RYGB offers better weight loss but higher readmission rates vs LSG

Combined DATO and SORReg offers insights into current clinical practice across three countries

Outcomes

The most common procedure was RYGB (Sweden, 64.0%; the Netherlands, 77.0%), while SG was the most common procedure in Norway (57.0%, p<0.001). The results revealed that patients who has RYGB had more preoperative comorbidities compared to SG patients (71.5% vs 64.3%, p<0.001), and patients operated in the Netherlands had more comorbidities than both Sweden and Norway (p<0.001). Gastroesophageal reflux disease (GERD) was about twice as common in RYGB patients from Norway and Sweden, although there was no difference between the two procedures for patients from the Netherlands. In total, 43,520 patients (8.1%) met the eligibility criteria for bariatric surgery (91.9% for the RYGB and 85.6% for SG patients, respectively, p<0.001).

Interestingly, we found that more RYGB patients were operated according to international guidelines for bariatric surgery than sleeve gastrectomy patients,” the authors commented. “This could be due the fact that there are some Swedish private clinics performing sleeve gastrectomy on patients with a BMI of 30 to 35 kg/m2 or 35 to 40 kg/m2 without any obesity-related comorbidity.”

In total, 868 patients (1.6%) had severe complications (CD-Grade IIIb after RYGB and 341 [2.4%] patients after SG [p<0.05]). Subsequent reinterventions (due to severe complications) were performed in 667 patients (1.0%) after RYGB and 290 (2.1%) patients after SG (p<0.01). Thirty-day mortality was 0.1% (n=5) after RYGB and 0.0% (n=0) after SG (p=0.81). Bleeding (0.5%), leakage (0.7%) and wound infection (0.5%) were the three most common combined complications after RYGB and SG, although there was no statistical difference between the two procedures.

Bariatric surgery improves sexual life experience after five years

Approximately half of women and men who reported pre-surgical dissatisfaction with sexual life experienced post-surgical improvements in satisfaction five years after bariatric surgery, according to researchers in the school of pharmacy at North Dakota State University, Fargo. In addition, a large percentage of patients experienced improvements in the frequency of sexual desire and activity and in the quality of sexual activity. Nevertheless, the percentage of participants with improvements in the frequency of sexual desire and activity decreased between five and ten years.

The study, “Changes in Sexual Functioning in Women and Men in the 5 Years After Bariatric Surgery,” published in JAMA Surgery, sought to determine the percentage of adults who experience durable improvements in sexual functioning after bariatric surgery and to identify factors associated with improvements. Using data from The Longitudinal Assessment of Bariatric Surgery-2 (LABS2) study, conducted at ten hospitals in six US clinical centers, the study included 2,215 participants eligible for sexual function follow-up, 2,096 (94.9%) completed one or more follow-up

Gut microbes, genes and bariatric surgery

METABASE and BARINAFLD projects assessing relationship of microbes and bariatric procedures

ICET that have undergone weight loss surgery experience a change in the composition of their gut bacteria and the functioning of their genes, leading scientists to explore the possibility of mimicking these changes to develop a non-surgical treatment for obesity and liver disease in humans. Obesity and associated metabolic diseases such as lifestyle-related type 2 diabetes result from genetic and environmental influences. According to the World Health Organization, obesity has nearly tripled since 1975 and more than 670 million adults were obese in 2016. For the same year, the prevalence of obesity among Europeans was an estimated 23.5%, yet effective treatment remains a challenge.

“Bariatric surgery has been around for 50 years and we still don’t know why we see improvement in metabolic diseases,” said Dr Frederik Bäckhed, an expert in microbiology and mouse physiology at the Sahlgrenska Academy at the University of Gothenburg in Sweden. Bäckhed has spent the past 15 years researching the microorganisms that live in the digestive tracts of both humans and rodents. His aim is to understand the relationship between human health and gut bacteria. Around 2008, he first developed a hypothesis about bariatric surgery, “I started thinking perhaps this surgery has that profound effect on gut physiology.”
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Reveal • Interpret • Improve
RYGB offers better weight loss but higher readmission rates vs LSG

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Two procedures. Patients who had RYGB had a shorter hospital stay (1.6 days vs 1.7 days, respectively, p<0.001). The length of hospital stay after RYGB and SG was comparable in the Netherlands, although in Norway and Sweden, hospital stay was shorter after RYGB than SG in the same country (p<0.001).

The readmission rate was higher for patients who underwent RYGB than SG (4.3% vs 3.4%, p<0.001), with the lowest readmission rates in the Netherlands, with Swedish hospitals having significantly higher readmission rates after RYGB (7.5%) than the overall average (p<0.001).

Total Weight Loss of more than 20% in the first year after surgery was reached more often after RYGB than SG (59.8% and 84.6%, respectively, p<0.001). There was a significant difference in

TWL after SG in Sweden (75.3%), Norway (93.4%) and the Netherlands (90.8%) (p<0.001), while the difference was smaller after RYGB (Sweden: 94.5%, Norway: 95.4%; Netherlands: 96.6% p<0.001).

Conclusions

The authors noted that national databases and registries collect detailed data on patient characteristics, treatment and individual hospitals, and this data can be made available for monitoring, ensuring quality indicators, facilitating comparisons relative to a national and an international benchmark analysis.

The standardisation of registries and consensus on definitions of measures included facilitate comparisons between countries that may impact the standardisation of the treatment given on an international level, they concluded.

Gut microbes, genes and bariatric surgery

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would affect the microbiota, too.

METABASIS

Through a project called METABASIS, he and his team have been studying how mice and human gut bacteria might change after bariatric surgery, and whether this is in turn modulates the procedure’s beneficial effects.

Four years ago, his team at the university had a breakthrough when they showed him data proving that human microbiota altered after bariatric surgery and contributed to reduced fat mass gain in mice. They compared the microbiota in patients who underwent a gastric bypass and a vertical banded gastroplasty. They realised that the more effective the surgery for weight loss, gastric bypass, has a more profound the effect on the microbiota.

Then, by transferring the microbiota found in the faeces of humans before and after surgery to mice, they were able to see that mice with microbiota from post-surgery patients did not gain much fat mass. In a more recent experiment, they performed a sleeve gastrectomy on mice both with and without microbiota to compare and analyse the relevance of the bacteria itself.

“What we know is that the microbiota is altered after bariatric surgery in mice and humans and that the altered microbiota can contribute, in part, to the improved metabolic parameters like body weight and insulin resistance,” said Bäckhed. “It was very important for me to see that this modification through the surgery could contribute to some of the effects of the procedure.”

Comparing a microbiota-free mouse to one colonised with post-surgery bacitracin also showed that gut bacteria contributes to obesity in people with Western-style diets, according to Bäckhed. Microbiota can alter metabolism by affecting nutrient processing and generation of energy.

The team will continue to study how microbiota changes after surgery, and are now trying to figure out what part of the operation induces changes in mice. Alternatively, the analysis may reveal whether it is possible to induce those microbiotic alterations that lead to weight loss and improvements in metabolism without having surgery.

“It depends what we find,” added Bäckhed. “Perhaps we find a new drug that will change the microbiota in a similar fashion as the surgery or we can identify bacteria (in humans) that can have (an) effect.”

BARINAFLD

As the head of a lab at the Hebrew University of Jerusalem, Israel, system biologist Dr Danny Ben-Zvi is looking for molecular processes that can lead to the development of Non-Alcoholic Fatty Liver Disease (NAFLD) by studying how bariatric procedures affect mice.

It is caused by the accumulation of fat in the liver cells without the consumption of alcohol. It is often linked to obesity and affects one in four adults globally, with the highest prevalence in the Middle East and South America and the lowest in Africa. For some people, this disease is only a precursor to other conditions, such as severe liver inflammation called NASH (Non-Alcoholic Steatohepatitis), cirrhosis, liver failure and cancer. Because there are no clear symptoms, many lean people can have it without knowing that they do.

Ben-Zvi was studying diabetic mice when he discovered one type that underwent bariatric surgery but did not lose weight — despite their lives becoming healthier at that point. The mice turned out to have a mutation in their receptors for hormone collection which made them eat all the time.

“It was very strange and exciting at the same time,” he said. “These mice were obese but no longer sick.”

Ben-Zvi found that bariatric surgery completely altered the expression patterns of genes in the mice livers, something that has also been observed in human patients.

He started the BARINAFLD project in November 2018 to identify exactly which genes and genetic pathways are changed by the surgery. By understanding this, Ben-Zvi believes it will be possible to mimic the positive effects of surgery for NAFLD by tapping into certain genes and without ever turning to the scalpel. Instead, the same result could be obtained through nutrition and drugs that activate or repress a gene pathway, he added.

“I think we will have a handle on how we can treat fatty liver in human patients,” concluded Ben-Zvi. “And I hope we will be able to use this tool to explore other diseases that are currently alleviated by bariatric surgery, such as arteriosclerosis.”

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Bariatric surgery improves sexual life experience after five years

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assessment 1,431 (64.6%) at year five, of whom 1,057 (78.6%) were women.

A self-administered questionnaire was used to assess clinically meaningful differences before and after surgery in past-month sexual satisfaction, desire, and activity and physical health limitations to sexual activity among subgroups who reported sexual functioning at less than domain-specific thresholds before surgery.

At the pre-surgery assessment, median (interquartile range) age was 47 (37-55) years, and the median (interquartile range) body mass index 43.8 (34.1-57.3). Among those who were not satisfied with their sexual life before surgery, 1,035 or 14,486 women, 69.7%, 314 of 409 men (77.5%), 56% of women and 41.3% of men experienced clinically meaningful improvements in the first year; these percentages did not significantly differ during further follow-up. Among those who reported physical limitations to sexual activity at baseline (953 of 1,490 women, 59.6% and 267 of 406 men, 66.8%), the percentage experiencing improvement in this domain decreased during follow-up, but 73.6% of women and 62.6% of men continued to report improvements in the fifth year.

Greater postsurgical reduction in depressive symptoms was independently associated with improvement in four domains of sexual life among women (frequency of sexual desire p<0.001; frequency of sexual activity p<0.001; the degree to which physical health limited sexual activity p<0.001, and satisfaction with sexual life p<0.001) and two domains among men (physical health limitations p<0.001 and satisfaction with sexual life p<0.001). The type of surgical procedure was not associated with improvement.

In females, fewer pre-surgical depressive symptoms and a postsurgical decrease in depressive symptoms were associated with a higher chance of improvement in the degree of physical health limits sexual activity and satisfaction with sexual life, and stopping antidepressant use was associated with a higher chance of improvement in three domains.

“Depressive symptoms and antidepressant medication were associated with sexual functioning among adults who underwent bariatric surgery,” the authors concluded. “Clinicians should assess patient satisfaction with sexual functioning before and after bariatric surgery. They should also consider interventions targeted to modifiable factors that may influence the likelihood of improvement.”

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Based on the World Health Organization (WHO) data, Kuwait has the second highest prevalence of obesity at 38.3% in the Arabian Gulf.

The State of Kuwait Ministry of Health publishes 1st National Bariatric Registry Report

State of Kuwait Ministry of Health publishes 1st National Bariatric Registry Report

Based on the World Health Organization (WHO) data, Kuwait has the second highest prevalence of obesity at 38.3% in the Arabian Gulf. Report demonstrates that bariatric procedures in Kuwait are safe for patients with a 0.0% reported in-hospital operative mortality rate.
Mini gastric bypass—one anastomosis gastric bypass (MGB-OAGB) is now the 3rd most commonly performed bariatric procedure in the world, and is believed by some of its proponents to be equal to, if not better than, Roux-en-Y gastric bypass (RYGB). Bariatric News spoke with Dr Karl P Rheinwalt (Head of Department of Obesity, Metabolic and Plastic Surgery, St Franziskus-Hospital Cologne, Cologne, Germany, President 2019 of the International MGB-OAGB-Club and Congress-President of the Annual MGB-OAGB-Consensus Conference 2019), who discussed the merits of MGB-OAGB and the benefits of banded MGB-OAGB as a revision procedure to reduce instances of dumping syndrome and weight regain.

Dr Rheinwalt began by stating that MGB-OAGB is the preferred primary procedure at his institution, unless there are contra-indications to laparoscopic bypass surgery (major previous surgery on the small bowel, Crohn’s disease, current smokers, liver cirrhosis etc) and/or the patient has a preference for another procedure. As a bypass procedure, he said that the MGB-OAGB is easier to perform than the RYGB and the majority of the studies so far have shown that MGB has a significantly shorter operating time. Of all the bariatric procedures, MGB-OAGB is also an attractive procedure because the MGB is relatively simple to revise or perform as a revision procedure, he added.

"The evidence so far shows that MGB-OAGB also results in fewer complications and the same, if not more, weight loss compared with RYGB, as well as improvements in comorbidities. In my opinion, MGB-OAGB is at least as good, if not better than, the RYGB," said Dr Rheinwalt. "MGB-OAGB has fewer complications, particularly as we do not have to deal with a second anastomosis and possible issues of tension, we have fewer instances of internal hernia and around half the number of patients with accelerated gastric pouch emptying, compared with RYGB patients. I think MGB is gaining in popularity because it is perhaps a ‘compromise’ procedure with strong enteroendocrine effects, a small degree of restriction and mild to moderate malabsorption."

