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

Rubino F, et al (2016) Diabetes Care [1]

Background: Despite growing evidence that bariatric/metabolic surgery powerfully improves type 2 diabetes (T2D), existing diabetes treatment algorithms do not include surgical options.

Aim: The 2nd Diabetes Surgery Summit (DSS-II), an international consensus conference, was convened in collaboration with leading diabetes organizations to develop global guidelines to inform clinicians and policymakers about benefits and limitations of metabolic surgery for T2D.

Methods: A multidisciplinary group of 48 international clinicians/scholars (75% nonsurgeons), including representatives of leading diabetes organizations, participated in DSS-II. After evidence appraisal (Medline [1st January 2005–30 September 2015]), three rounds of Delphi-like questionnaires were used to measure consensus for 32 data-based conclusions. These drafts were presented at the combined DSS-II and 3rd World Congress on Interventional Therapies for Type 2 Diabetes (London, UK, 28–30 September 2015), where they were open to public comment by other professionals and amended face-to-face by the Expert Committee.

Results: Given its role in metabolic regulation, the gastrointestinal tract constitutes a meaningful target to manage

T2D. Numerous randomized clinical trials, albeit mostly short/midterm, demonstrate that metabolic surgery achieves excellent glycemic control and reduces cardiovascular risk factors. On the basis of such evidence, metabolic surgery should be recommended to treat T2D in patients with class III obesity (BMI ≥ 40 kg/m²) and in those with class II obesity (BMI > 35.0 – 39.9 kg/m²) when hyperglycemia is inadequately controlled by lifestyle and optimal medical therapy. Surgery should also be considered for patients with T2D and BMI > 30.0 – 34.9 kg/m² if hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications. These BMI thresholds should be reduced by 2.5 kg/m² for Asian patients.

Conclusions: Although additional studies are needed to further demonstrate long-term benefits, there is sufficient clinical and mechanistic evidence to support inclusion of metabolic surgery among antidiabetes interventions for people with T2D and obesity. To date, the DSS-II guidelines have been formally endorsed by 45 worldwide medical and scientific societies. Health care regulators should introduce appropriate reimbursement policies.

Commentaire : Ce travail est issu du dernier DSS (Diabetes Surgery Summit), organisé à Londres en septembre 2015 par Francesco Rubino. Cet article comprend d'abord une méta-analyse des 15 essais contrôlés randomisés ayant comparé la chirurgie métabolique au traitement médical chez les patients diabétiques de type 2 obèses. Tous ont montré que la chirurgie métabolique permettait d'obtenir un contrôle à court et moyen terme du diabète et une diminution du risque cardiovasculaire indépendamment de la sévérité de l'obésité (IMC > 35 kg/m² vs IMC ≤ 35 kg/m²). La chirurgie métabolique a démontré son efficacité, mais également son innocuité [2,3]. Partant de ces données, un consensus s'est dégagé, voté par un panel comprenant plus de médecins que de chirurgiens et adopté par plus de 40 sociétés savantes, dont la SOFFCO-MM, la Société française de diabétologie (SFD) et l'American Diabetes Association (ADA). Ce consensus valide l'introduction de la chirurgie dans l'algorithme thérapeutique du diabète de type 2 chez les patients obèses modérés IMC : 30–35 kg/m² (–2,5 kg/m² chez les patients d'origine asiatique) et ayant un diabète non contrôlé par un traitement antidiabétique optimal. Les recommandations du DSS sont là, il reste désormais

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à obtenir des recommandations nationales émanant de la Haute Autorité de santé ainsi qu'un remboursement des actes dans cette indication pour en permettre la diffusion. Cette indication est limitée pour l'instant à quelques pays ayant des recommandations spécifiques pour la chirurgie métabolique [4]. Je vous invite à télécharger l'intégralité des articles du numéro de juin de *Diabetes Care*, entièrement en accès libre et dédié à la chirurgie métabolique <http://care.diabetesjournals.org/content/39/6>.

