

Endorsed by  
over **50**  
international  
organisations

# Surgical Treatment for Type 2 Diabetes

Summary of **Recommendations  
and Guidelines** from the  
**2nd Diabetes Surgery Summit  
(DSS-II)**



Endorsed by





*Metabolic surgery is now among the recommended treatment options for type 2 diabetes among select obese individuals*

American Diabetes Association- Standards of Care 2017<sup>(1)</sup>

*“Why surgery is the next big thing for Type 2 Diabetes”*

Nature (cover page) 26 May 26, 2016

nature

*“Surgery should be an option for diabetics”*

time.com/4345470/gastric-bypass-surgery-diabetes/

TIME

*“One of the most significant changes in treating diabetes since the discovery of insulin in 1921”*

New Scientist, 28 May, 2016

NewScientist

*“Metabolic Surgery for Type 2 Diabetes: Changing the Landscape of Diabetes Care”*

Diabetes Care 2016 Jun; 39 (6): 857-860

Diabetes Care

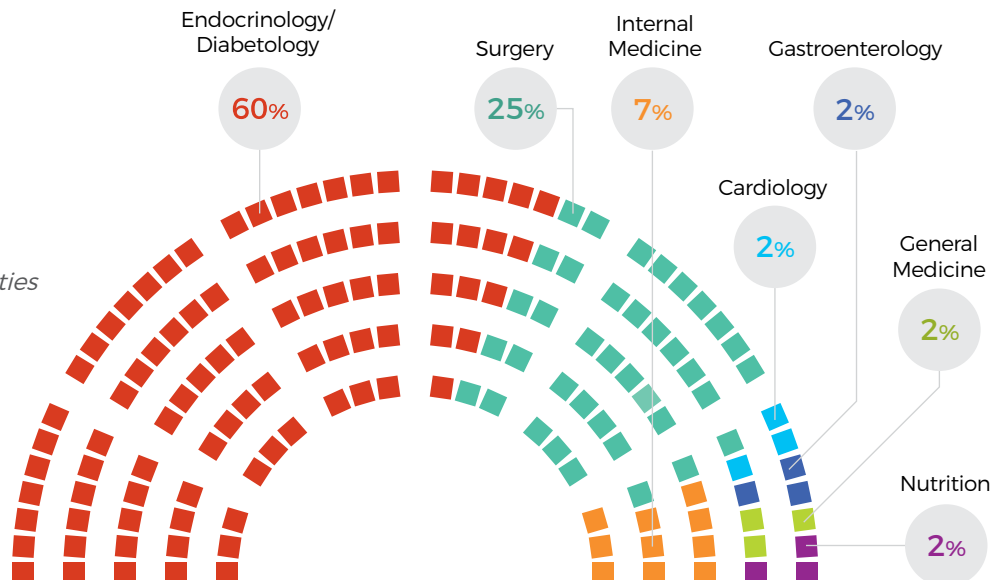
## The 2nd Diabetes Surgery Summit (DSS-II): an International Consensus Conference<sup>(2)</sup>

Rubino F, Nathan D, Eckel R et al. Diabetes Care 2016

- The DSS organising committee and the five partner diabetes organisations (ADA, IDF, Diabetes UK, CDS, Diabetes India) - tasked a group of **48 multi-disciplinary international scholars** to develop a set of evidence-based recommendations for surgical treatment of Type 2 diabetes (T2D).
- Two independent moderators coordinated the appraisal of evidence by the group. **Rounds of Delphi-like questionnaires** were used to develop consensus for **32 evidence-based conclusions**.
- Draft recommendations were open to **public comment by other experts in the field** and by the audience at the 2015 World Congress of Interventional Diabetes Therapies in London.
- A **face-to-face meeting** of the expert committee defined a final consensus document.
- Guidelines were submitted for **formal ratification** by relevant professional organisations.