He cited his centre’s own experience where only 5% of MGB-OAGB patients have reported episodes of symptomatic accelerated gastric pouch emptying (dumping syndrome), compared with approximately 6% of RYGB patients.

What can account for the differences in rates of dumping syndrome? According to Dr Rheinwalt one possible explanation was put forward by Professor Jacques Himpens – following experimental studies (unpublished data) – who suggested that for the body to absorb carbohydrates and sugars one requires a sodium glucose pump in the small bowel wall. The sodium is provided via bile fluid, however, following RYGB, the sugars are deposited into the alimentary limb, and therefore cause early dumping symptoms such as dizziness, sweating, tachycardia etc. In the MGB-OAGB procedure, there is no alimentary limb so the carbohydrates and sugars are mostly absorbed by the sodium.

"We have observed similar rates of late (one hour after eating) dumping syndrome or postprandial hypoglycaemia in our MGB-OAGB and RYGB patients, compared to twice the rate of early dumping in RYGB patients vs MGB-OAGB patients," he explained. "This of course is better for the MGB-OAGB patients in terms of quality of life and possible revision procedures."

### Weight regain

Dr Rheinwalt said there are several causes for weight regain following bariatric surgery adding that there is a tendency among some surgeons to blame the patient for non-compliance to postsurgical treat regimes claiming they are not exercising and are eating the wrong types of food.

"However, I believe there are several genetic causes – in the same respect that after bariatric surgery there are responders and non-responders – some patients are more prone to weight regain, whereas others have long-term sustained weight loss. Therefore, I think we have to accept that some patients are going to have a ‘second step’ procedure after their primary operation."

He explained most of the banded-MGB procedures in his centre are for revision procedures to treat dumping and in such cases, he places the MiniMizer Ring (Bariatric Solutions) on the lower part of the gastric pouch to eliminate the dumping. The Ring also has the benefit of adding an extra element of restriction, thereby possibly preventing dilatation of the gastric pouch and weight regain.

"I do not perform banded-MGB as a primary procedure because in my opinion, we do not have evidence to support primary banded-MGB as a first procedure. I do believe there is good evidence to support primary banded-RYGB vs no-banded RYGB in terms of long-term weight loss and resolution of comorbidities. In addition, I also believe there is good evidence to support placing a ring around the gastric pouch for revision RYGB procedure to prevent dumping and weight regain. But as a primary procedure, we need more comparative, long-term data to support primary banded-MGB. One revision option for MGB is to lengthen the biliopancreatic limb, however if the patient has deficiencies in iron and other micronutrients then lengthening the limb is not an option and the banded-MGB is a better option."

### Learning curve

"We have had some instances of food intolerance, so we have had to adjust the diameter of the Ring. In our experience, we have learnt to leave a greater space between the Ring and the Pouch - so if you initially think to close the Ring at 6.5 cm, you should probably close at 7 cm and so on. This has reduced our centre’s instances of food intolerance substantially."

Dr Rheinwalt said there are several causes for weight regain following bariatric surgery adding that there is a tendency among some surgeons to blame the patient for non-compliance to postsurgical treat regimes claiming they are not exercising and are eating the wrong types of food.

He said that the procedure to fix the MiniMizer Ring is quite straightforward and the Ring has several innovating design enhancements that facilitates ease of use. For example, the tip of the Ring has pre-formed soft tip that allows it to pass safely behind the posterior wall of the gastric pouch. He advises users not to create too large a space behind the gastric pouch, rather ‘a small pathway should suffice’, to avoid the risk of slipping. As the device does not add direct pressure to the pouch, there have been no instances of device penetration.

"In summary, I believe there is still a lack of evidence to support primary banded-MGB and its use is still controversial, but for me there is an advantage of placing a Ring in some revision procedures particularly to prevent dumping and weight regain." Dr Rheinwalt concluded. "However, we will discuss this and many other questions and controversies at the forthcoming 6th Annual Consensus Conference of the MGB-OAGB International Club, in Cologne, Germany, from 20-21 June, and I look forward to welcoming colleagues from around the world to this exciting meeting.”
**Lifestyle—not diet—a greater indication for weight regain after surgery**

In the years following bariatric surgery, a person’s overall eating behaviours and the amount of time spent watching television, playing video games and using other screen time for recreation are a better indication of long-term weight loss success than specific weight control practices like counting calories, according to findings by the University of Pittsburgh School of Public Health.

The study, *I*, published in the *Annals of Surgery*, also indicate that despite the thorough weight loss evaluation of obese超 heavy patients for preparation for bariatric surgery, mental health and eating habits prior to surgery were not correlated with which patients would struggle most with keeping the weight off after surgery. The research is believed to be the largest long-term study to examine patient behaviours and characteristics associated with post-bariatric surgery weight regain.

“Bariatric surgery is the most effective treatment for obesity, but it results in sustained weight reduction and remission of diabetes and other health problems in the majority of patients,” said lead author, Dr Wendy King, a professor in Pitt Public Health’s Department of Epidemiology.

However, as with all types of weight loss interventions, patients usually regain at least some of the weight they initially lose.

King’s previous work, which quantified the tremendous variation among patients in the timing and amount of weight loss following maximum weight loss from bariatric surgery, highlighted the need for this study to identify behaviours related to weight regain and patients at risk for regaining the most weight.

“This study is important for prevention and early intervention efforts,” she added.

In the study, King and her colleagues followed 1,956 women who underwent the so-called Roux-en-Y gastric bypass surgery and had their weight measured an average of 8.3 times over a period that averaged 6.6 years. The participants were enrolled in the National Institutes of Health-funded Longitudinal Assessment of Bariatric Surgery-2 (LABS-2), a prospective, observational study of patients undergoing weight loss surgery at one of 40 hospitals across the US.

Reducing sedentary behaviour, avoiding fast food, addressing problematic eating behaviours including eating continuously, eating when full, loss of control and binge eating; and promoting self-weighting at least weekly were all behavioural targets the research team identified that patients should strive for and doctors should promote as part of post-surgical patient care.

In addition to evaluating behaviours, the researchers also identified patient characteristics related to higher weight regain. Younger patients and those with a previous previous sedentary lifestyle, which is a disease of the venous accompanied by sores on the skin, difficulty with daily physical function, such as bathing, dressing and walking; or ongoing symptoms of depression gained more weight, suggesting they may warrant enhanced monitoring.

“This may sound like common sense,” said King. “But several behaviours and characteristics that clinicians hypothesized to matter were not related to weight regain. For example, while frequency of fast food consumption was associated with greater weight regain, frequency of meals or eating at restaurants was not.”

Wendy King, Anita Coucoulas

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**Sleeve gastrectomy: A simple operation that is not that simple**

Vertical resection of the stomach to reduce the gastric reservoir in the bilipancreatic diversion operation (BPD) was introduced by Hess in order to decrease the incidence of marginal ulcer in that operation and by maintaining the pylorus to enhance the restrictive effect of the operation and also decrease the incidence of dumping. The volume of the gastric pouch created by Hess was 250-300 ml akin to the size of the transverse fundal pouch in the Scopinaro procedure. This pouch size was to reduce the caloric intake that resulted in the initial weight loss of the BPD in early studies documented by Hess that led to minimal weight regain and the thinking before the discovery of the role of chyle.

Since the BPD was rarely done because of its complications, the problem of the pouch (caloric malnutrition), the incidence of frequent stools and the foul body odor and flatus after the operation, similarly the BPD-DS modification by Hess was rarely done and abandoned because of the same reasons. However, the reports from surgeons who did either the BPD or BPD-DS established that these operations are the most effective for weight loss, weight maintenance and complications.

Creation of this vertical gastrectomy component of the bilipancreatic diversion with the switch (BPD-DS) was introduced in the second part of the nineties patients (Selvam et al. 1990) and the concept of a controlled vertical gastric transection as stage 1 followed by the stage 2 duoendectomy and the Roux-Y duodenoilestomy. The thinking by the vertical gastrectomy with a large pouch of weight loss that will make the second stage operation easier particularly in super obese patients. The seminal observation that some of the patients with the pouch were weight and in the short to medium period maintained the weight loss after the stage one vertical gastrectomy gave birth to the sleeve gastrectomy as a stand-alone operation. Unfortunately, this operation received the endorsement of the EASBS with minimal studies and scoring.

It was not long after many surgeons started doing the sleeve as a standalone operation using the large pouch of the BPD-DS that it became apparent that there was a high incidence of weight regain after an initial weight loss. Dilatation of the sleeve pouch was the most common cause for this problem. Intuitively and patient safety the surgeons thought the pouch did not have a natural limit and the patients with the pouch was a honeymoon period when no matter what the surgeon did the patient would not lose a certain amount of weight. This reason is very clear if a lifelong disease but the follow up after bariatric metabolic procedures beyond two years is very poor. I foresee a time in the not to far future when we will see the demise of the sleeve gastrectomy if we do not objectively address the shortcomings of this operation.

This is not to be condoning malpractice, retrospective studies on the sleeve gastrectomy like the French multi-center study by Robert Maud and his team on the OAGB. All patients have preoperative endoscopies and the size of the sleeve standardized. Okash and Bhandari and many others have published You tube videos on standardized the size of the sleeve so as it is not made to narrow. All patients will have routine surveillance endoscopies. With this protocol we can give the sleeve gastrectomy its rightful place in the armamentarium of bariatric metabolic procedures. Sleeve gastrectomy is a simple operation that is not that simple.

The article was authored by Mathew A. L. (MA) PhD · MD · NCDS, FICS, FRCN, FRCSI · Clinical Director, Associate Professor and the Director of Clinical Research and Training at Mohan Bariatric and Robotic Surgery Center in India, India. He was the Medical Director and Chief Surgeon at the Center for Surgical treatment of Obesity in Los Angeles from 1999 to 2016. He is a past President of the Council of Bariatric Surgeons of India (CBSI). He is the President of the IFSO Foundation, past President of IOFS and Past Chair of the Board of Trustees of IFSO.

Self-harm and suicidal ideation required throughout post-op care

Bariatric surgery candidates should be screened for their potential to self-harm and/or commit suicide before surgery and throughout long-term post-operative care, according to researchers from the US. It is known that self-harm/suicidal ideation and self-harm/suicidal behaviour are rare among those who have undergone bariatric surgery than the general population. Furthermore, while psychosocial factors such as surgical suicide ideation are at increased risk for post-surgery ideation and this latest research found that although suicidal ideation slightly decreased at year-one post-surgery, it returned to pre-surgery levels at year five.

In the paper, *A Longitudinal Examination of Suicide-Related Thoughts and Behaviors among Bariatric Surgery Patients*, published in *SCARE*, the investigators sought to compare the prevalence of self-harm/suicidal ideation over time and identify pre-surgery risk factors for post-surgery self-harm/suicidal ideation. Using data from the Longitudinal Assessment of Bariatric Surgery-3 (LABS-3) study, 2,458 adults with severe obesity underwent bariatric surgery between March 2008 and July 2009. Self-reported history of suicidality was assessed retrospectively via the Suicide Behavior Questionnaire-Revised (SBQ-R). Self-reported history of lifetime suicidal ideation was assessed prospectively via the Beck Depression Inventory-1 (BDI-1).

**Outcomes**

The SBQ-R was completed by 1,540 participants and 2,237 completed the BDI-1 pre- and post-surgery. Over 75% of participants were female, with a median age of 46 years (range 21-72). Approximately one-fourth of participants (937,554) reported a pre-surgery history of suicidal thoughts and/or behaviour (SBQ-R). The prevalence of lifetime suicidal ideation (BDI-1) was 5.7% (95% CI, 3.7-6.8) pre-surgery and 2.8% (95% CI, 1.5-4.5) post-surgery.

Prevalence increased over time post-surgery to 6.6% (95% CI, 4.8-8.6) at year-five (p<0.01) but was not significantly different pre-surgery (p=0.12). A large cohort of adults with severe ore obesity undergoing bariatric surgery had a prevalence of self-harm/suicidal ideation that may have decreased in the first post-operative year but increased significantly after that time. Screening for self-harm/suicidal ideation is warranted throughout long-term post-operative care, “the authors conclude.

Several risk factors were identified that may help with enhancing monitoring.

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FICS, FACN, a clinical professor of surgery at SAIMS JIO University Director and Chief Surgeon at the Center for Surgical treatment of Obesity in Los Angeles from 1999 to 2016. He is a past President of the Council of Bariatric Surgeons of India (CBSI). He is the President of the IFSO Foundation, past President of IOFS and Past Chair of the Board of Trustees of IFSO.
Gastric bypass surgery causes type 2 diabetes to go into remission in most patients

The authors also found that the risk of microvascular complications was 47% lower in the RYGB group than in the control population, with large decreases in the risk of diabetic retinopathy (48%) and diabetic kidney disease (46%) in the risk of diabetic retinopathy (48%) and diabetic kidney disease (46%). Lowering drug use along with HbA1c <48 mmol/mol (<6.5%), or metformin monotherapy with HbA1c <42 mmol/mol (<6.0%). Various medical registries were used to obtain data about postoperative complications, and relapse was defined as HbA1c rising to 48 mmol/mol or above, or the patient being prescribed glucose-lowering drugs following an initial discontinuation. The health of participants was followed until the end of the study period (December 2015), except in cases where they had left North Denmark or died prior to that date. During the first six months after the operation, 66% of RYGB patients had their diabetes go into remission. This rose to 74% at 6-12 months and remained above 75% for every six-month period in the following four years. The probability of those who were in remission within the first year of follow up, 6%, 13%, 18%, and 27% had undergone relapse at two, three, four and five years, respectively, thus 75% of those in remission after one year were still free of the disease five years after their operation.