Body-Mass Index and All-Cause Mortality: Individual-Participant-Data Meta-analysis of 239 Prospective Studies in Four Continents

Global BMI Mortality Collaboration (2016) *Lancet* [5]

Background: Overweight and obesity are increasing worldwide. To help assess their relevance to mortality in different populations we conducted individual-participant data meta-analyses of prospective studies of Body-Mass Index (BMI), limiting confounding and reverse causality by restricting analyses to never-smokers and excluding pre-existing disease and the first 5 years of follow-up.

Methods: Of 10,625,411 participants in Asia, Australia and New Zealand, Europe, and North America from 239 prospective studies (median follow-up 13.7 years, IQR 11.4–14.7), 3,951,455 people in 189 studies were never-smokers without chronic diseases at recruitment who survived 5 years, of whom 385,879 died. The primary analyses are of these deaths, and study, age, and sex adjusted hazard ratios (HRs), relative to BMI 22.5–<25.0 kg/m².

Findings: All-cause mortality was minimal at 20.0–25.0 kg/m² (HR: 1.00, 95% CI: 0.98–1.02 for BMI 20.0–<22.5 kg/m²; 1.00, 0.99–1.01 for BMI 22.5–<25.0 kg/m²), and increased significantly both just below this range (1.13, 1.09–1.17 for BMI: 18.5–<20.0 kg/m²; 1.51, 1.43–1.59 for BMI: 15.0–<18.5) and throughout the overweight range (1.07, 1.07–1.08 for BMI: 25.0–<27.5 kg/m²; 1.20, 1.18–1.22 for BMI: 27.5–<30.0 kg/m²). The HR for obesity grade 1 (BMI: 30.0–<35.0 kg/m²) was 1.45, 95% CI: 1.41–1.48; the HR for obesity grade 2 (35.0–<40.0 kg/m²) was 1.94, 1.87–2.01; and the HR for obesity grade 3 (40.0–<60.0 kg/m²) was 2.76, 2.60–2.92. For BMI over 25.0 kg/m², mortality increased approximately log-linearly with BMI; the HR per 5kg/m² units higher BMI was 1.39 (1.34–1.43) in Europe, 1.29 (1.26–1.32) in North America, 1.39 (1.34–1.44) in East Asia, and 1.31 (1.27–1.35) in Australia and New Zealand. This HR per 5 kg/m² units higher BMI (for BMI over 25 kg/m²) was greater in younger than older people (1.52, 95% CI: 1.47–1.56, for BMI measured at 35–49 years vs 1.21, 1.17–1.25, for BMI measured at

70–89 years; pheterogeneity < 0.0001), greater in men than women (1.51, 1.46–1.56, vs 1.30, 1.26–1.33; pheterogeneity < 0.0001), but similar in studies with self-reported and measured BMI.

Interpretation: The associations of both overweight and obesity with higher all-cause mortality were broadly consistent in four continents. This finding supports strategies to combat the entire spectrum of excess adiposity in many populations.

Commentaire : Cette étude épidémiologique en population mondiale nous montre ce que d'autres avaient déjà observé, à savoir que l'insuffisance pondérale (IMC < 20 kg/m²) et l'obésité (IMC ≥ 30 kg/m²) sont responsables d'une surmortalité par rapport à la population de poids standard (20–25 kg/m²). De plus, cette étude met également en évidence l'impact négatif du surpoids (IMC ≥ 25 kg/m²) sur la mortalité. L'effet est moindre que l'obésité, mais néanmoins significatif. Le risque de décès était corrélé positivement à l'IMC. Ces données sont à mettre en parallèle avec celles d'une autre étude de population parue récemment dans le *Lancet* [6], observant la progression de la pandémie d'obésité avec, pour 2025, une prévalence mondiale de l'obésité estimée à 18 % chez les hommes (dont plus de 6 % d'obésité sévère) et 21 % chez les femmes (dont plus de 9 % d'obésité sévère).

The Impact of Different Surgical Techniques on Outcomes in Laparoscopic Sleeve Gastrectomies: the First Report from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)

Berger ER, et al (2016) *Ann Surg* [7]

Objective: Questions remain regarding best surgical techniques to use for a laparoscopic sleeve gastrectomy (LSG) including the use of staple line reinforcement (SLR), bougie size (BS), and distance from the pylorus (DP) where the staple line is initiated. Our objectives were to assess the impact of these techniques on 30-day outcomes and to evaluate the impact of these techniques on weight loss and comorbidities at 1 year.

