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### Ten-year Outcomes of a Prospective Randomized Trial of Laparoscopic Gastric Bypass versus Laparoscopic Gastric Banding

Nguyen NT, et al (2017) Ann Surg [1]

**Objective:** The primary endpoints of this study were long-term weight loss, morbidity, and changes in comorbidities and quality of life.

**Background:** Bariatric surgery is an effective option for the treatment of severe obesity and its related comorbidities. However, few studies have reported on the long-term outcome (>5 years) of bariatric surgery.

**Methods:** Between 2002 and 2007, 250 patients with a body mass index (BMI) of 35 to 60 kg/m<sup>2</sup> were randomly assigned to undergo laparoscopic gastric bypass or laparoscopic gastric banding. After exclusions, 111 patients underwent gastric bypass and 86 patients underwent gastric banding. Factors predictive of improved weight loss were analyzed using multiple logistic regressions.

**Results:** At baseline, the mean age was 43 ± 10 years and the mean BMI was 46.5 ± 5.6 kg/m<sup>2</sup>. At 10-year follow-up, the mean total body weight loss for the entire cohort was -37.5 ± 19.4 kg, -42.4 ± 19.6 kg for gastric bypass versus -27.4 ± 14.5 kg for gastric banding. Late reoperation was significantly higher after gastric banding compared with the gastric bypass group (31.4 vs 8.1%, respectively,  $P < 0.01$ ). For the entire cohort, improvement or remission of diabetes occurred in 68%; 61% for hypertension; and 57% for dyslipidemia. The long-term mortality for the entire cohort was 1.0% at a mean follow-up of 9.5 ± 0.4 years. Factors predictive of improved weight loss included the type of operation (ie, gastric bypass), female sex, and the absence of diabetes at baseline. At long-term follow-up, quality of life continues to be improved from baseline for both the groups.

**Conclusions:** Bariatric surgery is an effective treatment for severe obesity with durable 10-year weight loss and improvement in comorbidities and quality of life. Compared with gastric banding, gastric bypass was associated with better long-term weight loss, lower rate of late reoperation, and improved remission of comorbidities.

**Commentaire :** Cette étude randomisée gastrique by-pass (111 patients) versus anneau gastrique (86 patients) fait suite à la publication de 2009 dans Annals of Surgery [2]. Celle-ci présentait ces résultats à quatre ans. Cette étude initiale mettait en évidence une augmentation des complications à 30 jours pour le gastrique by-pass (21,6 versus 7 %) mais une perte de poids plus importante (68 versus 45 %). Il s'agit ici de l'étude la plus longue sur dix ans, comparant de manière randomisée l'anneau gastrique et le by-pass gastrique, sur l'efficacité au long terme de la chirurgie sur la perte de poids et l'amélioration ou non des comorbidités. Dans cette étude, malgré le biais important que les patients n'étaient pas randomisés en préopératoire en fonction de leurs poids et de leurs comorbidités, celle-ci met en évidence des réinterventions plus importantes dans le groupe anneau gastrique (31,4 versus 8,1 %), avec une efficacité moindre tant sur la perte de poids et sur les comorbidités. Par contre, concernant la qualité de vie postchirurgie, celle-ci était améliorée de manière identique dans les deux groupes. Ces données sont confirmées par les dernières méta-analyses [3,4].

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## Laparoscopic Ileal Interposition with Diverted Sleeve Gastrectomy versus Laparoscopic Transit Bipartition with Sleeve Gastrectomy for Better Glycemic Outcomes in T2DM Patients

Yormaz S, et al (2017) Obesity [5]

**Background:** Metabolic procedures provide better outcomes for obese patients with type 2 diabetes mellitus. Our aim was to compare the glycemic regulation in patients that have undergone the laparoscopic ileal interposition with diverted sleeve gastrectomy (II-DSG), laparoscopic transit bipartition with sleeve gastrectomy (TB-SG), and laparoscopic sleeve gastrectomy (LSG) throughout a 12-month follow-up period retrospectively.

**Methods:** This study considered patients with T2DM who underwent metabolic procedures. The postoperative changes in the glucose, C-peptide, HbA1c, HOMA-IR, insulin, cholesterol, body mass index, and total weight loss (TWL) were compared retrospectively. The intended outcome was to reach a long lasting fasting blood glucose (FBG) < 126 mg/dl. A multivariate regression analysis was applied to define the predictive markers in glucose regulation.