The authors note that the strongest predictor of a patient not going into remission was if they required insulin to control their disease. This resulted in a 43% lower remission rate than the average for the cohort. Other factors included age with participants aged 60 or over having a 17% lower remission rate than those under 40, as well as a lower average starting HbA1c level (48 vs 57 mmol/mol). The remission group also had a lower average duration of living with the disease at 2-6 years, compared with 7-9 years for the non-remission group.

During the follow-up period of the study (median 5.3 years of follow-up), the authors also found that the risk of microvascular complications was 47% lower in the RYGB group than in the control population, with large decreases in the risk of diabetic retinopathy (48%) and diabetic kidney disease (46%). There was a smaller impact on the risk of macrovascular events, which were 24% lower among patients who had received bariatric surgery - however, this difference was not large enough to achieve statistical significance.

Readmission due to surgical complications during the 30 days after RYGB surgery occurred in 7.3% of patients, which the authors point out is “higher than we previously reported among RYGB-operated individuals overall (3.5%), most likely because type 2 diabetes per se disposed to surgical complications.” They add, however, that surgical short-term mortality was very low (under 0.1%).

“The findings from this study add to the growing body of evidence on effects of bariatric surgery, specifying that RYGB does cause remission of type 2 diabetes and is associated with a reduced risk of microvascular, and possibly macrovascular complications...Predictors of remission success seem to be very consistent in randomised controlled trials, studies of selected cohorts and population-based studies,” the authors conclude. “On the other hand, there is a substantial risk of relapsing into type 2 diabetes, which should be accounted for when advising patients and planning post-surgery care.”
Bariatric embolization is not proposed as a replacement for bariatric surgery, but as a supplemental method to facilitate weight loss with lifestyle modification.

Although bariatric embolization is unlikely to promote weight loss as effectively as bariatric surgery, it is at least as effective as, or perhaps more effective than, several medications (ie, liraglutide, orlistat, lorcaserin), which are available for lifestyle modification. Bariatric embolization shows promise as a treatment for obesity (BEAT Obesity) trial, who assessed the procedure’s effects (28), according to researchers from the Bariatric Embolization of Arteries for Treatment of Obesity (BEAT Obesity) study. "This is a great step forward for this individualised disease that requires a multifaceted approach to the treatment of obesity, a disease increasingly understood to differ from patient to patient. "The reality is that obesity itself is an individualised condition that requires individualised treatments," explained Weiss. "It’s a day when there will be a multifaceted obesity clinic where six or seven different practitioners get together to treat the patient. This is already happening at some sites, but they are rare and they need to be more widespread, like multidisciplinary cancer centers." show that the retracted bariatric embolization is not proposed as a replacement for bariatric surgery, but as a supplemental method to facilitate weight loss with lifestyle modification. "Bariatric embolization will be well tolerated and promotes clinically relevant weight loss in adults with severe obesity," the authors concluded. "It may provide needed assistance to patients who are struggling to succeed in lifestyle modification-based weight loss programmes."

To access this paper, please visit: https://pubmed.ncbi.nlm.nih.gov/31019823/
European Obesity Day to be held on 18 May 2019

European Obesity Day, held each year to draw attention to Europe’s growing obesity epidemic and the need for better prevention and treatment, is to be held this year on Saturday 18 May. Individuals, healthcare providers and organisations throughout Europe will be taking part with events ranging from providing free health check-ups and healthy eating advice, to holding open days at hospitals and treatment centres, walks and runs to encourage exercise, and information and training workshops for healthcare professionals.

The campaign is an initiative of the European Association for the Study of Obesity (EASO), Europe’s leading organisation responsible for research into obesity. Since European Obesity Day (EOD) was first held in 2010, it has continued to gain awareness and support across 31 European countries.

In the spirit of the tagline, Tackling Obesity, Together, people from all walks of life are being encouraged to participate to create greater awareness and understanding of obesity, which is predicted to affect more than one half of the European population by 2030.

According to World Health Organization, obesity is one of the greatest public health challenges of the 21st century as its prevalence has tripled in many countries in Europe since the 1980s.

In particular, EASO wants to draw attention to the impact that obesity has on society and the economy, and the huge benefits to be gained from prevention and treatment.

Among EASO’s European initiatives will be a major policy conference in Brussels on 16 May to which EU Member State authorities have been invited to share and prioritise best practices.

It will also be attended by representatives from various European institutions and will include keynote speakers and panellists from the World Health Organization, OECD, and the European Commission.

Further details of how to support European Obesity Day and where to find more information on obesity and obesity treatment, please visit: www.europeanobesityday.eu

For further details and registration for the policy conference, please visit: https://www.europeanobesityday.eu/easo-annual-policy-conference/easo-policy-conference-2019/

Little difference in access to surgery in Sweden based on socioeconomic status

The prevalence of individuals with low income, low education, no employment and who were single were highest in the BMI30–39 and >40 groups.

HERE is very little difference in access to bariatric surgery in Sweden with regards to socioeconomic status among patients with BMI>40, according to researchers from Lund University, Lund, Sweden. Although some differences were found in favour of those with a low socioeconomic status, the investigators concluded that this “indicates that the Swedish healthcare system seems to have achieved equal access to health care for bariatric surgery.” The authors noted that this is the first nationwide study that considers socioeconomic characteristics in relation to rates of bariatric surgery, including levels of BMI.

The paper, “Socioeconomic factors, body mass index and bariatric surgery: a Swedish nationwide cohort study,” published in BMC Public Health, investigated if there is an association between socioeconomic factors and bariatric surgery by taking BMI into account. The researchers collected data from 2005 to 2012 from the Swedish Inpatient Register and included 7,433 women and 1,961 men who underwent bariatric surgery.

The researchers calculated family income and classified patients as low income, middle income (50% of the study population) and high income – the researchers also included educational attainment and employment status. Patients were subsequently divided into the four BMI groups according to the WHO classification.

Outcomes

Both women and men, the prevalence of individuals with high income, high education, employment and who were married/cohabiting was highest in the group with BMI>40. In contrast, the prevalence of individuals with low income, low education, no employment and who were single were highest in the BMI30–39 and >40 groups.

For women, the HRs for bariatric surgery were higher for low and middle levels of income and education compared to high income and educational levels. The HRs were also higher for those who were employed and/or were married/cohabiting. After controlling for the other individual factors, the highest HR for bariatric surgery was found among those with a high income.

Low and middle levels of education were strongly associated with bariatric surgery for a middle educational level. As in women, the highest HRs were found in those who were employed and/or were married/cohabiting. In those with BMI>40, none of the socioeconomic variables were associated with bariatric surgery, except for middle educational level in women. In those with BMI30–39, women had higher HRs for low and middle family income and education. Those women who were single had a lower HR than those who were married/cohabiting. For men, the HR was significantly higher for low and middle education. The effect of BMI on surgery for men was modified by marital status, those who were married had a higher rate of surgery.

The present nationwide study shows differences between socioeconomic groups and rates of bariatric surgery, favouring those with a low socioeconomic status,” the authors concluded. “However, socioeconomic differences disappeared in those individuals with a BMI>40, which indicates that severe obesity rules out socioeconomic differences in bariatric surgery rates. The Swedish healthcare system seems to have achieved its goal of equal health care for the entire population regarding bariatric surgery.”

To access this paper, please visit: https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-6585-8
Endoscopic sleeve gastroplasty well-tolerated, safe and effective in 1,000 patients

Endoscopic sleeve gastroplasty (ESG) appears to be well-tolerated, safe and effective, according to a report from Children’s National, which included 1,000 consecutive patients. The study found that the procedure resulted in significant weight loss during the first 18 months without mortality or significant morbidity, although a minority of patients required revision or reversion during the first year.

The paper, ‘Short-term outcomes of endoscopic sleeve gastroplasty in 1,000 consecutive patients’, published in the journal Gastrointestinal Endoscopy, reported on the safety and short-term efficacy of ESG with regards to weight loss, morbidity, revisions and co-morbidity resolution, during the first 18 months after primary ESG.

ESG is an endoscopic minimally invasive weight loss procedure based on full-thickness endoscopic suturing using Apollo Endosurgery’s OverStitch device. In the ESG procedure, a series of sutures are placed through the gastric wall reducing the stomach volume by 80%, creating a restrictive endoscopic sleeve. The result allows a patient to consume less food and remain satiated longer.

Key data reported from the 1,000 patients who underwent the ESG procedure included:

- Mean age was 34.4±9.5 years, and mean BMI 33.3±4.5

Mean % total weight loss at 18 months was 14.8 ± 8.5%

Mean % total weight loss at 18 months was 14.8 ± 8.5%

Significant impact to obesity related comorbidities occurred by month three:

- 15 of 17 cases of type 2 diabetes were in complete remission
- All 28 cases of hypertension were in complete remission
- 18 of 32 cases of dyslipidemia were in complete remission
- 24 of 45 patients were admitted to the hospital due to post operative complaints. No patient required an emergency airway intervention and there were no mortalities.

‘Our experience has been that patients who have the ESG are very appealing and for our practice it is now an established option for our patients. In these first 1,000 consecutive patients that we treated with Endoscopic Sleeve Gastroplasty, patients experienced a 100% remission for hypertension related comorbidities, a 70% remission rate for type 2 diabetes with the remaining 30% showing significant improvement,’ said Professor Aayed AlQahtani, Professor of Surgery at King Khalid University Hospital and Director of Obesity Chair at King Saud University. “We confirmed that ESG is a safe, well-tolerated, and a trend to show effective patient outcomes, we also achieved 64.7% excess weight loss at 18 months follow-up.”

LINX® Reflux System reduces costs vs. laparoscopic Nissen fundoplication

TREATMENT with the LINX® Reflex Management System reduces costs vs. the more invasive anti-reflux surgery, more significantly than laparoscopic Nissen fundoplication (LNF), a more invasive anti-reflux surgery, and more than offsets the slightly higher cost of the procedure, according to a study presented at the 2019 Annual Meeting of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES 2019).

The research was partially funded by Ethicon, in collaboration with Highmark Health’s VITAL Innovation Platform—a test-and-learn environment for health innovations.

“The higher initial cost of a LINX® procedure compared to a Nissen fundoplication is perceived as a drawback by insurers, who made getting insurance approval challenging,” said lead researcher Dr Blair Jobe, Director, Esophageal and Lung Institute at Allegheny Health Network. “This study suggests that perception may be short-sighted, that insurer-reimbursement equations can provide better care for their GERD patients at a similar cost to laparoscopic Nissen fundoplication when you factor in the greater reductions in medical costs after the procedure.”

LINX is a flexible ring of small magnets surrounds the lower part of the oesophagus, the body’s natural barrier to reflux, during a minimally invasive procedure. The magnetic ring expands when a patient swallows to allow food to enter the stomach but then contracts to prevent stomach contents from flowing back into the oesophagus and causing GERD, a condition that affects about 20 percent of people in the US. In LNF, a surgeon wraps a portion of the upper stomach (fundus) around the lower part of the oesophagus to help prevent acid from moving up into the oesophagus.

The prospective observational study was performed at Highmark Health’s Allegheny Health Network, a health system serving western Pennsylvania, in conjunction with Highmark, the region’s largest health insurance company. Researchers compared the total procedural cost and the disease-related and overall medical claim costs 12 months before and 12 months after a LINX procedure (180 patients) or LNF (1,131 patients).

The study found the mean PMPM (per member per month) medical reimbursement claims related to upper gastrointestinal (GI) disease one year after LINX dropped by 66 percent (US$935 to US$314) compared to 46 percent (US$233 to US$126) after LNF.

Overall PMPM medical reimbursement claims decreased by 10.7 percent for LINX patients and only by 1.4 percent for LNF patients. Specific reimbursements for proton pump inhibitors (PPIs), acid suppression drugs for gastrointestinal reflux disease (GERD), dropped by 95 percent after LINX and by 90 percent after LNF.

The median cost of a LINX procedure was US$1,532 (mean US$1,795) and US$1,588 (mean US$1,661) for LNF, a difference that researchers say is offset or surpassed by a lower cost of care for the insurer in the one year following surgery.

“This study demonstrated that the LINX System was cost effective and should be more widely covered by insurers,” said Tom O’Brien, President, Worldwide Endomechanical, Ethicon. “Ethicon will continue to help support studies that enable clinicians, patients, insurers and health systems to make the best possible decisions about which treatments work best for which patients and at what cost.”

Previous studies on LINX showed 88 percent of patients reported that bothersome heartburn had been eliminated five years after treatment, 85 percent were free from dependence on PPIs, 85 percent were free from dependence on acid suppression drugs, and 85 percent were free from dependence on antacids.

“This study demonstrated that the LINX System was cost effective and should be more widely covered by insurers,” said Tom O’Brien, President, Worldwide Endomechanical, Ethicon. “Ethicon will continue to help support studies that enable clinicians, patients, insurers and health systems to make the best possible decisions about which treatments work best for which patients and at what cost.”