Methods: Using the MBSAQIP data registry, univariate analyses and hierarchical logistical regression models were developed to analyze outcomes for techniques of LSG at patient and surgeon-level.

Results: A total of 189,477 LSG operations were performed by 1634 surgeons at 720 centers from 2012 to 2014. Eighty percent of surgeons used SLR, 20% did not. SLR cases were associated with higher leak rates (0.96% vs 0.65%, odds ratio [OR]: 1.20, 95% confidence interval [CI]:

1.00–1.43) and lower bleed rates (0.75% vs 1.00%, OR: 0.74, 95% CI: 0.63–0.86) compared to no SLR at patient level. At the surgeon level, leak rates remained significant, but bleeding events became nonsignificant. $BS \geq 38$ was associated with significantly lower leak rates compared to $BS < 38$ at patient and surgeon level (patient level: 0.80% vs 0.96%, OR: 0.72, 95% CI: 0.62–0.94; surgeon level: 0.84% vs 0.95%, OR: 0.90, 95% CI: 0.80–0.99). $BS \geq 40$ was associated with increased weight loss. DP had no impact on leaks or bleeds but showed an increase in weight loss with increasing DP.

Conclusion: LSG is a safe procedure with a low morbidity rate. SLR is associated with increased leak rates. A surgeon should consider risks, benefits, and costs of these surgical techniques when performing a LSG and selectively utilize those that, in their hands, minimize morbidity while maximizing clinical effectiveness.

Commentaire : *Le MBSAQIP est le programme de collecte de données de l'ACS et de l'ASMBS, ce qui explique, au moins en partie, la force de cette étude. Ce travail rend des conclusions comparables à celles de la méta-analyse de Parikh et al. concernant l'impact de la calibration dans la survenue de la fistule post-sleeve [8]. Les résultats présentés (presque 200 000 sleeve) démontrent également que l'utilisation d'un matériel de renforcement diminue le risque d'hémorragie mais augmente le risque de fistule ! L'ajout d'un renforcement par suture continue ou discontinu en plus péjorait un peu plus ces résultats. Les données pondérales présentées sont des données à un an avec seulement 30 % des données disponibles, limitant la valeur à porter sur l'impact positif d'une calibration « large » (≥ 40 Fr) et de la distance par rapport au pylore sur la perte d'excès de poids. Ces données sont à prendre en compte étant donné qu'une étude randomisée contrôlée comparant les mêmes conditions avec les mêmes variables sera très difficilement réalisable étant donné la faible incidence des fistules (2 %) [9], et le coût élevé des matériels de renforcement.*

Endoscopic Devices for Obesity

Sampath K, et al (2016) *Curr Obes Rep* [10]

Abstract: The obesity epidemic, recognized by the World Health Organization in 1997, refers to the rising incidence of obesity worldwide. Lifestyle modification and pharmacotherapy are often ineffective long-term solutions; bariatric surgery remains the gold standard for long-term obesity weight loss. Despite the reported benefits, it has been estimated that only 1% of obese patients will undergo surgery. Endoscopic treatment for obesity represents a potential

cost-effective, accessible, minimally invasive procedure that can function as a bridge or alternative intervention to bariatric surgery. We review the current endoscopic bariatric devices including space occupying devices, endoscopic gastroplasty, aspiration technology, post-bariatric surgery endoscopic revision, and obesity-related NOTES procedures. Given the diverse devices already FDA approved and in development, we discuss the future directions of endoscopic therapies for obesity.