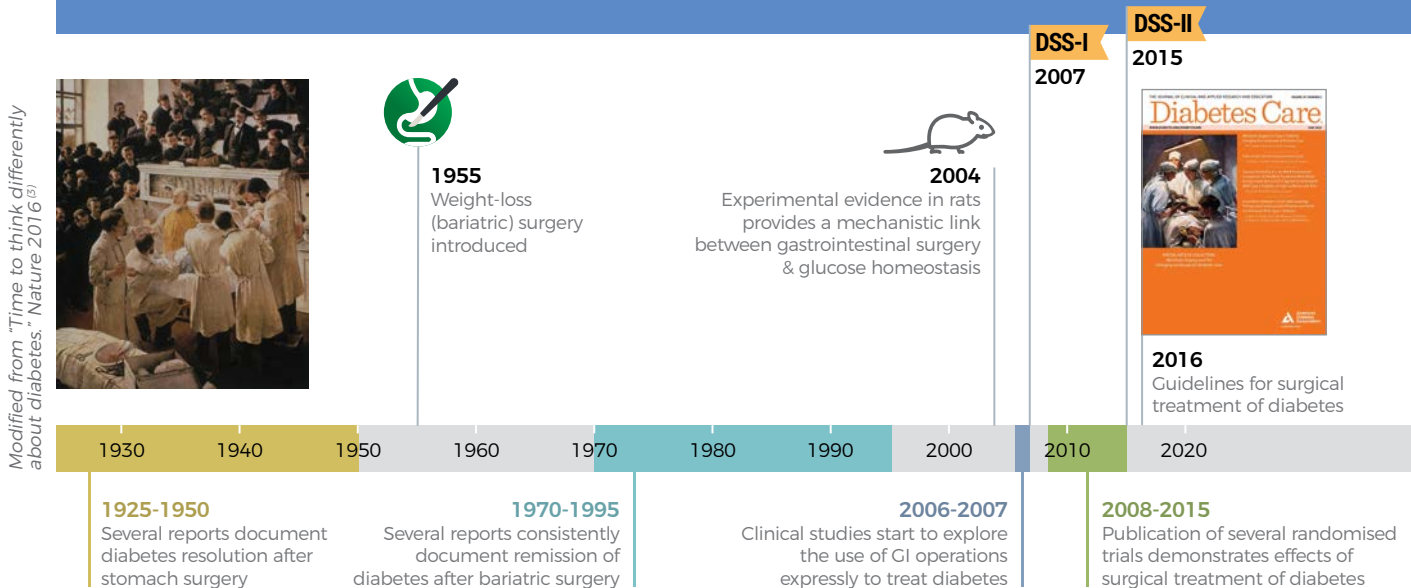
### DSS-II expert committee

- 48 members
- 7 medical specialities
- 14 countries



# What is Metabolic Surgery?

*"Metabolic surgery is defined as the use of gastrointestinal operations with the intent to treat T2D and obesity." DSS-II<sup>(2)</sup>*

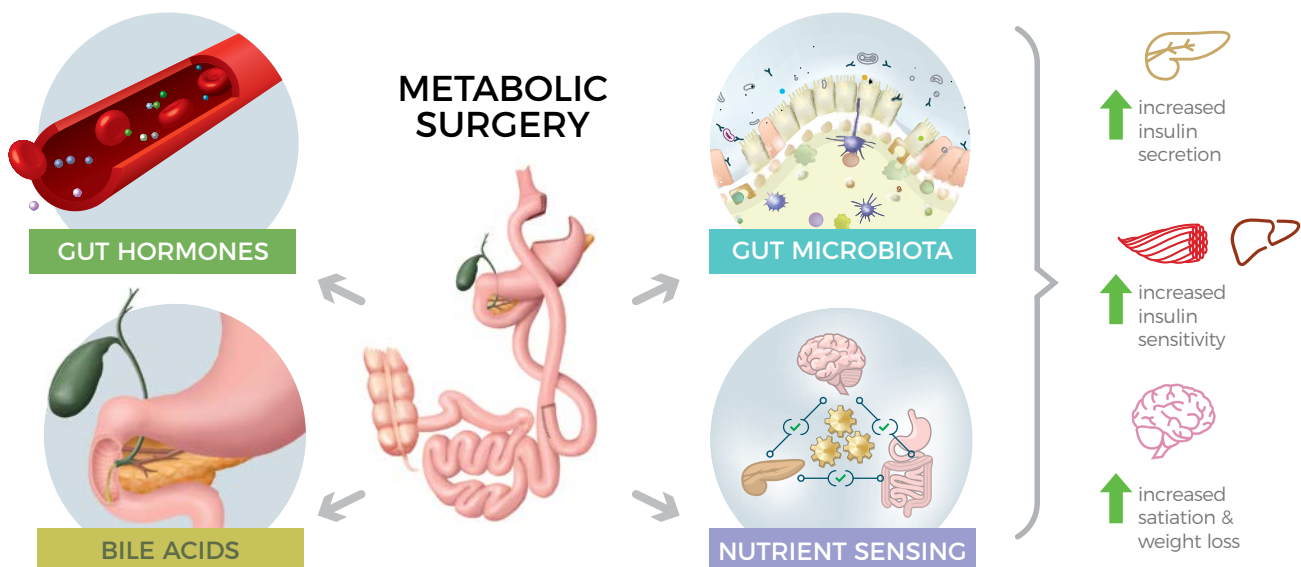


**A long road.** Observations that Type 2 diabetes can be improved or even resolved by surgical operations have been reported for almost a century. Reports in the early 1920's showed that gastrointestinal (GI) operations for ulcers/cancer could cause dramatic improvement of diabetes. After the advent of bariatric surgery in the 1950's, observations of diabetes remission following GI surgery were increasingly reported.