Cognitive functioning not a predictor of weight-loss for adolescents

Young people with cognitive impairments and developmental disabilities (CI/DD), including Down syndrome, have similar weight-loss trajectories to those with typical cognitive function after bariatric surgery, according to a study by psychologists at Children’s National Hospital in Washington DC. Though young people with intellectual disabilities or cognitive impairment have greater rates of obesity and other comorbidities that impact their health and well-being, bariatric care providers are often reluctant to discuss or refer these patients for bariatric surgery due to concerns about their ability to consent to both the surgery and the ongoing diet and lifestyle changes after surgery.

The study, ‘Sleeve Gastrectomy for Youth With Cognitive Impairment or Developmental Disability’, published in the Journal of Surgical Innovation, is the first study to report post-surgical outcomes for this subgroup of adolescent bariatric surgery patients. The authors recommend making the determination on a case-by-case basis.

This study adds to the body of research that is helping to create standard criteria for bariatric surgery in adolescents and teenagers.

A 3-year longitudinal study that was designed to challenge the assertion that an adolescent who is cognitively impaired understands what it means to have a clinical psychologist at Children’s National and the study’s first author. “A very important determinant of post-surgical success for any young candidate, however, is a support structure to help them with weight-loss surgery requirements. Often, we see that adolescents with lower cognitive function already have a well-established support system in place to assist them with other care needs, that can easily adapt to providing structure and follow through after weight-loss surgery, too.”

In the study, the authors reviewed outcomes for 64 adolescents ages 13 to 24 years old with an average BMI of 53.2, all of whom were part of the bariatric surgery programme at Children’s National Health System. The participants were diagnosed with cognitive impairment or intellectual disability via standardised cognitive assessments as part of a pre-operative psychological evaluation or through previous diagnos.

They reported that there were no significant differences between adolescents with or without CI/DD in terms of preoperative BMI, age, and sex. Furthermore, having CI/DD did not significantly impact weight loss or weight loss trajectory in the two years after surgery, although modelling revealed a trend among individuals with CI/DD losing more weight over time. Similarly, intelligence scores did not predict weight loss after surgery.

“Bariatric surgery may be a helpful tool for adolescents with severe obesity and CI/DD,“ the researchers concluded. “They could benefit from the surgery as much as those with typical development and having CI/DD should not be used as a criterion to deny surgery. Continuing research with this population can be used to determine long-term outcomes in addition to defining best practices."

“We’re happy to contribute evidence that can help families and care providers make informed health decisions for young people with intellectual disabilities or cognitive impairments. So many families are hoping to make sure that their children, despite disabilities, can be as healthy as possible in the long term,” said Dr Eleanor Mackey, who is also a clinical psychologist at Children’s National and served as the study’s senior author. “Though the sample size is small, it does give credence to the idea that for many adolescents and teenagers, weight loss surgery may be a realizable option regardless of pre-existing conditions such as intellectual ability or cognitive function.”

Children’s National is one of only a few children’s hospitals with accreditation from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) of the American College of Surgeons and the American Society for Metabolic and Bariatric Surgery to offer bariatric surgery for adolescents with severe obesity. The extraordinary diversity of the patient population in Washington DC, including high rates of young people with obesity, allows the team to collect more comprehensive information which is comparable to real-world interventions across subgroups, including cognitive impairment or developmental disabilities, than nearly every other centre in the United States.
Bariatric fellowships reduce the learning curve for LRYGB

There were no significant difference between the two groups for length of stay, total complications, readmissions or reoperations.

BARIATRIC fellowships reduce the learning curve for laparoscopic Roux-en-Y gastric bypass surgery (LRYGB) and helps to achieve excellent outcomes in the first and over seven years of independent practice, according to a study by researchers at the Department of Upper Gastrointestinal and Bariatric Surgery, Homerton University Hospital, London, UK. The researchers noted that to their knowledge, this represents the first such study in the literature.

The paper, ‘Bariatric fellowship positively influences early outcomes for laparoscopic Roux-en-Y gastric bypass surgery over seven years of independent practice’, published in the Annals of the Royal College of Surgery of England, examined the long-term effect of fellowship by comparing the 30-day outcomes of LRYGB between the first year of a surgeon’s independent practice with the subsequent six years. The Lead researcher had undergone a bariatric fellowship in a reputed bariatric centre for a year prior to starting independent practice and also published previously about impact of fellowship on learning curve after one year of independent practice.

For the study, the investigators reviewed the data from a prospective database of patients undergoing primary LRYGB under a single surgeon from March 2010 until February 2017. Patients were divided into two groups: first year (<1 year) of practice and the subsequent six years. The overall complication rate was 1.35% in the ≥1 year group and 5.85% in the 25 year group (p=0.20). There were no conversions to open surgery, anastomotic leaks or inpatient mortality in either of the groups within 30 days of surgery.

With regards to length of stay, there were no differences between the groups (<1 year vs ≥1 year) or reoperations (p=0.20). readmissions (p=1.00) or complications (p=0.20). There were no significant difference between the two groups. There was one death in the <1 year group due to a drug overdose in the community, which was unrelated to surgery. One patient (s.5% was readmitted within 30 days in the <1 year group compared with 4.4% in the ≥1 year group (p=0.04). There was one (0.35%) reoperation within 30 days in the <1 year group compared with four reoperations (1.95%) in the ≥1 year group (p=0.06).

‘Bariatric fellowship reduces the learning curve for LRYGB and also helps in excellent outcomes both in the first and subsequent years of independent practice,’ the authors concluded. The ‘higher risk profile of the ≥1 year group did not equal to an increase in postoperative complications, suggesting that experience may play a role in handling complex cases without significantly increasing the complications.')

Organised through Bariatric and Metabolic Surgery UK

SDM Programme highlights:
- Lectures, debates and panel discussions from world-renowned UK and international faculty
- BARIATlink Live with Dr Bruno Dillemans
- Dedicated parallel AHP sessions

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For more information and to register, please visit: www.libss.org (going live May 2019)
Studies show there is a major link between personality traits and personal body image, but the relationship between personality and attitudes toward others’ bodies has gone largely unexplored.

Excess body weight responsible for four percent of cancers

Policies, economic systems, and marketing practices that promote the consumption of energy-dense, nutrient-poor food, changing behavioural patterns that couple high total energy intake with insufficient physical activity, and human-built environments that amplify these factors are driving a worldwide rise in excess body weight, according to a report.

American Cancer Society investigators, at the American Cancer Society, state that excess body weight accounted for approximately 622,600 deaths worldwide in 2012, a figure that will undoubtedly rise in the coming decades.

The review, co-authored by investigators at the American Cancer Society, Imperial College London, and the Harvard TH Chan School of Public Health, presents global and regional patterns in excess body weight, as well as factors that drive the problem and possible solutions that might address it.

Excess body weight, estimated to be 1.9 billion adults worldwide, is associated with a wide range of health risks and a number of non-communicable diseases that can influence cancer development.

The prevalence of excess body weight has increased worldwide since the 1980s. In 2016, 25% of adults and 18% of children had excess body weight, equating to almost 1.1 billion adults and 340 million children around the globe.

The prevalence of excess body weight is higher in most countries across all population groups. Some of the steepest increases are in low- and middle-income countries, likely the result of the spread of the "Western lifestyle," consisting of energy-dense, nutrient-poor foods alongside reduced physical activity. In 2015, an estimated 4 million children died attributable to excess body weight.

High-income Asian Pacific countries account for approximately 34% of all cases worldwide, with the proportion varying from less than 1% in low-income countries to 7% to 8% in some high-income Western countries, the Middle East and Northern African countries.

Overweight and obesity have been linked to an increased risk of 13 cancers of the breast (postmenopausal), colon and rectum (colonrectal), corpus uteri, oesophagus (adenocarcinoma), gallbladder, kidney, liver, ovary, pancreas, stomach (cardia) and thyroid, as well as meningioma and multiple myeloma. More recently, there is epidemiologic evidence that excess body weight is a probable cause of advanced prostate cancer as well as cancers of the mouth, pharynx and larynx. National wealth is the most apparent systematic driver of population obesity. The economic transition to a wealthier lifestyle brings with it an environment that precipitates obesity. Each US$1,000 increase in average national income is associated with a 4.1 increase in body mass index across adults. However, prosperity is not always correlated with excess body weight; obesity prevalence is quite low in high-income Asian Pacific countries (range, 4%-7%), which is likely a result of adherence to traditional dietary habits, which are conducive to lower calorie consumption, and an active transportation system that usually entails walking as part of daily activity. Meanwhile, the prevalence of obesity is very high in low-income and lower-middle income countries, such as some Pacific Island nations (range, 40%-65%) and Egypt (45% among women and 24% among men).

Halting the rise in obesity is one of the World Health Organization (WHO)'s nine 2030 targets to address the growing global burden of noncommunicable diseases, including cancer. While the current pace of increasing and existing challenges makes achieving this goal appear unlikely, the WHO says high-priority strategies that should be adopted by governments, industries and civil societies include: population-wide, policy-led interventions to restrict the production, distribution and marketing of unhealthy foods and changes in the built environment to promote adequate levels of physical activity. These interventions include eliminating trans-fat from the developed world's banishment to its food chain, reducing sugar consumption through effective taxation on sugar-sweetened beverages; implementing subsidies to increase the intake of fruits and vegetables; limiting portion and package size to reduce energy intake and the risk of excess body weight; ensuring that urban design incorporates the core elements of residential density, green areas and street networks that include sidewalks, easy access to a diversity of destinations, and access to public transport; and providing convenient and safe access to quality public open space and adequate infrastructure to support walking and cycling.

There is emerging consensus on opportunities for obesity control through the multi-sectoral coordinated implementation of core policy actions to promote an environment conducive to a healthy diet and active living, the authors write. The rapid increase in both the prevalence of excess body weight and the associated cancer burden highlights the need for a refocused effort on identifying, implementing, and evaluating interventions to prevent and control excess body weight.

Excess body weight could trigger treatment gap for adolescents with obesity

Medications could fill treatment gap for adolescents with obesity

Excess body weight is an emerging field, and there are no official guidelines to help clinicians manage patients with conditions that were originally introduced in the adult population.

While there has been great interest in the relationship between personality traits and personal body image, there has been limited research on the relationship between personality and excess body weight. While there are exceptions, there is evidence that people with personality traits of neuroticism and conscientiousness are more prone to developing excess body weight.

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How the brain influences our eating habits and weight gain

Two separate teams of researchers have identified how genes involved in neural development can affect body weight and how brain cells involved in memory play an important role after a meal in reducing future eating behaviour. The first team - led by investigators at the University of Cambridge and Children's Hospital Los Angeles (CHLA) have pinpointed a set of molecules that wire the body weight centre of the brain.

In a study, "Human Semaphorin y Variants Link Melanocortin Circuit Development and Energy Balance", published in the journal Cell, Dr Sadaf Farooqi of the University of Cambridge and CHLA's Sebastien Bouret, PhD led research teams to uncover key genes that guide the process of brain development.

"We know that the brain, in particular an area called the hypothalamus, has a very important role in the regulation of food intake and blood sugar," explained Bouret, who is also an associate professor of pediatrics at the Keck School of Medicine of USC. Researchers have focused on the hypothalamus for years in an effort to study the epidemic of obesity, which affects nearly 14 million children and adolescents in the United States. "What we don't yet understand is how these circuits in the hypothalamus are being organized. We want to know how the brain puts itself together and what exactly governs that process."

Understanding this is key because circuits must be established properly in order for the brain to ultimately perform complex functions like maintaining proper weight.

Bouret's laboratory investigated how this precise wiring is achieved. Understanding how brain cells in the hypothalamus form these specific, complex connections - and how this process can be adversely affected - could provide insight into the development of childhood obesity.

Bouret studied a group of molecules called semaphorins, which are found in abundance in the developing hypothalamus. Brain cells release semaphorins to communicate with other brain cells. These messages act as a sort of road map, guiding cells towards or away from other cells.

Dr Sophie Crozier, who led the study in Bouret's lab, blocked semaphorin signaling in cells of the hypothalamus. She discovered that brain cells no longer grew the way they were supposed to, showing that semaphorins are important in maintaining healthy body weight.

"We have now discovered the genes that establish the precise neural connections that form these circuits," added Dr Agatha van der Klaauw, who led the study in Farooqi's lab and is co-first author on the paper. "This work provides new insights into the development of hypothalamic circuits that regulate appetite and metabolism."

This multifaceted study reveals a much clearer picture of what occurs in the developing brain. Semaphorin signalling appears to shape the physical architecture of the brain and influence circuitry governing body weight.

Memory

In the second study, researchers led by Georgia State University, found that brain cells involved in memory play an important role after a meal in reducing future eating behaviour, a finding that could be key in understanding and fighting obesity.

The study, "Postmeal optogenetic inhibition of dorsal or ventral hippocampal pyramidal neurons increases future intake", suggests neurons in the hippocampus, a brain region that is vital for personal memories, inhibit future eating behaviour by consolidating the memory of the preceding meal. The findings are published in the journal eNeuro.

"Memories of recently eaten foods can serve as a powerful mechanism for controlling eating behaviour because they provide you with a record of your recent intake that likely outranks most of the hormonal and brain signals generated by your meal," said Dr Marie Parent, associate director of the Neuroscience Institute and professor of neuroscience and psychology at Georgia State. "But surprisingly, the brain regions that allow memory to control future eating behaviour are largely unknown."