Commentaire : *Cette revue exhaustive fait la difficile synthèse des données concernant les dispositifs endoscopiques récents homologués et encore disponibles. La tendance est toujours la même : que ce soit à visée pondérale, métabolique (comorbidités) ou révisionnelle après échec d'une chirurgie bariatrique initiale, l'efficacité à court terme (6–12 mois) de ces dispositifs est patente, cependant l'absence de données à plus long terme et le faible nombre d'études randomisées et de patient inclus ne permettent toujours pas de définir la place à leur donner dans la prise en charge de l'obésité.*

Perspectives on Treatment for Nonalcoholic Steatohepatitis

Lassailly G, et al (2016) *Gastroenterology*

It is important to provide treatment to patients with nonalcoholic steatohepatitis (NASH) because one third of patients with the metabolic syndrome die of liver disease. Basic research studies have elucidated mechanisms of NASH pathogenesis, which could lead to therapeutic targets. Health agencies have confirmed strategies for the optimal management of NASH and approved new drugs and treatments, which urgently are needed. The US Food and Drug Administration recently endorsed end points for NASH therapy. The reversal of NASH with no evidence of progression to advanced fibrosis has been defined as the end point for phase 2b and phase 3 trials in patients with NASH and early stage fibrosis. Although a decrease in the nonalcoholic fatty liver disease activity score could serve as an end point in clinical trials, it is not clear whether patients with lower scores have a lower risk of progression to advanced fibrosis. End points for clinical trials of patients with NASH cirrhosis currently are based on model for end-stage liver disease and Child-Pugh-Turcotte scores, as well as the hepatic venous pressure gradient. Different strategies are being explored to reduce liver diseases that are linked to a sedentary lifestyle, overeating, and genetic factors. In association with insulin resistance and deregulation of the lipid metabolism (accumulation of lipotoxins that promote hepatic lipogenesis, adipose tissue lipolysis, and impaired

β -oxidation), these factors could increase the risk of liver steatosis with necroinflammatory lesions and fibrosis. We review the pathogenic mechanisms of NASH and therapeutic options, as well as strategies that are being developed for the treatment of injury to the liver and other organs.

Commentaire : Cette revue est sûrement la plus complète publiée sur la physiopathologie et la prise en charge thérapeutique de la nonalcoholic steatohepatitis (NASH). L'équipe lilloise a une grande expertise sur cette thématique et a montré que la chirurgie bariatrique induisait une diminution à long terme des lésions de NAFLD (nonalcoholic fatty liver disease) [11] et de la NASH dans 85 % des cas un an après by-pass gastrique Roux-en-Y ou anneau gastrique ajustable [12]. À lire d'urgence !

Fast-track Bariatric Surgery: Safety of Discharge on the First Postoperative day after Bariatric Surgery

Khorgami Z (2016) Soard [13]

Background: Fast-track recovery pathways have resulted in a multidisciplinary approach to enhance postoperative recovery.

Objectives: To assess feasibility and outcome of early discharge after laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB).

Setting: The American College of Surgeons National Surgical Quality Improvement Program database was analyzed to identify patients with body mass index ≥ 35 kg/m² who underwent LSG or LRYGB in 2012 and 2013.

Methods: Patients were allocated to early discharge (ED) when discharged on postoperative (POD) 1 and late discharge (LD) when discharged on POD 2 or 3. Baseline characteristics and 30-day outcomes were compared between the 2 groups.

Results: Records of 15,468 LSG and 16,483 LRYGB patients were analyzed; 5,220 patients with LSG (33.7%) and 2,960 patients with LRYGB (18%) were discharged on POD 1. The early discharge group had significantly fewer co-morbidities and lower rate of complications and readmission. Thirty-day readmission rate in LSG was 2.8% in ED versus 3.6% in LD ($P = .008$), and in LRYGB, it was 4.3% in ED versus 5.8% in LD ($P = .001$). Based on multivariate analysis, early discharge was not an independent risk factor for a higher readmission rate after LSG or LRYGB. Predictors of late discharge were age > 50 years, body mass index > 50 kg/m², Hispanic or non-Hispanic black race/ethnicity, impaired functional status, diabetes on insulin, chronic steroid/immunosuppressant use, bleeding disorder, being on dialysis, chronic obstructive pulmonary disease, albumin < 3.5 mg/dl, longer operative time, and concurrent cholecystectomy.

Conclusion: Discharge on POD 1 after LSG and LRYGB is feasible in a considerable proportion of patients. In this subgroup, early discharge is well tolerated and may be associated with lower complication and readmission rates.