Since the 2000's, experimental evidence that changes in GI anatomy can directly influence glucose homeostasis provided a mechanistic rationale for the use of surgery as an intentional treatment of diabetes. DSS-I and DSS-II assessed clinical evidence, including from numerous Randomised Clinical Trials (RCTs) performed over the last decade, leading to current guidelines.

## How does surgery improve diabetes

Metabolic Surgery changes various mechanisms of GI physiology involved in metabolic regulation<sup>(3,4)</sup>

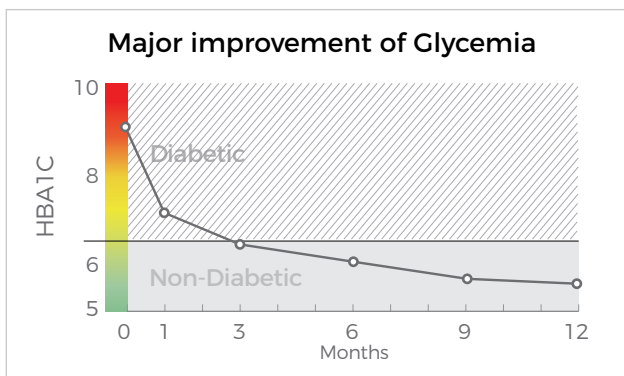


*"Given its role in metabolic regulation, the GI tract constitutes a clinically and biologically meaningful target for the management of T2D." DSS-II<sup>(2)</sup>*

# Clinical Evidence<sup>(2, 5)</sup>

11 randomised trials (RCTs - Level 1 Evidence) as well as large, long-term case-controlled studies (level 2 evidence) comparing surgery in overweight/obese people with type 2 diabetes show that metabolic surgery results in:

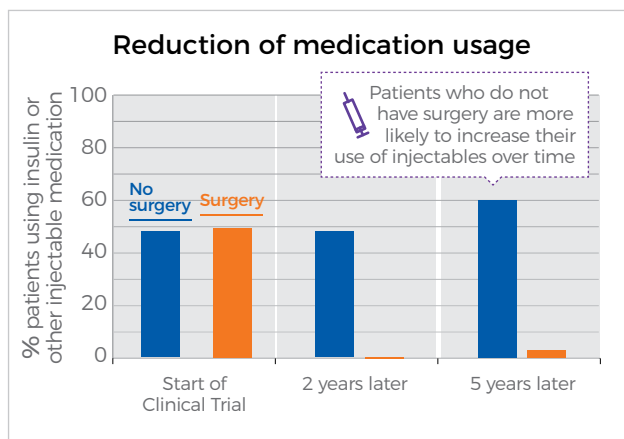
- ✓ greater improvement of glycemic control (Level 1 evidence)
- ✓ reduction of medication usage (Level 1 evidence)
- ✓ reduction of cardiovascular disease (CVD) risk (Level 1 evidence)
- ✓ reduction of heart attacks, strokes, cancer and overall mortality (Level 2 evidence)
- ✓ greater weight loss (Level 1 evidence)
- ✓ better quality of life (Level 1 evidence)



**Chance of Disease Remission:** A substantial proportion of patients (between 30% and 60%, depending on the procedure) experience durable ( $\geq 5$  year) normalisation of blood sugar levels without the need for ongoing pharmacologic treatment (disease remission)