Hippocampal cells receive signals about hunger status and are connected to other brain areas that are important for starting and stopping eating. The researchers set out to determine if disrupting hippocampal function after a meal is eaten, when the memory of the meal is being stabilized, could promote eating later when these cells are functioning normally.

They tested this prediction using an advanced method called optogenetics that uses light to control individual cells. Using this technique to inhibit hippocampal cells after rats ate a meal caused the animals to eat their next meal sooner and caused them to eat almost twice as much food during that next meal, even though the cells were no longer inhibited while the animals ate their next meal. This effect was observed regardless of whether the rats were offered rodent chow, a sugar solution or water sweetened with saccharin.

The researchers found it interesting that rats would eat more saccharin after they interfered with their hippocampal function because this noncaloric sweetener produces very few gastrointestinal chemical signals generated by food. They concluded the effect they saw was most likely explained by an effect on memory consolidation, rather than by an impaired ability to process gastrointestinal messages.

The findings have significant implications for understanding the causes of obesity and the ways to treat it. This research supports the idea that techniques that promote hippocampal-dependent memories of what, when and how much one eats could prove to be promising strategies for reducing eating and promoting weight loss.

To access the first study, please visit: https://tinyurl.com/yxkejkrt
To access the second study, please visit: (login maybe required): https://tinyurl.com/yy7vealaw
**Highlights from ENDO 2019**

The following presentations are some of the highlights from ENDO 2019, the Endocrine Society’s Annual Meeting in New Orleans, LA.

**Patients with obesity can decrease frequency of migraines by losing weight**

OR migraine sufferers with obesity, losing weight can decrease headaches and improve quality of life, according to researchers from Italy and the United States. The results of their meta-analysis, SAT-106. Effects of Bariatric and Non-surgical Weight Loss on Headache in Obesity. A Systematic Review and Meta-Analysis, were presented at ENDO 2019, the Endocrine Society’s annual meeting in New Orleans, LA.

"If you suffer from migraine headaches and are obese, losing weight will ameliorate the quality of your family and social life as well as your work and school productivity," said lead study author Dr. Claudio Pagano, an associate professor of internal medicine at the University of Padova in Padova, Italy. "Your overall quality of life will greatly improve. Weight loss in adults and children with obesity greatly improves migraine headache by improving all the main features that worsen migraineurs’ quality of life. When people lose weight, the number of days per month with migraine decreases, as does pain severity and headache attack duration."

To investigate the effects of weight loss achieved through bariatric surgery or behavioural intervention on migraine frequency and severity, Pagano and colleagues reviewed the standard online medical research databases for studies that considered pain intensity, duration, frequency, and severity of migraine headaches. A total of 473 patients in ten studies met the researchers’ inclusion criteria, they found that weight loss was linked with significant reductions in headache frequency, pain intensity and disability (all p<0.001), as well as attack duration (p<0.01).

Migraine improvement was not linked with either degree of obesity at baseline or amount of weight loss with Gelesis100. "We have already demonstrated preclinical data suggesting that the company’s proprietary hydrogel formulation, Gel-B (G5300), repairs the seal between intestinal epithelial cells and its earlier prototypes have been studied in more than 450 patients at high risk of diabetes or diabetes-related complications," said Dr. Scott Kahan, director of the National Center for Weight and Wellness and a physician specializing in obesity.

In a separate analysis found that patients with high insulin resistance – a significant driver of diabetes – had positive metabolic responses to treatment with Gelesis100. Insulin resistance was measured by homeostatic model assessment – insulin resistance (HOMA-IR). Patients with high HOMA-IR at the start of the clinical trial (mean baseline HOMA-IR=5.9) had a statistically significant reduction in HOMA-IR over the six-month treatment period (-2.3 +/- 9.5, p=0.011). Importantly this reduction was observed both in patients that were weight-loss responders (with 5% or greater weight loss) and also in non-weight-loss responders. The HOMA-IR decrease in the subgroup overall was driven by a significant reduction in fasting insulin serum.

The GLOW study was designed to assess change in body weight in adults with overweight or obesity after six months of treatment with Gelesis100. Topline results of the study were announced in September 2017. The study had two predefined co-primary endpoints: at least 3% of patients taking Gelesis100 achieving ≥ 5% weight loss (categorical endpoint) and placebo adjusted weight loss to be assessed in two ways (superiority margin of 5% and also non-inferiority). The study met and exceeded the pre-defined categorical endpoint, with 55% of adults in the treatment group achieving weight loss of 5% or greater. As previously announced, the study did not meet the 5% super-superiority endpoint but demonstrated superiority of the Gelesis100 treatment over the placebo group (1.6% vs. -4.4%, P<0.007). Gelesis100-treated individuals had twice the odds of achieving at least 5% and at least 10% weight loss vs. placebo (adjusted odds ratio [OR]; 2.0, 95% confidence interval 1.3–3.0, P<0.007; adjusted OR, 2.1, P=0.017, respectively).

The overall incidence of adverse events in the Gelesis100 treatment group was no different than placebo (7% in both groups). The most common AEs were gastrointestinal disorders (186 AEs in 96 [47%] subjects in the Gelesis100 arm, compared to 134 events in 73 [34%] subjects receiving placebo), infections and infestations (49 events in 74 [33%] subjects with Gelesis100 and 101 events in 70 [35%] subjects with placebo), and musculoskeletal and connective tissue disorders (18 events in 12 [15%] subjects with Gelesis100 and 45 in 34 [16%] subjects with placebo). There were no serious adverse events (SAE) in the Gelesis100 treatment group, whereas there was one [1] SAE in the placebo treatment group.

Gelesis100 has been extensively evaluated in clinical studies and has been submitted to the US FDA for review.

**Restoring gut barrier function**

Gelesis also announced preclinical data suggesting that the company’s proprietary hydrogel formulation, Gel-B (G5300), restored gut barrier function after damage. The gut barrier plays a key role in blocking intestinal toxins from entering the circulation and triggering disease. Building on previous preclinical work, Gel-B was engineered to elicit the mechanical and physical properties required to optimize intestinal tissue healing. The hydrogel, which represents a pioneering advance in the emerging field of mechanobiology, is being studied in diseases affected by gut barrier dysfunction, such as inflammatory bowel disease.

The study, also presented at ENDO 2019, assessed the effect of Gel-B on gut barrier function in mice following a severe insult to the gut wall by administering 3% dextran sodium sulfate for five days. Mice were randomly divided into four doses of Gel-B (0.5–4 %), control or an active anti-p40 mAb group. The mice treated with Gel-B had fewer epithelial barrier breaks in distal colon samples and lower infiltration of an ingested fluorescent agent into their circulation.

"These preclinical data support the ability of Gel-B to reverse intestinal permeability in a DSS mouse model," said Dr Elaine Chiquette, Chief Scientific Officer of Gelesis. "We are continuing to advance our understanding of how our proprietary hydrogel platform technology can mechanically influence intestinal tissue repair."
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Highlights from ENDO 2019

Oral semaglutide shows superior reductions in HbA1c and weight vs sitagliptin

RAL oral semaglutide 7 mg and 14 mg demonstrated superior HbA1c and body weight reductions compared to Januvia (sitagliptin 100 mg), although non-inferiority for oral semaglutide 3 mg for HbA1c reductions at 26 weeks was not confirmed. The data from PIONEER 3 was a phase 3 trial investigating the efficacy and long-term safety of oral semaglutide 3 mg, 7 mg and 14 mg compared with sitagliptin 100 mg in adults with type 2 diabetes inadequately controlled with metformin, or with sulfonylurea, over 78 weeks. Oral semaglutide is an investigational once-daily glucagon-like peptide-1 (GLP-1) analogue in a pill.

“Many people living with type 2 diabetes do not meet their blood glucose targets despite many available oral antidiabetic therapies,” said Dr Dale Allison, PIONEER 3 investigator and director of the Diabetes Research Center, Waco, Texas. “The PIONEER 3 findings are encouraging, as oral semaglutide demonstrated a clinically significant improvement in HbA1c and this encouraging, as oral semaglutide demonstrated a reduction in HbA1c of 0.6% vs. 0.4% in the placebo group (p=0.002), 1.1% vs. 0.7% in the placebo group (p=0.006). There was no statistically significant difference with oral semaglutide 3 mg (TPA estimand) or 7 mg (TPA estimand).

Reductions in body weight from baseline, which was dose dependent, were statistically significant with oral semaglutide 3 mg, 7 mg and 14 mg at week 78 with reductions of 1.8 kg, 2.7 kg and 3.2 kg, respectively, compared to a 0.9 kg reduction with sitagliptin (all p<0.05). Both oral semaglutide 7 mg and 14 mg demonstrated superior body weight reductions with sitagliptin (both p<0.05). Oral semaglutide 3 mg demonstrated a reduction in HbA1c of 0.6%, non-inferiority vs. sitagliptin was not confirmed (p=0.09). Furthermore, all weight gain, oral semaglutide 3 mg and 14 mg demonstrated superior body weight reductions vs. sitagliptin at 0.4 kg and 3.2 kg, both vs. a 0.6 kg reduction for sitagliptin (p<0.05).

When applying the secondary statistical approach at week 26, oral semaglutide 7 mg and 14 mg demonstrated statistically significant reductions in body weight from baseline, as well as an autonomic 7.3% weight reduction with sitagliptin (both p<0.001). Reductions in HbA1c seen with oral semaglutide 3 mg were 0.5% and compared to reductions seen with sitagliptin, the difference is statistically significant in favour of all three oral semaglutide doses.

In a supportive secondary endpoint at week 78, oral semaglutide 14 mg demonstrated statistically significant reductions in body weight from baseline, as well as an autonomic 7.3% weight reduction with sitagliptin (both statistical approaches (1.1% vs. 0.7%; p<0.004, 1.1% vs. 0.4%; p<0.001). There was no statistically significant difference with oral semaglutide 3 mg (TPA estimand) or 7 mg (TPA estimand).

Automated drug delivery system combats post-bariatric hypoglycaemia

NEW automated drug delivery system can help prevent dangerously low blood sugar in patients who have undergone weight-loss surgery, according to the study, "DBL 3: Closed Loop Glucagon Pump: A Novel and Effective Strategy for Post-Bariatric Hypoglycaemia."

An increasingly recognised complication of weight-loss surgery is low blood sugar, or post-bariatric hypoglycaemia (PBH). This condition can cause severe and debilitating low blood sugars after meals. Severe uncontrolled hypoglycaemia can cause seizures, loss of consciousness and death.

“Furthermore, acceptable available treatments are not always effective for severely affected patients,” said lead researcher, Dr Christopher M Mulla of Joslin Diabetes Center in Boston, MA. “This study demonstrated that our glucagon automated delivery system can detect imminent low blood sugar and deliver a small dose of glucagon, yielding improvements in blood glucose levels after meals and during hypoglycaemia in patients with PBH. Further research and development of this system will help treat this challenging disease.”

The researchers tested a new automated drug delivery system, similar to an insulin pump, which can detect when glucose levels are dropping quickly and deliver the hormone glucagon to patients to prevent low blood sugar. A novel hypoglycaemia detection and mitigation algorithm was embedded in the Artificial Pancreas System connected to a continuous glucose monitor (CGM, Dexcom) driving a patch infusion pump (Insulet) filled with study drug (Zirix liquid glucagon or vehicle).

The study included 12 participants (11 women and 1 man) with PBH who had undergone weight-loss surgery an average of eight years earlier; their average age was 52. They wore continuous glucose monitors and an automated pump system, filled with glucagon on one day and a placebo on the second day. Neither the participants nor the study team knew what the pumps contained. Participants were given a liquid meal on both days, and the device measured their glucose levels.

The system autonomously delivered up to 2 doses of study drug (0.1/0.1 ml of glucagon or equal volume vehicle) if triggered by the hypoglycaemia mitigation algorithm. If plasma glucose fell to <55 mg/dl or neuroglycopenia occurred, rescue IV dextrose was given per protocol. During a 2nd study visit, the protocol was repeated, with pump filled with the other study drug. Twelve participants (11F/1M, age 52±2, postoperative duration 8±1 years, mean±SEM) completed all study visits.

For the 12 participants receiving glucagon vs. vehicle during two study visits, predictive hypoglycaemia alerts prompted automated drug delivery at mean 49.6±10.9 vs. 39.0±4.1 (p=0.041) minutes post meal, when sensor glucose was 114±71, 121±75 mg/dl (p<0.05). Four participants did not require rescue during either visit; one participant required rescue during both visits. Seven participants required rescue glucose after vehicle but not after glucagon (p=0.008).

Similarly, five participants had severe hypoglycaemia (plasma glucose <55 mg/dl) after vehicle but not after glucagon (p=0.05). Nadir plasma glucose was higher in study visits with glucagon vs. vehicle delivery (67±42.7 vs. 58±51.9 mg/dl, p=0.04). Glucose levels were not elevated at time of alert (15.6±41.9 mg/dl) but rose after glucagon delivery (121±207 vs. vehicle 16±31.49 mg/dl at 30 minutes, p=0.001). No rebound hyperglycaemia occurred. Fatigue occurred before study drug delivery in two visits. Transient pain at injection site was reported during both glucagon (n=10 of 12) and vehicle (n=6 of 12) study visits. No other adverse events were observed.

