更多。

至於醫療費用的方面,請阿國先生不用擔心,由於阿國先生的目前病情符合健保給付做減重手術,如有意願接受減重手術,手術費用能由健保支付。

感謝聆聽 Thanks for your attention

Clinical state and circumstances

"實證醫學 (evidence-based medicine; EBM) 是結合 臨床問題、病患價值、研究證據 與 臨床經驗的學問…"

Brian Haynes MD, PhD

Patients' preferences and actions

Research

感謝聆聽 Thanks for your attention

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