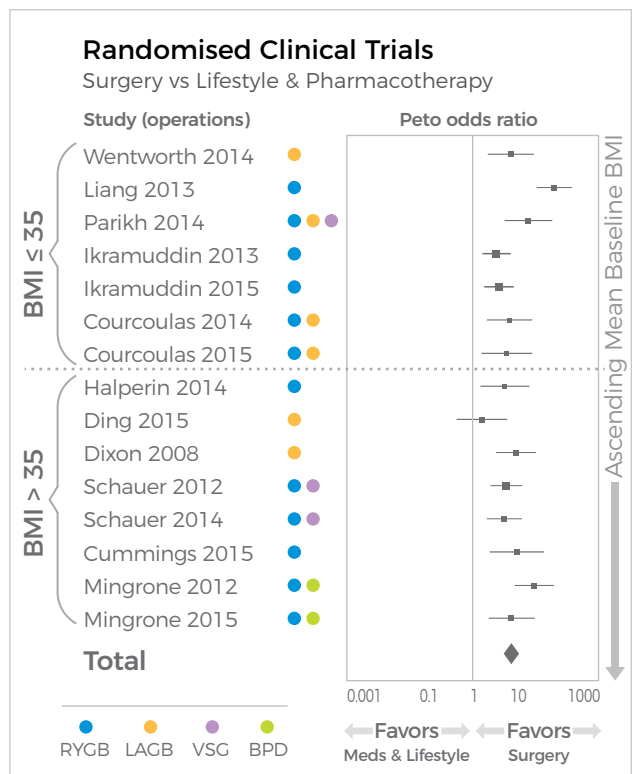
**Cost Effectiveness:** Economic analyses have also shown that surgical treatments for diabetes are cost-effective, Cost per quality-adjusted life-year (QALY) is approximately \$3,200- \$6500, well below \$50,000/QALY (which is deemed appropriate for coverage).



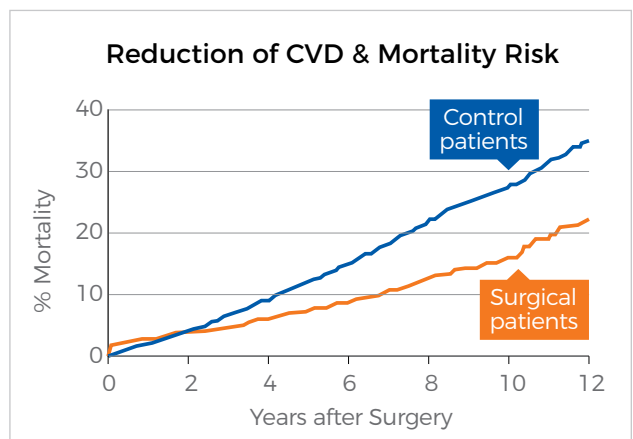
Based on Migrone G. et al. Lancet 2015; 386 (9997): 964-973



With the introduction of laparoscopic (minimally invasive) approaches, multidisciplinary care models and specialised high volume centers there has been a dramatic reduction of mortality and morbidity of bariatric/metabolic surgery over the past two decades. Laparoscopic surgery also allows earlier recovery from surgery and minimises hospital stay.



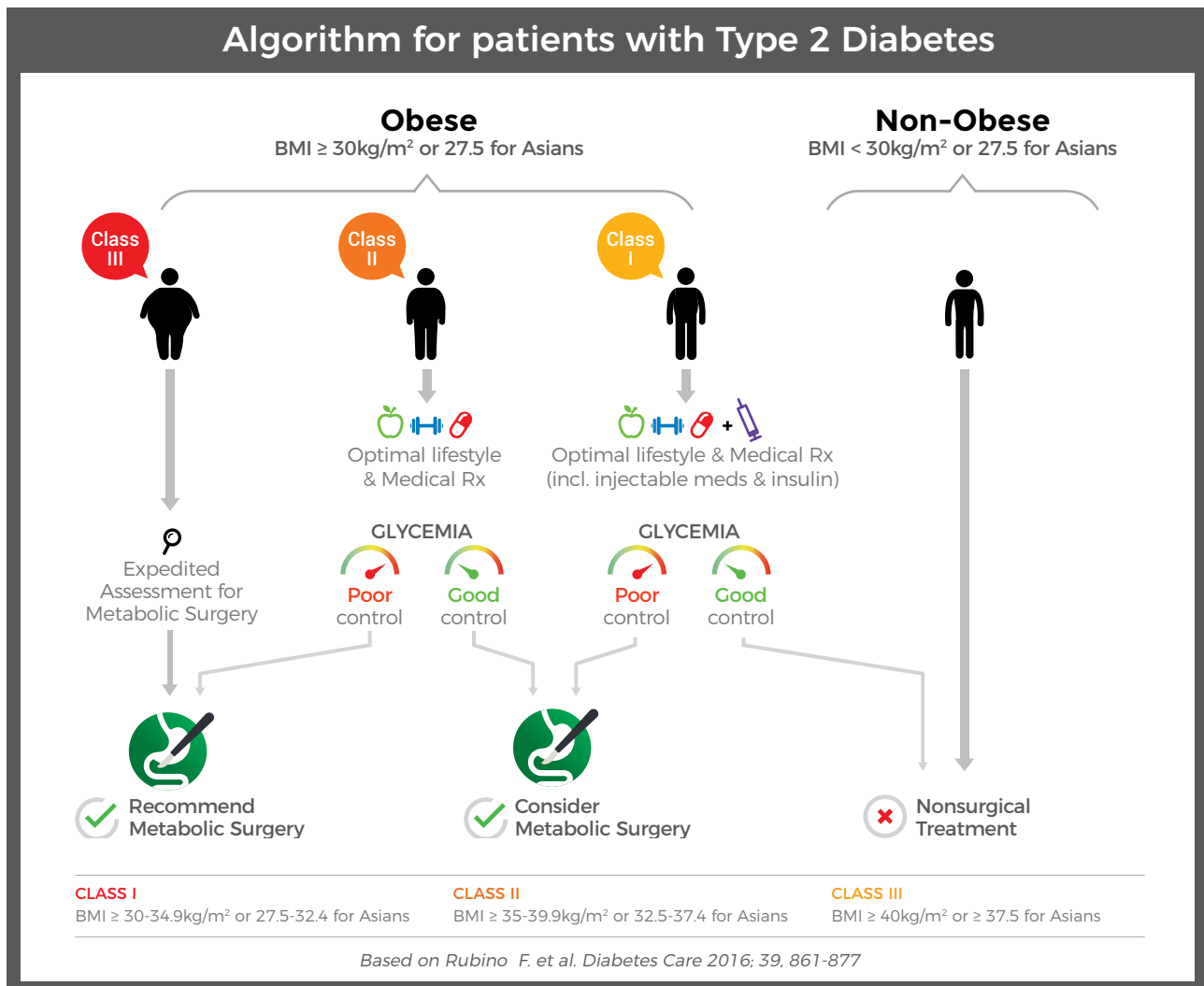
Based on Rubino F. et al. Diabetes Care 2016; 39, 861-877