Glucose levels were higher on the day they received glucagon than on the day they received a placebo. This indicates that the glucagon was effective at preventing severe low blood sugar, Mulla said. Side effects of the study medication were minimal and included temporary pain where the treatment entered the body.

The team of researchers included engineers from Harvard Paulson School of Engineering and Applied Sciences led by Dr Evy Dassau, and the endocrinology team led by Dr Mary Elizabeth Parthasarathy.

Testosterone can help men with hypogonadism lose weight

ONG-TERM testosterone therapy can help men with hypogonadism lose weight and maintain weight loss, according to a post-hoc analysis presented at ENDO 2019 by researchers from Germany and the US, who reported ten-year results of an ongoing study. "Obesity is very common in men with testosterone deficiency (hypogonadism)," said lead study author, Dr Karim Haider, a urologist and andrologist in private practice in Bremenhar, Germany. "Men with hypogonadism and obesity receiving long-term testosterone therapy achieved progressive and sustained weight loss, while uncontrolled treatments failed. The favourable decreases in weight and waist circumference may have contributed to the observed reductions in mortality and major cardiovascular events."

Haider and his colleagues are conducting an ongoing observational registry study of men with hypogonadism in one urological office for this ten-year report, they followed 850 patients with hypogonadism who were, on average, in their late fifties to mid-sixties. The 460 (54 percent) patients with obesity were given the choice whether to be treated with long-term testosterone therapy (TTT) with testosterone undecanoate injections (TU) or every 12 weeks.

During ten years, the testosterone-treated men lost 20.1 percent of their baseline weight (0.58 kg; 21.4 kg), their waist circumference dropped by 12.5 cm (4.9 in.), BMI decreased by 7.3, and the waist-to-height ratio decreased by 0.07.

By contrast, the untreated men gained 1.9 percent of their baseline weight (0.38 kg; 1.7 lb), and their waist size increased by 6 cm (1.8 in). In this group, BMI increased by 0.9, and waist-to-height ratio increased by 0.05.

During this time, 12 (4.4 percent) men in the testosterone group died, while in the untreated control group, 17 deaths (3.0 percent), 47 myocardial infarctions (2.4 percent) and 44 strokes (2.3 percent) occurred.

"Our study found long-term testosterone therapy in men with hypogonadism and obesity resulted in significant improvement in measures of body size and composition," added Haider. "In addition, testosterone therapy was associated with a reduced risk of death, heart attack and stroke. This suggests testosterone levels should be measured in men with obesity, and testosterone therapy should be offered if indicated."
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**Integrative therapy treating obesity and depression is effective**

Participants receiving integrated therapy reported a decline in depression severity scores based on responses to a questionnaire from 1.5 to 1.1, compared with a change from 1.5 to 1.4 among those in the control group.

A new intervention combining behavioural weight loss treatment and problem-solving therapy with as-needed antidepressant medication for participants with co-occurring obesity and depression improved weight loss and depressive symptoms compared with routine physician care, according to researchers from the University of Illinois at Chicago College of Medicine. Approximately 50 percent of adults with depression are obese, and adults with obesity are at increased risk of experiencing depression. To treat both conditions, patients must visit multiple practitioners usually including dietitians, wellness coaches and mental health care providers or psychiatrists. The burden associated with visiting multiple health care providers consistently over the long periods of time needed to treat obesity and depression can be significant and lead to dropping out of therapy altogether. A large number of these health services may not be available due to a lack of trained providers or reimbursement, and the cost of seeing numerous specialists can be prohibitive.

“Treatments exist that are effective at treating obesity and depression separately, but none that address both conditions in concert, which is a critical unmet need because of the high prevalence of obesity and depression together,” said Dr Jun Ma, professor of medicine in the University of Illinois at Chicago College of Medicine. In addition to the psychological stress that delivering obesity and depression therapy in one integrated program using dually trained health coaches who work within a care team that includes primary care physicians, psychiatrists, and other health care providers can help people achieve the dual targets of weight loss and improvement in depressive symptoms.

“Treating both conditions simultaneously can improve patient health outcomes,” said Dr Ma. “Not only can it improve weight loss, but it also decreases depression severity. Our study findings show promise and benefit for patients receiving integrated care.”

Two hundred and four participants were randomly assigned to receive the integrated collaborative care program and were seen by a health coach for one year. In the first six months, they participated in five individual counseling sessions and six group sessions on healthy lifestyles. In the following six months, participants had monthly telephone calls with their health coach. Two hundred and five participants randomly assigned to the usual care control group did not receive any additional intervention.

Participants in the integrated care program experienced more weight loss and decline in the severity of depressive symptoms over one year compared with control participants receiving usual care. On average, patients in the integrated program experienced a decline in BMI from 36.7 to 35.9 while participants in the usual care group had no change in BMI. Participants receiving integrated care reported a 19 percent decline in depression severity scores based on responses to a questionnaire from 1.5 to 1.1, compared with a change from 1.5 to 1.4 among those in the control group.

“While the demonstrated improvements in obesity and depression among participants receiving the integrated therapy were modest, the study represents a step forward because it points to an effective, practical way to integrate fragmented obesity and depression services into one combined therapy, with good potential for implementation in primary care settings, in part because the integrated mental health treatment in primary care settings is now also reimbursable by Medicare,” explained Ma. “For patients, there is a critical need for an effective alternative to seeing multiple practitioners each charging for their services as is done traditionally. We and colleagues are currently investigating ways to tailor the integrated therapy for individual patients by targeting underlying neurobehavioral mechanisms to further improve outcomes.”

The study assessed a comprehensive intervention that included behavioral weight loss treatment and problem-solving psychotherapy, in addition to addressing the biological mechanisms that underlie obesity and depression. The integrated therapy included nutritional and physical activity interventions, along with problem-solving therapy, which was designed to teach participants coping skills to address their emotional responses and improve their ability to engage in healthy behaviors.

“The integrated therapy provides a unique treatment approach,” said Dr Flanagan. “By targeting the biological mechanisms underlying obesity and depression, we can improve the effectiveness of treatment, ultimately leading to better health outcomes.”

**Insulin receptor and gene expression link leads to new research**

Produced by specialised cells in the pancreas, the hormone insulin serves as the main signal to cells to absorb glucose from the bloodstream and begin the production and metabolism of carbohydrates, fats and proteins. This process is essential for normal cell function, growth, and nutrient storage.

Dysfunctions in insulin signalling contribute to a number of serious chronic diseases. In type 1 diabetes, pancreatic cells fail to produce enough insulin, and in type 2 diabetes, cells become resistant to insulin. Without proper insulin signalling, glucose accumulates in the blood where it damages tissues and organs. Insulin resistance has also been implicated in neurodegenerative diseases such as Alzheimer’s and Parkinson’s, and excessive insulin signalling contributes to a variety of cancers.

Flanagan and colleagues were broadly interested in studying how cell surface receptors communicate with the interior of a cell and performed screens to identify proteins associated with the insulin receptor. Their experiments suggested that one of the most prominent such proteins is RNA polymerase, an enzyme responsible for transcribing DNA into RNA, the first step in gene expression.

This was an intriguing result, said Flanagan, because RNA polymerase enzymes inside the nucleus of a cell are far away from the surface of the cell where the insulin receptor is located. Additional analyses revealed an unexpected explanation. The team found that after the insulin receptor binds insulin, it is physically transported from the cell surface to the nucleus via a yet unidentified mechanism. Once there, it binds to RNA polymerase on chromatin - the protein-DNA complex that cells use to store their genomes.

A genome-wide search revealed around 400 sites in the genome where the insulin receptor bound with a degree of specificity that essentially makes random chance impossible. The insulin receptor at these sites were promoters, or DNA sequences that initiate the expression of genes.

A high proportion of the targeted genes were involved in insulin-related functions, particularly the synthesis and storage of lipids and proteins. Certain subsets of genes were associated with different tissue types. The analyses also identified numerous insulin-related genes, including genes linked with diabetes, cancer, and neurodegeneration.

**Paradox**

Contrary to expectations, the researchers found the insulin receptor does not directly target genes involved in carbohydrate metabolism, one of the primary functions of insulin signalling.

This was an intriguing result for many reasons, said Flanagan, because RNA polymerase enzymes inside the nucleus of a cell far away from the surface of the cell where the insulin receptor is located. Both types of insulin receptors play a crucial role in recruiting the entire insulin receptor complex and binds insulin. Once there, it moves to the nucleus and we can improve our knowledge of the biological effects of insulin in health and in disease, as well as other receptor tyrosine kinases, which are attractive targets for drug development due to their involvement in such a broad range of diseases.

While the insulin receptor has been studied intensely for decades, these findings represent a new pathway for insulin signalling that could shed light on potential mechanisms for the long-term effects of insulin in the body. Intriguingly, as far back as the 1970s, scientists had clues that the insulin receptor and other members of the insulin superfamily are involved in insulin-related functions. It was known that insulin receptor tyrosine kinases, known as insulin receptors, could be found within the cell nucleus in insulin-resistant cells, but these observations remained poorly understood, and the process behind them never fully explained.

The identification of this pathway opens new avenues of investigation into the insulin receptor and other members of the same receptor family, which function as key on- or off switches for a large number of important cellular processes.

“We were surprised to find that insulin receptors can move to the entire insulin receptor complex moves to the nucleus, and we were initially very skeptical,” concluded Flanagan. “We still don’t know how exactly this happens, but we’ve pinned down the details of much of this pathway on a genome-wide scale. A better understanding will help us improve our knowledge of the biology of insulin signalling in health and in disease, as well as other receptor tyrosine kinases, which are attractive targets for drug development due to their involvement in such a broad range of diseases.”
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Excess body weight before age 50 may be more strongly associated with pancreatic cancer mortality risk than excess weight at older ages, according to results of a study presented at the AACR Annual Meeting 2019.

Pancreatic cancer is relatively uncommon, accounting for just over 1 percent of all new cancer cases. However, it is an extremely deadly type of cancer, with a five-year survival rate of just 9 percent, according to the National Cancer Institute’s Surveillance, Epidemiology, and End Results Database. In the US, the pancreatic cancer is the third leading cause of cancer death, after lung and colorectal cancer, and is expected to cause about 46,000 deaths in 2019.

Pancreatic cancer rates have been steadily increasing in recent decades, according to the American Cancer Society’s lead author, Dr. Eric J. Jacobs, senior scientific director of Epidemiology Research at the American Cancer Society. Jacobs explained that increased weight in the US population is a likely suspect, but previous studies have indicated that excess weight is linked with only a relatively small increase in risk, which doesn’t look large enough to fully explain recent increases in pancreatic cancer rates.

In a new study, however, Jacobs and colleagues presented at the AACR Annual Meeting 2019, using data from the American Cancer Society’s ongoing Cancer Prevention Studies II, a nationwide study of cancer mortality that began in 1976 and followed participants through 2014. All participants reported their weight and height just once, at the start of the study, when some were as young as 50 while others were in their 70s or 80s. The researchers used this information to calculate BMI, a measure of weight relative to height, as an indicator of excess weight.

During the follow-up period, 8,554 participants died of pancreatic cancer. As expected, higher BMI was linked with increased risk of dying of pancreatic cancer, but this increase in risk was largest for BMI at earlier ages. An increase of five units of BMI, about 32 pounds for a 5-foot, 7-inch adult, was associated with 21 percent increased risk in those who had their BMI assessed between ages 30 and 49, and 19 percent increased risk in those assessed between ages 50 and 59, 14 percent increased risk in those assessed between ages 60 and 69, and 13 percent increased risk in those assessed between ages 70 and 79.

Researchers noted that while the study only had information on deaths from pancreatic cancer, the disease is nearly always fatal, so results are expected to be similar to those for new diagnoses of pancreatic cancer.

He added that the study results indicate that excess weight could increase risk of death from pancreatic cancer, and the earlier and heavier the weight gain, the higher the risk becomes. Furthermore, Jacobs noted that recent generations are reaching early middle age with more excess body weight.

Therefore, he anticipates that excess weight will explain a larger proportion of pancreatic cancer risk in the future as newer and heavier generations reach the older age categories and trends continue to occur. For example, he estimates that 28 percent of pancreatic cancer deaths in Americans born between 1970 and 1979 will be attributable to excess weight, compared to only 15 percent of pancreatic cancer deaths among Americans born in the 1950s, a group that was much less likely to be obese in early middle age.

“Our results strongly suggest that to stop and eventually reverse recent increases in pancreatic cancer rates, we will need to be smarter in preventing excess weight gain in children and younger adults, an achievement which would help prevent many other diseases as well,” Jacobs said.
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Oestrogen can decrease insulin resistance reducing T2DM incidences

Studies have shown the reduction of oestrogen in postmenopausal women accelerates the development of insulin resistance and T2DM but clinical trials of oestrogen replacement therapy in postmenopausal women have demonstrated a lowered insulin resistance as well as reductions in plasma glucose level.