**Results:** Present study consisted of 83 patients with a mean age of  $47.25 \pm 6.58$  years, mean preoperative BMI of  $37.36 \pm 2.71$  kg/m<sup>2</sup>, and mean outcomes in the HbA1C and FBG of  $9.05 \pm 1.33\%$  and  $237 \pm 15$  mg/dl, respectively. There were similar correlations in BMI and total weight loss (TWL). At 12-month follow-up period, compared to LSG group, TBSG and II-DSG groups have higher remission proportions (35.3, 67.9, 54.7, respectively,  $P < 0.05$ ) with similar TWL% (22.35, 27.14, 23.16%) outcomes. The II-DSG and TB-SG results drew closer together toward the end of this study interval unlike the LSG group.

**Conclusion:** Our results showed that II-DSG and TB-SG ensured significant regression rates during the follow-up period. Since the TB-SG achieved these outcomes by finite anastomoses and intervening segments, it was considered to be a superior procedure compared to II-DSG and LSG procedures.

**Commentaires :** Cette étude, une des premières publiées, compare les nouvelles techniques malabsorptives : la bipartition iléale et l'interposition iléale réalisée après une sleeve gastrectomie à la sleeve gastrectomie seule. Les auteurs sont partis du constat suivant : l'amélioration du diabète de type 2 était plus importante après une chirurgie malabsorptive type gastrique by-pass, diversion biliopan-créatique, etc. [6,7]. Dans cette étude, comparant pour la première fois ces techniques, les 83 patients présentaient

un diabète avec une HbA1c supérieure à 7 % et un IMC supérieur à 30 kg/m<sup>2</sup>. En préopératoire, il n'existait aucune différence sur les paramètres métaboliques entre les trois groupes. À un an postopératoire, la bipartition iléale, en prenant en compte les complications per- et postopératoires, semble préférable à la transposition iléale (une nécrose iléale sur les 29 patients opérés), en comparaison à la sleeve gastrectomie. En effet, la rémission du diabète est de plus de 55 versus 35 % pour la sleeve gastrectomie. Un des paramètres non étudiés concerne les carences notamment vitaminiques après ces nouvelles techniques. Des études plus longues sur de plus grand effectif dans le cadre d'essai semblent nécessaires avant de promouvoir celle-ci.

## Laparoscopic Sleeve Gastrectomy versus Roux-Y-Gastric Bypass for Morbid Obesity-3-Year Outcomes of the Prospective Randomized Swiss Multicenter Bypass or Sleeve Study (SM-BOSS)

Peterli R, et al (2017) Ann Surg [8]

**Objective:** Laparoscopic sleeve gastrectomy (LSG) is performed almost as often in Europe as laparoscopic Roux-Y-Gastric Bypass (LRYGB). We present the 3-year interim results of the 5-year prospective, randomized trial comparing the 2 procedures (Swiss Multicentre Bypass or Sleeve Study; SM-BOSS).

**Methods:** Initially, 217 patients (LSG,  $N = 107$ ; LRYGB,  $N = 110$ ) were randomized to receive either LSG or LRYGB at 4 bariatric centers in Switzerland. Mean body mass index of all patients was  $44 \pm 11$  kg/m, mean age was  $43 \pm 5.3$  years, and 72% of patients were female. Minimal follow-up was 3 years with a rate of 97%. Both groups were compared for weight loss, comorbidities, quality of life, and complications.

**Results:** Excessive body mass index loss was similar between LSG and LRYGB at each time point (1 year:  $72.3 \pm 21.9\%$  vs  $76.6 \pm 20.9\%$ ,  $P = 0.139$ ; 2 years:  $74.7 \pm 29.8\%$  vs  $77.7 \pm 30\%$ ,  $P = 0.513$ ; 3 years:  $70.9 \pm 23.8\%$  vs  $73.8 \pm 23.3\%$ ,  $P = 0.316$ ). At this interim 3-year time point, comorbidities were significantly reduced and comparable after both procedures except for gastro-esophageal reflux disease and dyslipidemia, which were more successfully treated by LRYGB. Quality of life increased significantly in both groups after 1, 2, and 3 years postsurgery. There was no statistically significant difference in number of complications treated by reoperation (LSG,  $N = 9$ ; LRYGB,  $N = 16$ ,  $P = 0.15$ ) or number of complications treated conservatively.