Based on Arterburn D. et al; JAMA. 2015; 313 (1): 62-70

# Indications for Surgical Treatment

“There is now sufficient clinical and mechanistic evidence to support inclusion of metabolic surgery among antidiabetes interventions for people with T2D and obesity.” DSS-II<sup>(2)</sup>



- “Metabolic surgery should be a recommended option to treat T2D in appropriate surgical candidates with class III obesity (BMI  $\geq 40\text{ kg/m}^2$ ), regardless of the level of glycemic control or complexity of glucose-lowering regimens, as well as in patients with class II obesity (BMI  $35.0\text{-}39.9\text{kg/m}^2$ ) with inadequately controlled hyperglycemia despite lifestyle and optimal medical therapy.” DSS-II<sup>(2)</sup>
- “Metabolic surgery should also be considered to be an option to treat T2D in patients with class I obesity (BMI  $30.0\text{-}34.9\text{ kg/m}^2$ ) and inadequately controlled hyperglycemia despite optimal medical treatment by either oral or injectable medications (including insulin).” DSS-II<sup>(2)</sup>
- “All BMI thresholds should be reconsidered depending on the ancestry of the patient. For example, for patients of Asian descent, the BMI values above should be reduced by  $2.5\text{ kg/m}^2$ .” DSS-II<sup>(2)</sup>

## Contraindications

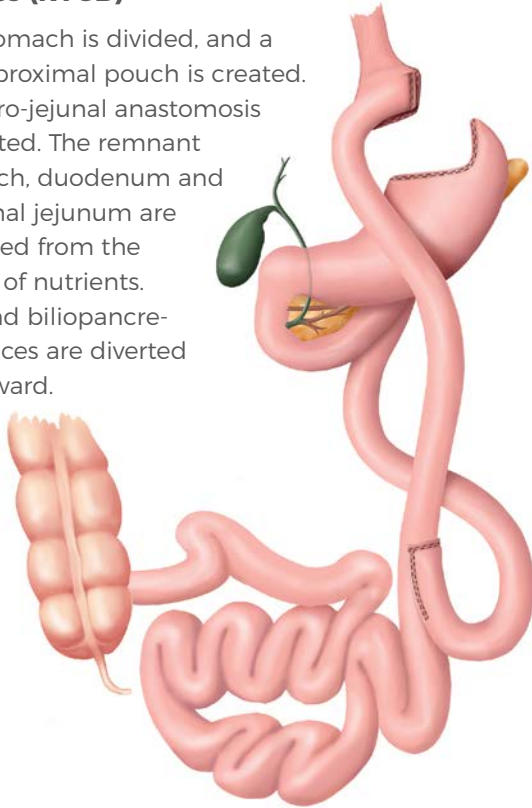
“Contraindications for metabolic surgery include diagnosis of Type 1 Diabetes (unless surgery is indicated for other reasons, such as severe obesity); current drug or alcohol abuse; uncontrolled psychiatric illness; lack of comprehension of the risks/benefits, expected outcomes, or alternatives; and lack of commitment to nutritional supplementation and long-term follow-up required with surgery.” DSS-II<sup>(2)</sup>