"This study aimed to quantify the risk of doing nothing by comparing results from a randomised controlled trial led by Wake Forest University researcher, Dr Ken Arterburn. Four research papers based on the study results have been accepted for publication in peer-reviewed journals including the Journals of Gerontology: Medical Sciences and the American Journal of Clinical Nutrition. The papers, ‘[Effects of a Hypocaloric, Nutritionally Complete, Higher Protein Meal Plan on Regional Body Fat and Cardiometabolic Biomarkers in Older Adults with Obesity],’ published in the Annals of Nutrition and Metabolism, and ‘[More protein and fewer calories help older people lose weight],’ published in the Journal of the American Geriatrics Society, provide important insights into the molecular and physiological mechanisms of metabolic diseases and provide a fundamental understanding that dietary intervention can play a crucial role in controlling obesity, diabetes and associated chronic diseases,' he said.

"This suggests Foxo is required for oestrogen to be effective in suppressing glucogenesis,' he said. "We further demonstrated that oestrogen suppresses hepatic glucose production through activation of oestrogen receptor signalling, which can be independent of insulin receptor substrates 1 and 2. This reveals an important mechanism for oestrogen in the regulation of glucose homeostasis."

Gao said study results support the hypothesis that improvement of glucose homeostasis by oestrogen is regulated by hepatic Foxo-mediated glucogenesecis rather than by promoting muscle glucose uptake. He said results may also help explain why premenopausal women have lower incidence of type 2 diabetes than age-equivalent men and suggest that targeting the oestrogen receptor ERα can be a potential approach to counteract the development of targeted oestrogen mimics that can provide the therapeutic benefits without unwanted side effects."

In this study, Gao and other researchers investigated the action of oestrogen on glucose homeostasis in male and ovariectomized female control and liver-specific Foxo1 knockout mice. "We wanted to understand the mechanism by which oestrogen regulates glucogenesecis by means of interaction with hepatic Foxo1," he added. "Foxo1 is an important component of insulin-signalling cascades regulating cellular growth, differentiation and metabolism."

"The identification of tissue-specific actions of oestrogen and direct targets of oestrogen receptors will facilitate the development of novel selective ligands that prevent type 2 diabetes, cardiovascular disease and obesity without promoting abnormal sex characteristics or breast cancer," he said.

Gao also noted some foods, such as soybeans, contain a certain amount of phytooestrogens, which function in a similar way to that of oestrogen, regulating bodily glucose metabolism and insulin sensitivity. "This study provides some important insights into the molecular and physiological mechanism of metabolic diseases and provides a fundamental understanding that dietary intervention can play a crucial role in controlling obesity, diabetes and associated chronic diseases," he said.
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Gut hormone and brown fat interact to tell the brain it’s time to stop eating

RESEARCHERS from Germany and Finland have shown that so-called ‘brown fat’ interacts with the gut hormone secretin in mice to relay nutritional signals about fullness to the brain during a meal, highlighting the importance of a long-suspected role of brown adipose tissue (BAT) – a type of body fat known to generate heat when an animal is cold – in the control of food intake.

“We demonstrate a connection between the gut, the brain, and brown tissue, uncovering a previously unknown facet of the complex regulatory system controlling food intake and satiety,” says lead author Dr Martin Klingenspor, chair of molecular nutritional medicine at the Technical University of Munich. “The view of brown fat as a mere heater organ must be revised, and more attention should be paid towards its function in the control of hunger and satiation.”

During a meal, signals encoded by gut hormones move the blood from the brain to active sites, and secretin also increased the amount of heat that secretin had suppressed appetites. Injecting mice with secretin also increased the amount of heat that brown fat produced. Mice with inactivated brown fat tissue, however, did not experience the same appetite suppression when they were injected with the hormone, suggesting that it is secretin’s effect on BAT that causes the feeling of fullness (Figure 1).

In a study to examining the effects of secretin on brown fat in mice, secretin levels were measured in 17 human volunteers. In a study in Finland, brown-tissue energy is calculated in the control of food intake.

To access this paper, please visit: https://tinyurl.com/yx3877rg

Genetic factors that may cause some people to become obese

PEOPLE with obesity are not only stigmatised, but are blantly dehumanised, according to a study by researchers from the University of Liverpool, UK. Previous research has suggested that people often hold stigmatising and prejudiced views about obesity. This new research, led by Dr Ineke Herking and Dr Eric Robinson, examined whether stigmatising views about obesity may be more extreme than previously thought and, if so, whether people believe that individuals with obesity are less evolved and human than those without obesity.

Obesity is now very common in most of developed countries. Around one third of US adults and one quarter of UK adults are now medically defined as having obesity. However, obesity is a complex medical condition defined by genetic, environmental and social factors. The paper, ‘Blatant Dehumanization of People with Obesity’, was published in Obesity.

As a part of a recognised research approach employed in a number of other studies, more than 1,000 participants, made up of people from the UK, USA and India, completed on-line surveys to indicate how they considered different groups of people to be a scale from 1 to 100.

The researchers also recorded the BMI of those completing the survey to find out whether those with a high body mass index (BMI) were more likely to consider health policies that discriminate against people because of their weight.

Outcomes

Participants on average rated people with obesity as ‘less evolved’ and human than people without obesity. On average, participants placed people with obesity approximately in points below people without obesity. Blatant dehumanisation was most common among thinner participants, but was also observed among participants who would be medically classified as being ‘overweight’ or ‘obese’. People who blatantly dehumanised those with obesity were more likely to support health policies that discriminate against people because of their weight.

Some of the first evidence that people with obesity are blatantly dehumanised was published in Obesity. The researchers reported their work in the paper, ‘Blatant Dehumanization of People with Obesity’, published in Obesity.

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The researchers also recorded the BMI of those completing the survey to find out whether those with a high body mass index (BMI) were more likely to consider health policies that discriminate against people because of their weight.

“Some of the first evidence that people with obesity are blatantly dehumanised was published in Obesity,” says lead author Dr Ineke Herking, a researcher at the University of Liverpool. “It’s too common for society to present and talk about obesity in dehumanising ways, using animalistic words to describe problems with food (e.g. ‘piggie out’) or using images that remove the dignity of people living with obesity. Obesity is a complex problem driven by poverty and with significant genetic, psychological and environmental components. Blatant or subtle dehumanisation of any group is morally wrong and in the context of obesity, what we all know is that the stigma surrounding obesity is actually a barrier to making long-term healthy lifestyle changes.”

Our results expand on previous literature on obesity stigma by showing that people with obesity are not only disliked and stigmatised, but are explicitly considered to be less human than those without obesity,” said Eric Robinson, a Reader at the University of Liverpool. “It’s too common for society to present and talk about obesity in dehumanising ways, using animalistic words to describe problems with food (e.g. ‘piggie out’) or using images that remove the dignity of people living with obesity. Obesity is a complex problem driven by poverty and with significant genetic, psychological and environmental components. Blatant or subtle dehumanisation of any group is morally wrong and in the context of obesity, what we all know is that the stigma surrounding obesity is actually a barrier to making long-term healthy lifestyle changes.”

The study’s findings show that people with obesity are blantly dehumanised and highlight the level of stigmatising views towards people with obesity in our current societal climate,” the study concluded. “The tendency to consider people with obesity as being less human is widespread and justifies discriminatory actions against people with obesity.”

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Exercise is more critical than diet to maintain weight loss

A study from the University of Colorado Anschutz Health and Wellness Center (AHWC) at the CU Anschutz Medical Campus has revealed physical activity does more to maintain substantial weight loss than diet. The findings reveal that successful weight-loss maintainers rely on physical activity to remain in energy balance (rather than chronic restriction of dietary intake) to avoid weight regain.

“This study addresses the difficult question of why so many people struggle to keep weight off over a long period,” said Dr Danielle Ostendorf, a postdoctoral fellow at the CU Anschutz Health and Wellness Center. “By providing evidence that a group of successful weight-loss maintainers engages in high levels of physical activity to prevent weight regain - rather than chronically restricting their energy intake - is a step forward to clarifying the relationship between exercise and weight-loss maintenance.”

In the study, “Physical Activity Energy Expenditure and Total Daily Energy Expenditure in Successful Weight Loss Maintainers”, published in the journal Obesity, successful weight-loss maintainers are individuals who maintain a reduced body weight of 30 pounds or more for over a year.

The study looked at successful weight-loss maintainers compared to two other groups: controls with normal body weight (BMI similar to the current BMI of the weight-loss maintainers); and controls with overweight/obesity (whose current BMI was similar to the pre-weight-loss BMI of the maintainers). The weight-loss maintainers had a body weight of around 150 pounds, which was similar to the normal weight controls, while the controls with overweight and obesity had a body weight of around 213 pounds.

Key findings include:
- The total calories burned (and consumed) each day by weight-loss maintainers was significantly higher (300 kcal/day) compared with that in individuals with normal body weight controls but was not significantly different from that in the individuals with overweight/obesity.
- Notably, of the total calories burned, the amount burned in physical activity by weight-loss maintainers was significantly higher (180 kcal/day) compared with that in both individuals of normal body weight and individuals with overweight/obesity. Despite the higher energy cost of moving a larger body mass incurred by individuals with overweight/obesity, weight-loss maintainers were burning more energy in physical activity, suggesting they were moving more.
- This is supported by the fact that the weight-loss maintainer group also demonstrated significantly higher levels of steps per day (12,000 steps per day) compared to participants at a normal body weight (9,000 steps per day) and participants with overweight/obesity (6,500 steps per day).

“Our findings suggest that this group of successful weight-loss maintainers are consuming a similar number of calories per day as individuals with overweight and obesity but appear to avoid weight regain by compensating for this with high levels of physical activity,” said Dr Victoria A Catenacci, a weight management physician and researcher at CU Anschutz Medical Campus.
Lyppla1 gene impacts obesity in a sex-specific manner

Men and women may be differently susceptible to obesity, insulin resistance, and other cardio-metabolic traits

Susceptibility to obesity, insulin resistance and other cardio-metabolic traits may also be dependent on a person’s sex. An international research team led by Professor Susanna Hofmann at the University of Southampton, a partner of the DZD, and Ludwig Maximilian University Münster, Germany, studied sex differences and sex-specific interactions in the genetic background in cardio-metabolic phenotypes. The researchers discovered, among other things, a sex-specific obesity locus of the Lyppla1 gene, which is associated with human obesity. The results of the study, entitled ‘[Gene-by-Sex Interactions in Mitochondrial Functions and Cardio-Metabolic Traits]’, were published in Cell Metabolism.

And men and women may be differently susceptible to obesity, insulin resistance, and other cardio-metabolic traits. Women often have more advantageous metabolic profiles. This has been described for mice but also for humans who interact with genes? What role does natural genetic variance play? And how does this affect the development of cardio-metabolic traits? In order to answer these questions, an international team of researchers used an animal model (hybrid mouse diversity panel) to search for sex-specific differences in 50 cardio-metabolic traits. The effect of sex on cardio-metabolic traits was investigated in terms of sex-specific correlations with specific disease phenotypes, their genetic architecture and the underlying expression networks in fat and liver. It was found that sex — depending on the genetic background — plays a role in gene expression and the development of cardio-metabolic traits. The research team discovered a sex-specific obesity locus for the Lyppla1 gene.

In addition, we were able to show that there is sex-specific regulation for the ‘beiging’ of adipose tissue and sex-specific interactions for mitochondrial function,” said UCLA Professor Aldonas J. Lasisis, last author and head of the study. The study showed that females have a higher mitochondrial activity and produce more brown adipose tissue (‘beiging’). This reduces fat mass and insulin resistance. In males, the interaction between genes and sex tends to lead to low mitochondrial activity and low beiging. Weight gain and insulin resistance increase.

Brown adipose tissue can produce heat through the oxidation of fatty acids. This takes place in numerous mitochondria, which are also responsible for the brown colourization of the tissue. If the ‘good’ brown fat is activated, the metabolism is stimulated and the ‘bad’ white fat deposits are reduced. The occurrence of brown or beige adipocytes in white adipose tissue is called browning or beiging, a phenomenon associated with increased energy consumption and, at least in the mouse model, with protection against obesity.

“In the literature reference there are already indications of major differences in adipose biology between sex, also in humans. This study provides insights into the depth and breadth of sex differences in metabolism. We believe that our results provide compelling evidence as to why males and females in biological research should be treated as distinct organisms as a whole, rather than as two sexes. If the ‘good’ brown fat is activated, these differences one molecule, at a time,” said DZD researcher, Professor Susanna Hofmann from the Institute for Diabetes and Regenerative Research of the Helmholtz Center Munich.

Her group, together with Professor Axel Walsh from the Core Facility Pathology & Tissue Analyticals at Helmholtz Zentrum München, measured the amount of brown fat tissue and analysed the sex differences in the browning of white adipose tissue.

“Many gaps in our understanding of the biology underlying these sex-specific differences remain to be addressed. As a long-term goal, the researchers therefore want to develop a biological network model that describes the differences between men and women (the ‘sex-ome’) at system level. Such a model will require, among other things, sex-specific network interactions to give rise to sex differences in the emergent phenotypes.

Excessive weight gain in early childhood impacts adolescent heart health

Excessive weight gain in children under two years can lead to cardiovascular and metabolic risk factors in later years, including increased cholesterol, being overweight and having fat around the middle, the findings of a new research from the University of Sydney Professor David Coleridge, Scandinavia’s Professor of Cardiology at Sydney Medical School and the Heart Research Institute said. “The early weight gain group also had significantly higher cholesterol levels compared to a group of healthy weight teenagers. Our study shows that the earlier the onset of excess fat before five years of age, the more likely the individual is to have fat around the middle by adolescence. The study also found that both early and late weight gain groups were more likely to have mothers with overweight or obesity and a high BMI, than healthy weight teenagers.”