**Conclusions:** In this trial, LSG and LRYGB are equally efficient regarding weight loss, quality of life, and complications up to 3 years postsurgery. Improvement of comorbidities is similar except for gastro-esophageal reflux disease and dyslipidemia that appear to be more successfully treated by LRYGB.

**Commentaire :** *Cette étude randomisée est de très grande qualité et concerne les patients obèses sévères et morbides. Celle-ci complète les résultats de la seule étude randomisée ayant comparé la sleeve au by-pass et qui concernait uniquement des patients obèses diabétiques indépendamment de la sévérité de l'obésité [9]. Cette étude confirme la tendance observée dans les études observationnelles [3]. À trois ans, ces deux techniques ont une efficacité comparable avec cependant de meilleurs résultats sur les comorbidités après by-pass. La publication des résultats à cinq ans de cette cohorte permettra sans doute de confirmer les excellents résultats à long terme de la sleeve rapportés dans de nombreuses rétrospectives [3].*

### **Reflux, Sleeve Dilation, and Barrett's Esophagus after Laparoscopic Sleeve Gastrectomy: Long-Term Follow-Up**

Felsenreich MD, et al (2017) *Obes Surg* [10]

**Background:** Laparoscopic sleeve gastrectomy (SG) has become the most frequently performed bariatric procedure worldwide. De novo reflux might impact patients' quality of life, requiring lifelong proton pump inhibitor medication. It also increases the risk of esophagitis and formation of Barrett's metaplasia. Besides weight regain, gastroesophageal reflux disease (GERD) is the most common reason for conversion to Roux-en-Y gastric bypass.

**Methods:** We performed 24-h pH metries, manometries, gastroscopies, and questionnaires focusing on reflux (GIQLI, RSI) in SG patients with a follow-up of more than 10 years who did not suffer from symptomatic reflux or hiatal hernia preoperatively.

**Results:** From a total of 53 patients, ten patients after adjustable gastric banding were excluded. From the remaining 43, six patients (14.0%) were converted to RYGB due to intractable reflux over a period of 130 months. Ten out of the remaining non-converted patients ( $N = 26$ ) also suffered from symptomatic reflux. Gastroscopies revealed de novo hiatal hernias in 45% of the patients and Barrett's metaplasia in 15%. SG patients suffering from symptomatic reflux scored significantly higher in the RSI ( $P = 0.04$ ) and significantly lower in the GIQLI ( $P = 0.02$ ) questionnaire.

**Conclusions:** This study shows a high incidence of Barrett's esophagus and hiatal hernias at more than 10 years

after SG. Its results therefore suggest maintaining pre-existing large hiatal hernia, GERD, and Barrett's esophagus as relative contraindications to SG. The limitations of this study-its small sample size as well as the fact that it was based on early experience with SG-make drawing any general conclusions about this procedure difficult.

**Commentaire :** *Les résultats de ce travail ont été présentés lors du dernier congrès de la SOFFCO-MM. La morbidité à long terme de la sleeve était encore peu rapportée. Dans cette étude, l'équipe de Gerhard Prager montre qu'à très long terme ( $\geq 10$  ans), la présence d'un reflux de novo après sleeve est associée à la présence d'une hernie hiatale chez près de la moitié des patients. Par ailleurs, des lésions d'endobrachyœsophage étaient relevées chez 15 % des patients, soit dix fois plus que dans la population générale. Ces résultats sont à confirmer plus largement mais posent la question de la surveillance à réaliser chez les patients présentant un reflux paucisymptomatique sous traitement antiacide en postopératoire.*

### **Adding Chemoprophylaxis to Sequential Compression Might Not Reduce Risk of Venous Thromboembolism in Bariatric Surgery Patients**

Gagner M, et al (2012) *Surg Obes Relat Dis*, novembre-décembre

**Background:** Anticoagulation, the use of sequential compression devices on the lower extremities perioperatively, and early ambulation are thought to reduce the incidence of venous thromboembolism (VTE) postoperatively and are recommended to reduce VTE risk. However, the evidence on which this recommendation has been based is not particularly strong. We have demonstrated that even a large, multicenter cohort with carefully collected prospective data is inadequate to provide sufficient evidence to support, or refute, this recommendation.