# Standard Metabolic Surgical Procedures

Evidence shows a gradient of efficacy among the main four accepted surgical approaches for weight loss and diabetes remission, as follows: BPD > RYGB > VSG > LAGB. The opposite gradient exists for comparative safety of these operations. <sup>(2,5)</sup>

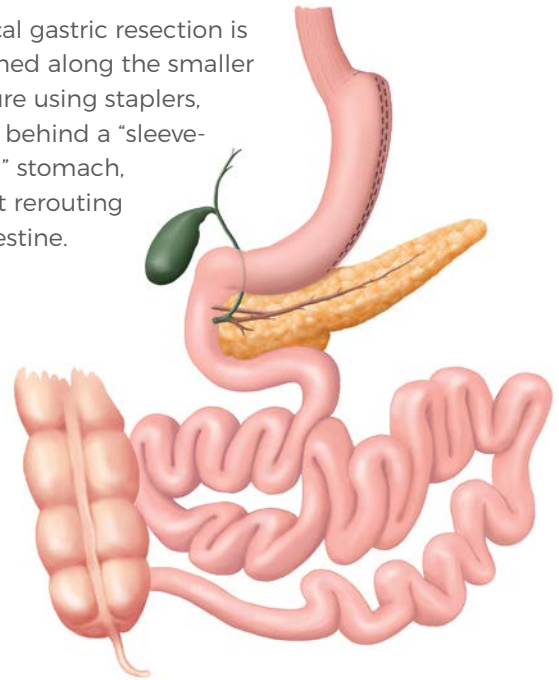
## Roux-en-Y Gastric Bypass (RYGB)

The stomach is divided, and a small proximal pouch is created. A gastro-jejunal anastomosis is created. The remnant stomach, duodenum and proximal jejunum are excluded from the transit of nutrients. Bile and biliopancreatic juices are diverted downward.



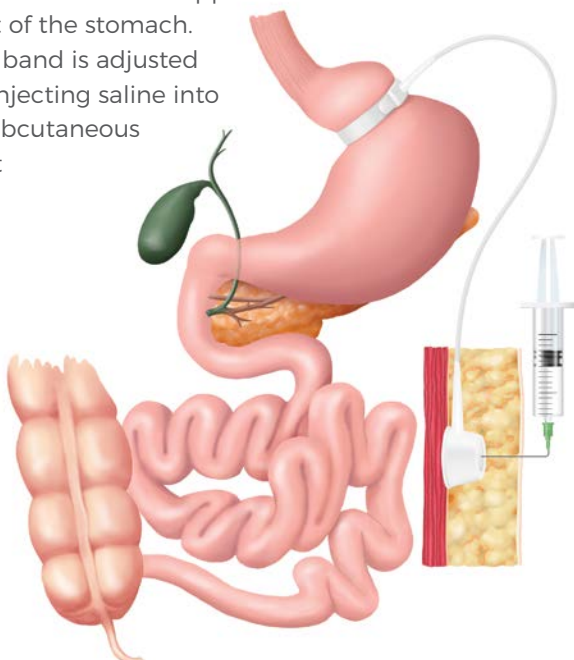
## Vertical Sleeve Gastrectomy (VSG)

A vertical gastric resection is performed along the smaller curvature using staplers, leaving behind a "sleeve-shaped" stomach, without rerouting the intestine.



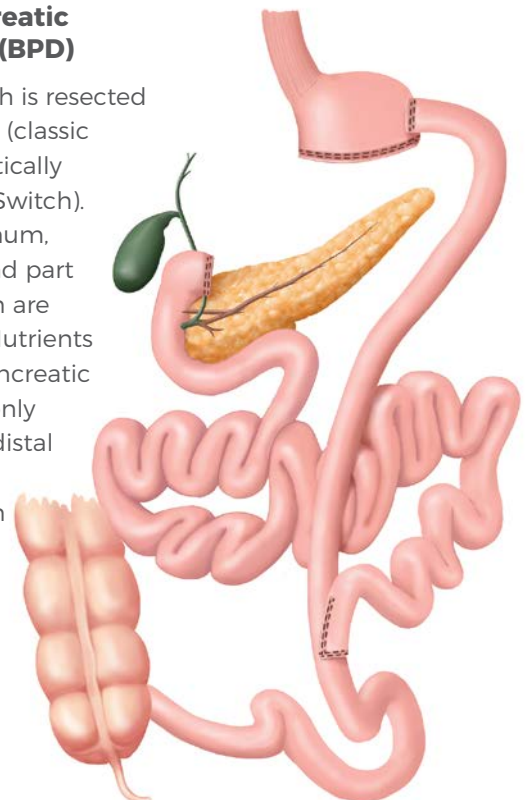
## Laparoscopic Adjustable Gastric Banding (LAGB)

An inflatable band is placed around the upper part of the stomach. The band is adjusted by injecting saline into a subcutaneous port.