Commentaire : Cette étude réalisée à partir du registre national NSQIP de l'American College of Surgeon valide ce que d'autres séries rétrospectives et prospectives avec de moindres effectifs avaient mis en évidence [14] : les programmes de réhabilitations précoces en chirurgie bariatrique sont efficaces et sûrs. Cette étude montre également que le fast-track permet de faire sortir les patients à J1 postopératoire sans majorer le risque de réadmission et de complications. Les facteurs d'échec de ce type de programme sont sensiblement les mêmes que ceux de l'ambulatorio. Ce travail souligne deux points importants : 1) ces prises en charge permettent d'optimiser les prises en charge en hospitalisation conventionnelle ; 2) le fast-track peut s'envisager comme la première étape vers la mise en place d'une activité ambulatoire.

Closure of Mesenteric Defects in Laparoscopic Gastric Bypass: a Multicentre, Randomised, Parallel, Open-Label Trial

Stenberg E, et al (2016) Lancet [15]

Background: Small bowel obstruction due to internal hernia is a common and potentially serious complication after laparoscopic gastric bypass surgery. Whether closure of surgically created mesenteric defects might reduce the incidence is unknown, so we did a large randomised trial to investigate.

Method: This study was a multicentre, randomised trial with a two-arm, parallel design done at 12 centres for bariatric surgery in Sweden. Patients planned for laparoscopic gastric bypass surgery at any of the participating centres were offered inclusion. During the operation, a concealed envelope was opened and the patient was randomly assigned to either closure of mesenteric defects beneath the jejuno-jejunostomy and at Petersen's space or non-closure. After surgery, assignment was open label. The main outcomes were reoperation for small bowel obstruction and severe postoperative complications. Outcome data and safety were analysed in the intention-to-treat population. This trial is registered with ClinicalTrials.gov, number NCT01137201.

Findings: Between May 1, 2010, and Nov 14, 2011, 2,507 patients were recruited to the study and randomly assigned to closure of the mesenteric defects ($N = 1,259$) or non-closure ($N = 1,248$). 2,503 (99.8%) patients had follow-up for severe postoperative complications at day 30 and 2,482 (99.0%) patients had follow-up for reoperation due to small bowel obstruction at 25 months. At 3 years after

surgery, the cumulative incidence of reoperation because of small bowel obstruction was significantly reduced in the closure group (cumulative probability 0.055 for closure vs 0.102 for non-closure, hazard ratio 0.56, 95% CI 0.41–0.76, $P = 0.0002$). Closure of mesenteric defects increased the risk for severe postoperative complications (54 [4.3%] for closure vs 35 [2.8%] for non-closure, odds ratio 1.55, 95% CI: 1.01–2.39, $P = 0.044$), mainly because of kinking of the jejunojejunostomy.

Interpretation: The results of our study support the routine closure of the mesenteric defects in laparoscopic gastric bypass surgery. However, closure of the mesenteric defects might be associated with increased risk of early small bowel obstruction caused by kinking of the jejunojejunostomy.

Commentaire : *Il s'agit de la première étude randomisée contrôlée évaluant l'efficacité et la morbidité de la fermeture des espaces intermésentériques dans le Roux-en-Y gastrique by-pass. Dans ce travail, le RYGB évalué était celui réalisé selon la technique de Lönroth (anastomose gastro-jéjunale antégastrique, antécolique), donc deux brèches : mésentérique et Petersen. La méta-analyse de Geubbels et al. parue l'année dernière avait montré que la fermeture des espaces dans cette technique permettait de diminuer l'incidence des hernies internes (1 versus 2 %). Cependant, une étude randomisée était nécessaire [16]. C'est désormais chose faite, plus de 1 000 patients dans chaque bras et deux résultats forts : 1) la fermeture systématique des brèches mésentériques diminue significativement le taux de réopération pour occlusion digestive et donc doit être réalisée lors de chaque procédure ; 2) ces gestes supplémentaires sont à l'origine d'une augmentation significative (X1.5) de la morbidité postopératoire et des réinterventions précoces pour occlusion sur kinking de l'anastomose jéjunojéjunale.*

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