**Methods:** Longitudinal Assessment of Bariatric Surgery participants from 10 centers in the United States who underwent their first bariatric surgery between March 2005 and December 2007 constituted the study group. We examined the ability to address the question of whether anticoagulation therapy, in addition to sequential compression, reduces the 30-day incidence of VTE or death sufficiently to recommend the use of prophylactic anticoagulation, a therapy that is not without risk.

**Findings:** Of 4,416 patients, 396 (9.0%) received sequential compression alone, and 4,020 also received anticoagulation therapy. The incidence of VTE within 30 days of surgery was low (0.25% among those receiving sequential compression alone and 0.47% when anticoagulation therapy

was added), and the 30-day incidence of death was also low (0.25% versus 0.34%, respectively, for sequential compression alone versus sequential compression plus anticoagulation therapy). Estimates of the number of cases required to address the question of whether a difference exists in the outcome related to VTE chemoprophylaxis or whether the outcome rates are equivalent have ranged from 13,680 to 35,760 patients, depending on whether superiority or equivalence was being analyzed.

*Interpretation:* Sufficient evidence from a clinical trial study to determine whether prophylactic anticoagulation added to compression devices further prevents VTE is not available, and such a trial is likely to be impractical. The data presented are insufficient to make a final recommendation concerning prophylactic treatment to prevent VTE in the 30 days after bariatric surgery.

*Commentaire :* Cette étude reprend les données de la LABS study déjà publiées dans le New England Journal of Medicine qui avait permis de faire le point sur la morbi-mortalité du by-pass gastrique et de l'anneau gastrique en périopératoire [11]. En se focalisant sur les complications thromboemboliques et sur la thromboprophylaxie, Gagner et al. font prendre conscience de la difficulté d'établir un consensus sur une thromboprophylaxie standardisée. En France, la SFAR recommande une anticoagulation deux fois par jour pour une durée minimum de dix jours sans donner de consigne sur la dose ni la durée idéale [12]. L'ASMBS a publié plus récemment des recommandations sensiblement identiques, mais intégrant dans les paramètres décisionnels : la notion de facteur de risque thromboembolique, l'intérêt de la reprise de la déambulation précoce et de la compression pneumatique veineuse intermittente dans la thromboprophylaxie. Les modalités de chimiothromboprophylaxie sont ici encore plus libres [13]. Dans l'étude de Gagner et al. 396/4 416 patients n'ont reçu aucun traitement anticoagulant sans augmenter le risque thromboembolique (0,25 % sans anticoagulant vs 0,47 % avec anticoagulation,  $p = 0,76$ ). Ces 396 sont sélectionnés sans qu'il n'y ait un contrôle sur les critères qui ont entraîné la décision thérapeutique. Le biais de sélection ainsi induit ne permet donc pas de conclure à l'absence d'intérêt des anticoagulants après chirurgie bariatrique. Cette étude démontre, néanmoins, qu'une partie des patients opérés d'une chirurgie bariatrique peuvent se passer d'anticoagulants en postopératoire, prenant à contre-pied les arguments suggérant d'augmenter la durée et les doses d'anticoagulants en postopératoire [14]. Enfin, le nombre de patients à inclure dans un essai randomisé pour répondre à cette question est particulièrement important. Il est peu probable qu'un tel essai puisse voir le jour pour des raisons logistiques, imposant une réflexion sur la méthodologie à entreprendre pour avancer dans le débat.

### Long-Term Incidence of Microvascular Disease after Bariatric Surgery or Usual Care in Patients with Obesity, Stratified by Baseline Glycaemic Status: a Post-hoc Analysis of Participants from the Swedish Obese Subjects study

Carlsson LMS, et al (2017) Lancet Diabetes Endocrinol [15]

*Background:* Bariatric surgery is associated with remission of diabetes and prevention of diabetic complications in patients with obesity and type 2 diabetes. Long-term effects of bariatric surgery on microvascular complications in patients with prediabetes are unknown. The aim of this study was to examine the effects of bariatric surgery on incidence of microvascular complications in patients with obesity stratified by baseline glycaemic status.