## Biliopancreatic Diversion (BPD)

The stomach is resected horizontally (classic BPD) or vertically (Duodenal Switch). The duodenum, jejunum, and part of the ileum are bypassed. Nutrients and biliopancreatic juices mix only within the distal 50-100 cm of the ileum (common channel).



## Choosing the Surgical Procedure

*"Among the 4 accepted operations, RYGB appears to have a more favorable risk-benefit profile in most patients with T2D".<sup>(2)</sup>*

*"However, the choice of surgical procedure should be based on evaluation of the risk-to-benefit ratio in individual patients, weighing long-term nutritional hazards, previous abdominal surgery versus effectiveness on glycemic control and CVD risk".<sup>(2)</sup>*

### A multidisciplinary approach

Patients' eligibility for metabolic surgery should be assessed by a multidisciplinary team including surgeon(s), internist(s) or diabetologist(s) / endocrinologist(s), and dietitian(s) with specific expertise in diabetes care.

Metabolic surgery should be performed in specialised high-volume centers with multidisciplinary teams experienced in management of diabetes and GI surgery



### Preoperative evaluation

as recommended by the DSS-II expert group

- ☑ **Standard preoperational tests used for GI surgery at individual providers' institutions.**
- ☑ **Recent tests to characterise current diabetes status, for example, but not limited to, HbA1c, fasting glucose, lipid profile, and tests for retinopathy, nephropathy, and neuropathy.**
- ☑ **Tests to distinguish T1D from T2D (fasting C-peptide; anti-GAD or other autoantibodies).**

## Side effects / complications<sup>(2, 5)</sup>

Safety of bariatric/metabolic surgery has improved significantly over the last two decades, with continued refinement of minimally invasive approaches (laparoscopic surgery), enhanced training and credentialing, and involvement of multidisciplinary teams. Reported mortality risk is 0.1-0.5%, similar to hysterectomy, cholecystectomy or hip replacement. Major peri-operative complications are uncommon, ranging from 2 to 6%; minor complications occur in up to 15%. Long-term surgical complications can

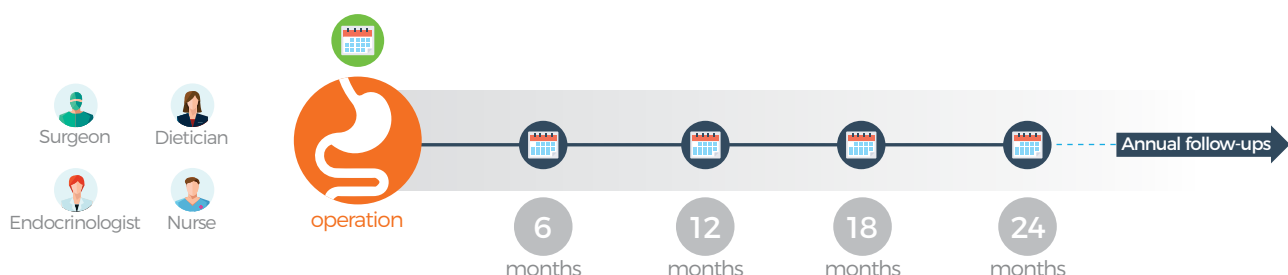
also occur, with variable frequency and depending on the type of procedure. They include but are not limited to internal hernia/small bowel occlusion (RYGB, BPD), marginal ulcers and anastomotic stricture (RYGB) and band slippage/erosion (LAGB). Nutritional complications also vary in frequency and severity depending on the type of procedure. Iron deficiency is commonly observed; less common complications include anaemia, bone fractures and postprandial hypoglycaemia (+RYGB), steatorrhea/diarrhoea and protein calorie malabsorption (++)BPD).