Differences were found between normal and excess BMI in children at 14 years of age. In addition, children with an early rising BMI trajectory had statistically significantly higher central adiposity and a more advantageous proportion of excess fat between five and 14 years than children with a late rising BMI trajectory (p<0.05). No differences between BMI trajectory groups in vascular structure or function was identified at age 14 years.

“This study has shown that it is important for families and the community to understand the risks of excess weight gain in early childhood and to encourage healthy eating and activity are supported from a very young age,” said co-author, Professor Louise Baur, Head of Child & Adolescent Health at the University’s Sydney Medical School and The Children’s Hospital at Westmead. “These findings may provide an opportunity to identify ‘high risk’ young children and trial interventions early, prior to the development of high cholesterol and centrally placed fat which becomes evident in adolescence and increases the risk of heart disease as an adult.”

“Breastfeeding should be supported where possible until at least 12 months, with solids introduced from around six months,” said Professor Baur, highlighting another example of how the health of one generation affects the health of the next, “And we must ensure all families are supported in their efforts.”

The new findings strengthen the case for primary prevention of childhood obesity: There are still many gaps in our understanding of the biology underlying these sex-specific differences remain to be addressed. As a long-term goal, the researchers therefore want to develop a biological network model that describes the differences between men and women (the ‘sex-ome’) at system level. Such a model will require, among other things, sex-specific network interactions to give rise to sex differences in the emergent phenotypes.

Risk of obesity influenced by changes in genes

A child’s risk of obesity as they grow up can be influenced by modifications to their DNA prior to birth, a new University of Southampton study has shown.

These changes, known as epigenetic modifications, control the activity of our genes without changing the actual DNA sequence. One of the main epigenetic modifications is DNA methylation, which plays a key role in the development of the embryo and the formation of different cell types, regulating when and where genes are switched on.

DNA methylation can be affected by a range of environmental factors such as parental health, diet and lifestyle.

Researchers from the University of Southampton, as part of the Epigen Global Consortium, analysed the levels of DNA methylation at the SLCA6A4 gene, which is involved in the regulation of serotonin in the body and has been implicated in mood and appetite regulation. The sample comprised umbilical cord tissue of babies born in the Southampton Women’s Survey at birth and compared with the amount of fat tissue in the child at four and six years of age.

They found that lower DNA methylation levels at the SLCA6A4 gene at birth was associated with a higher fat mass at six years of age. Each unit lower SLCA6A4 methylation at birth was associated with a seven per cent higher child’s fat mass at six years age. The Southampton team compared the results to the mother’s health during pregnancy and found that higher weight gain during pregnancy and a lower number of previous births was associated with lower SLCA6A4 DNA methylation.

“Our results add to the growing evidence that epigenetic changes are detectable at birth linked to a child’s health as they grow up,” said co-lead author Karen Lifcyrop, from the University of Southampton.

“Additionally, it also strengthens the body of evidence that shows a mother’s health during pregnancy can affect the future health of her child. It could allow us to more accurately predict the risk of obesity.”

The results, Differential SLCA6A4 methylation: a predictive marker of adiposity from birth to adulthood, were published in the International Journal of Obesity. The research was replicated in other groups of children and adults, notably the Western Australian Pregnancy Cohort Study and the UK BIOCLAIMS cohort.

“These results offer more evidence and more opportunity to allow us to develop strategies and interventions in early life that could reduce childhood obesity rates,” said Emma Garratt, co-author and Professor at the University of Southampton.

This latest Southampton study is another example of how the health of one generation affects the health of their future baby. The new findings strengthen the case that primary prevention of childhood obesity needs to begin before birth, and might ‘reset’ appetite levels in ways that protect infants and children from putting on excessive weight,” added Professor Keith Godfrey, a member of the research team and Director of the GlaxoSmithKline Clinical Research Institute examining whether diet and lifestyle interventions before and during pregnancy can affect the health of their future baby.

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IT’S TIME TO ACT ON OBESITY

DAY ONE: GENERAL

Keynote Session:
Burden of Obesity on Society
Global Burden of Obesity
National Burden of Obesity
Childhood Obesity Implications

Session A: Pathogenesis of Obesity
Session B: Co-Morbidities (Mental Health, CV Risk, Cancer, Diabetes, PCOS)

DAY TWO: SPECIALIST

Session A: Multi-Disciplinary Care
Psychology
Lifestyle and Behavioural Modifications
Pharmacotherapy
Surgery

Session B: Success and Continuity of After-Care
Session C: Stakeholder Declaration (Identify the problem, what is the size, what is the solution and what steps can all stakeholders take to resolve it)

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**GI Dynamics gains IRB approval for EndoBarrier Pivotal Trial**

GI Dynamics has received Institutional Review Board (IRB) approval to conduct its pivotal trial of EndoBarrier for type 2 diabetes and obesity. The pivotal trial of EndoBarrier, referred to as the 18-1 study, is a randomised (3:1) controlled double-blinded clinical trial designed to measure the efficacy and safety of EndoBarrier in conjunction with lifestyle therapy and diabetes medication for the treatment of type 2 diabetes and obesity vs. a sham control arm in conjunction with lifestyle therapy and diabetes medication, also for the treatment of type 2 diabetes and obesity.

The 18-1 study will occur in two stages: stage I consists of 50 EndoBarrier patients and approximately 17 control patients and will be completed with the filing of four Data Monitoring Committee (DMC) reports with the US Food and Drug Administration (FDA). Upon review of the four DMC reports by the FDA, the company will apply for approval to conduct Stage II of the trial, which is projected to include the balance of patients to complete the 18-1 study total of 240 patients (180 EndoBarrier and 60 control).

IRB approval is required by the FDA and is an essential step to allow the EndoBarrier pivotal trial to proceed. Western IRB (WIRB) is serving as the company’s central IRB. GI Dynamics was notified that the following EndoBarrier pivotal trial documentation is approved by WIRB: protocol, informed consent form and investigator’s brochure.

“When we announced that the FDA approved our Investigational Device Exemption (IDE) for the pivotal trial of EndoBarrier, the approval was conditional upon IRB approval,” said Scott Schorer, president and chief executive officer of GI Dynamics. “This IRB approval now satisfies that condition. In parallel, we continue to push forward with the clinical study sites that will be part of the 18-1 study and we anticipate being in a position to announce these clinical sites shortly.”

**First patients implanted with ReShape Vest in ENDURE II Trial**

ReShape Lifesciences announced that the company has successfully implanted its first patient in the ENDURE II trial designed to support CE Marking of the ReShape Vest. The ReShape Vest System is an investigational, minimally invasive, laparoscopically implanted medical device that wraps around the stomach, emulating the gastric volume reduction effect of conventional weight-loss surgery, and is intended to enable rapid weight loss in obese and morbidly obese patients without permanently changing patient anatomy. The ReShape Vest is intended for morbidly obese patients with BMI of between 35 and 55.

In a pilot study conducted outside the US, at 12 months, Vest patients demonstrated a mean percent excess weight loss (%EWL) of 85%, an average drop in HbA1c (Haemoglobin A1c) of 2.1 points, and an average waist circumference reduction of 38cm.

“We are very excited with the start of the ENDURE II study and expect enrolment to progress quickly with this innovative, world-class technology,” said Dr Jordi Pujol, Bariatric Surgeon at the Bellvitge University Hospital in Barcelona, Spain, where he is Principal Investigator for the ENDURE II trial. The ReShape Lifesciences ENDURE II trial is an investigatory, prospective, non-randomized, multi-center study to assess the safety and effectiveness of the ReShape Vest for treatment of obese patients. The study is intended to support CE Marking of the ReShape Vest. The trial will include up to 10 investigational sites located in Spain, the Czech Republic, Germany, Belgium and The Netherlands. Enrolled subjects will be followed for two years, with the application for CE Marking to be submitted when all patients have reached one-year of follow-up.

“It is so exciting to see this minimally invasive medical device being utilized to treat and improve the quality of life of patients,” added Dr Raj Nihalani, inventor of the Gastric Vest and Chief Technology Officer at ReShape Lifesciences. “The successful implantation of the first patient with the ReShape Vest is a significant milestone as we move towards CE marking and takes the company one step closer to bringing this novel technology to the millions of patients who battle obesity.”
Novo Nordisk UK launches semaglutide once-weekly GLP-1 RA for adults with T2DM

Novo Nordisk UK has announced that Ozempic® (semaglutide), a once-weekly GLP-1 analogue injection, is now available in the UK. According to the company, Ozempic works by mimicking the function of the GLP-1 (human glucagon-like peptide-1) hormone produced in the gut that lowers post-meal blood glucose levels and also slows glucose absorption into the bloodstream. Ozempic should be used alongside diet and exercise, as monotherapy when metformin is considered inappropriate due to intolerance or contraindications or in addition to other medicinal products for the treatment of diabetes, when type 2 diabetes is insufficiently controlled. The EU licensing of Ozempic is based on results from the SUSTAIN clinical trial programme which consistently demonstrated:

- Superior glycaemic control compared to dulaglutide, exenatide once weekly, sitagliptin and insulin glargine U100®
- Superior and sustained weight loss compared to dulaglutide, exenatide once weekly, sitagliptin and insulin glargine U100®
- Cardiovascular benefits vs placebo both in addition to standard of care in people with type 2 diabetes at high risk for CV events

“We know that people with uncontrolled type 2 diabetes are at risk of serious complications and that can have a real impact on their lives,” said Steve Bain, Professor of Medicine (Diabetes) at Swansea University and Assistant Medical Director for Research & Development for ABBV in the UK and Clinical Lead for the efficacy licence. “Being able to offer medicines such as Ozempic®, which patients only need to take once a week, is an important step in helping to control the condition and improve outcomes.”

There are currently over 4 million people in the UK living with diabetes and with one in every 11 people in England now at risk of developing the condition, diabetes is the fastest growing health threat facing the country. Type 2 diabetes costs the NHS £8.8bn a year, with 80% of that used to treat avoidable complications1.

In addition, a prespecified analysis of simple linear regression involved a broad range of people with type 2 diabetes, including some with high cardiovascular risk profiles and people with and without renal diabetes. Ozempic® was approved in EU on 9 Feb 2018.

The detailed All Wales Medicines Strategy Group (AWMSG) and Scottish Medicines Consortium (SMC) recommendation/advice can be found here:


References:

Scottish Medicines Consortium (SMC) recommendation/advice can be found here:


Novo Nordisk launches semaglutide once-weekly GLP-1 RA for adults with T2DM

G elesis has gained FDA approval for its lead product candidate, PLENITY (Gelesis100), as an aid in weight management in adults with a BMI ≥ 35–40, when used in conjunction with diet and exercise. According to the company, PLENITY represents a new prescription option for millions of adults. More than half of the approximately 150 million adults in the US with a BMI ranging from 25 to 40 are classified as overweight.

In a pivotal study, 29% of adults who did not have any prescription treatment options, so the safety and efficacy profile of PLENITY makes it well-suited for these individuals, the company claims. It is the only prescription weight management product to be cleared for use by overweight adults with a BMI as low as 25, with and also without comorbidities such as hypertension, type 2 diabetes or dyslipidemia. There is no restriction on how long PLENITY can be used to assist in weight management.

In clinical studies, PLENITY demonstrated a unique combination of effectiveness combined with a highly favourable safety and tolerability profile. Data from the PLENITY pivotal study, Gelesis38 (GLOW), were published in the Journal Obesity. PLENITY and its prototypes have been studied across five clinical studies throughout the US, Canada, and Europe. PLENITY, along with diet and exercise, helps to induce weight loss through increased satiety and reduced hunger, leading to a reduction in caloric intake. Though its clinical programme, PLENITY has demonstrated a consistently strong safety and efficacy profile. PLENITY was recently evaluated in a multicentre, double-blind, placebo-controlled pivotal study designed to assess change in body weight over 12 months in adults who were overweight or obesity (BMI≥27 and ≤40) after six months of treatment. The study had two predefined co-primary endpoints: at least 35% of patients taking PLENITY achieving ≥ 5% weight loss (categorical endpoint) and placebo-adjusted weight loss with a super-superiority margin of 3%.

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RYGB offers better weight loss but higher readmission rates vs LSG

Kuwait publishes 1st National Bariatric Obesity Registry Report

The study, ‘Changes in Sexual Function Follow-Up; 2,036 (91.9%) patients after RYGB and 83.0% for SG patients, respectively, p<0.001). The authors commented. “This could be due to the fact that bariatric surgery has been around longer than sleeve gastrectomy patients,” the authors commented. “This could be due to the fact that the functioning of their genes, leading to changes in the composition of their gut bacteria and mimicking these changes to develop a therapeutic intervention to improve obesity.”

ContinuousData2019 and Follow-up; 2,036 (91.9%) patients after RYGB and 290 (2.1%) patients after SG (p=0.771). In total, 846 patients (2.6%) had severe complications after RYGB and 290 (2.1%) patients after SG (p=0.771). In total, 846 patients (2.6%) had severe complications after RYGB and 290 (2.1%) patients after SG (p=0.771). In total, 846 patients (2.6%) had severe complications after RYGB and 290 (2.1%) patients after SG (p=0.771).

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