*Methods:* Patients were recruited to the Swedish Obese Subjects (SOS) study between September 1, 1987, and January 31, 2001. Inclusion criteria were age 37–60 years and BMI of 34 kg/m<sup>2</sup> or greater in men and 38 kg/m<sup>2</sup> or greater in women. Exclusion criteria were identical in surgery and control groups and designed to exclude patients not suitable for surgery. The surgery group ( $N = 2,010$ ) underwent gastric bypass (265 [13%]), gastric banding (376 [19%]), or vertical-banded gastroplasty (1,369 [68%]). Participants in the control group ( $N = 2,037$ ) received usual care. Body-weight was measured and questionnaires were completed at baseline and at 0.5, 1, 2, 3, 4, 6, 8, 10, 15, and 20 years. Biochemical variables were measured at baseline and at 2, 10, and 15 years. We categorised participants into subgroups on the basis of baseline glycaemic status (normal [fasting blood glucose concentration < 5.0 mmol/l], prediabetes [5.0–6.0 mmol/l], screen-detected diabetes [ $\geq 6.1$  mmol/l at baseline visit without previous diagnosis], and established diabetes [diagnosis of diabetes before study inclusion]). We obtained data about first incidence of microvascular disease from nationwide registers and about diabetes incidence at study visits at 2, 10, and 15 years. We did the main analysis by intention to treat, and subgroup analyses after stratification by baseline glycaemic status and by diabetes status at the 15-year follow-up. The SOS study is registered with ClinicalTrials.gov, NCT01479452.

*Findings:* 4,032 of the 4,047 participants in the SOS study were included in this analysis. We excluded four patients with suspected type 1 diabetes, and 11 patients with unknown glycaemic status at baseline. At baseline, 2,838 patients had normal blood glucose, 591 had prediabetes, 246 had screen-detected diabetes, and 357 had established diabetes. Median follow-up was 19 years (IQR: 16–21). We identified 374 incident cases of microvascular disease in the control group and 224 in the surgery group (hazard ratio [HR] 0.56, 95% CI: 0.48–0.66;  $P < 0.0001$ ). Interaction between baseline glycaemic status and effect of treatment on incidence of

microvascular disease was significant ( $P = 0.0003$ ). Unadjusted HRs were lowest in the subgroup with prediabetes (0.18, 95% CI: 0.11–0.30), followed by subgroups with screen-detected diabetes (0.39, 0.24–0.65), established diabetes (0.54, 0.40–0.72), and normoglycaemia (0.63, 0.48–0.81). Surgery was associated with reduced incidence of microvascular events in people with prediabetes regardless of whether they developed diabetes during follow-up.

*Interpretation:* Bariatric surgery was associated with reduced risk of microvascular complications in all subgroups, but the greatest relative risk reduction was observed in patients with prediabetes at baseline. Our results suggest that prediabetes should be treated aggressively to prevent future microvascular events, and effective non-surgical treatments need to be developed for this purpose.

*Commentaire :* Les nouvelles recommandations du DSS-II (2nd Diabetes Surgery Summit), fondées sur des études randomisées de qualité, recommandent une chirurgie chez un patient obèse sévère avec un diabète [16]. Néanmoins, la majorité des études reprises dans la méta-analyse fondent leurs résultats sur l'équilibre glycémique des patients diabétiques. S'il existe une relation linéaire entre le risque de macroangiopathie et l'équilibre glycémique (patients diabétiques ou prédiabétiques), cette relation est moins évidente pour le risque de microangiopathie [17]. En reprenant les données de 4 032 patients de la SOS study, Carlsson et al. permettent de répondre en grande partie à cette question. On y observe une diminution du risque de microangiopathie chez l'ensemble des patients opérés qu'ils soient diabétiques, prédiabétiques ou « métaboliquement sains » avant l'intervention. L'impact de la chirurgie sur la diminution de risque est plus important chez les patients prédiabétiques où le risque est divisé par 5 (HR : 0,18 ; 0,11–0,3). Au quotidien, le message du DSS-II n'est pas appliqué par l'ensemble de la communauté médicale. Les pratiques changent progressivement. Certains patients sont adressés pour la prise en charge chirurgicale d'un diabète et sont souvent des diabétiques sévères. Sous réserve des limites toujours présentes de la SOS study (absence de randomisation, choix des procédures principalement restrictives sans sleeve, et pas d'HbA1c dans le bilan), cette étude incite à modifier la pratique spontanée d'opérer surtout les patients ayant des diabètes sévères, et à militer pour une prise en charge chirurgicale précoce.

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