## Follow-up

*"Postoperative follow-up should include surgical and nutritional evaluations at least every 6 months, and more often if necessary, during the first 2 postoperative years and at least annually thereafter."<sup>(2)</sup>*

Even if patients experience diabetes remission, monitoring of glycemic control should be continued with the same frequency as recommended for patients with prediabetes because of the potential for relapse.<sup>(2)</sup>

Long-term monitoring of micronutrient status, nutritional supplementation and support must be provided to patients after surgery, according to guidelines by national and international societies.<sup>(2)</sup>





## PARTNER DIABETES ORGANISATIONS OF THE DSS-II

American Diabetes Association (ADA)    International Diabetes Federation (IDF)    Diabetes UK (DUK)    Chinese Diabetes Society (CDS)    Diabetes India (DI)

## ENDORISING SOCIETIES OF THE DSS-II CONSENSUS STATEMENTS & GUIDELINES (as of August 2017)

### INTERNATIONAL ORGANISATIONS

**IDF** International Diabetes Federation    **APBMSS** Asia-Pacific Bariatric and Metabolic Surgery Society    **EASO** European Association for the Study of Obesity    **IFSO** Int. Federation for the Surgery of Obesity & Metabolic Disorders    **ALAD** Latin American Association of Diabetes

### NATIONAL ORGANISATIONS / SOCIETIES

-  · Argentinian Society of Diabetes (SAD)
-  · Argentinian Society for Bariatric and Metabolic Surgery (SACO)
-  · Argentinian Society of Nutrition (SAN)
-  · Australian Diabetes Society (ADS)
-  · Belgian Diabetes Association (ABD)
-  · Brazilian Society of Diabetes (SBD)
-  · Brazilian Society of Bariatric and Metabolic Surgery (SBCBM)
-  · Czech Society for the Study of Obesity (CSSO)
-  · Chilean Society of Endocrinology and Diabetes (SCED)
-  · Chilean Society for Bariatric and Metabolic Surgery (SCCBM)
-  · Chinese Diabetes Society (CDS)
-  · French Society of Diabetes (SFD)
-  · French Society of Bariatric and Metabolic Surgery (SOFFCO)
-  · German Diabetes Society (DDG)
-  · German Society for Obesity Surgery (CA-ADIP)
-  · Hellenic Diabetes Association (HDA)
-  · Diabetes India (DI)
-  · Irish Endocrine Society (IES)
-  · Israel Diabetes Association (IDA)
-  · Italian Society of Bariatric & Metabolic Surgery (SICOB)
-  · Italian Society of Diabetology (SID)
-  · Italian Society of Clinical Endocrinologists (AME)
-  · Japan Diabetes Society (JDS)
-  · Mexican College of Bariatric and Metabolic Surgery (CMCOEM)
-  · Mexican Society of Nutrition and Endocrinology (SMNE)
-  · Portuguese Society of Diabetology (SPD)
-  · Qatar Diabetes Association (QDA)
-  · Saudi Diabetes and Endocrine Association (SDEA)
-  · Slovakian Diabetes Society (SDS)
-  · Obesity Section Slovakian Diabetes Society (OS SDS)
-  · South African Society for Surgery Obesity and Metabolism (SASSO)
-  · Spanish Society for Bariatric and Metabolic Surgery (SECO)
-  · Spanish Society of Diabetes (SED)
-  · Diabetes UK (DUK)
-  · Association of British Clinical Diabetologists (ABCD)
-  · British Obesity and Metabolic Surgery Society (BOMSS)
-  · Society for Endocrinology (SfE)
-  · American Diabetes Association (ADA)
-  · American Association of Clinical Endocrinologists (AACE)
-  · American College of Surgeons (ACS)
-  · American Gastroenterological Association (AGA)
-  · American Society for Metabolic and Bariatric Surgery (ASMBS)
-  · Endocrine Society
-  · Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)
-  · Society for Surgery of the Alimentary Tract (SSAT)
-  · The Obesity Society (TOS)

### DSS Co-directors:

Francesco Rubino (UK); David E. Cummings (USA); Lee M. Kaplan (USA); Phil R. Schauer (USA)

### References

- (1) ADA Standards of Medical Care in Diabetes 2017 Diabetes Care; Jan 2017; vol. 40 issue Suppl.1
- (2) Rubino F. et al. Diabetes Care Diabetes Care 2016 Jun; 39 (6): 861-877
- (3) Rubino F. Nature 2016; 533(7604):459-61
- (4) Evers SS et al. Annu Rev Physiol. 2017 Feb 10;79:313-334
- (5) Cummings DE and Cohen R. Diabetes Care 2016 Jun; 39 (6): 924-933



#### DSS statement:

Rubino F, Nathan D, Eckel R et al. Diabetes Care 2016 Jun; 39(6): 861-877

<http://care.diabetesjournals.org/content/39/6/861>



This brochure has been created with the support of King's College London and through an unrestricted educational grant by Ethicon Endosurgery