Randomized Comparative study between laparoscopic sleeve gastrectomy and Laparoscopic banded sleeve gastrectomy

Thesis

Submitted for partial fulfillment of the MD degree in general surgery

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2016

دراسة مقارنة بين الاستئصال الجزئى للمعدة بالمنظار الجراحى والاستئصال الجزئى للمعده بالمنظارالجراحى مع تركيب حزام للمعده

دراسة توطئة للحصول على درجة الدكتوراة فى الجراحة العامة

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2016

الملخص العربى

ان السمنة المفرطة هى مشكلة تتزايد فى العالم. وان لها العديد من المشكلات الصحية المصاحبة مما اثار ضرورة التصدى لها وعلاجها . ان طرق مواجهة السمنة تشمل تغيير نظام الغذاء وتحسين اسلوب الحياة بالاضافة الى العلاج النفسى ولكن الحل الجراحى هو الوسيلة المثالية لعلاج السمنة ومضاعفاتها على المدى الطويل.

من ضمن العمليات الجراحية المتعددة للسمنة ظهرت عملية تكميم المعدة وانتشرت بشكل كبير فى الاوساط الجراحية وذلك نظرا لنتائجها الجيدة على المدى القصير والطويل .

ان المميزات المتعددة التى اضافتها جراحة المناظير مقارنة بالجراحات التقليدية ادت الى الشغف للتطوير والتحديث لتحقيق نتائج افضل. ومن هنا بدات تظهر جراحات المناظير المتطورة من خلال مداخل الجسم الطبيعية وكذلك جراحة المناظير من خلال المدخل الواحد.

لقد بدا ظهور عده مضاعفات لجراحة تكميم المعده بالمنظار الجراحى ومنها عدم نقص الوزن بعد فترة طويلة من الجراحة نتيجة لكبر حجم المعده ولذلك تم التفكير فى وضع حزام للمعده بعد تكميم المعده بالمنظار الجراحى وذلك لتحقيق افضل معدل لنقص الوزن على المدى البعيد.

ولقد قمنا فى هذه الرسالة البحثية بدراسة مقارنة بين عملية تكميم المعدة عن طريق جراحة المنظار(المجموعة الاولى) وعملية تكميم المعدة بالمنظار الجراحى ووضع حزام للمعده (المجموعة الثانية) . من حيث الامان والفاعلية بالاضافة الى النتائج والمميزات والعيوب.

من خلال التجربة ، وجدنا ان بها العديد من الصعوبات والتحديات التقنية ولكن مع العمل المتكرر والاستمرار فقد نجحنا فى تحقيق معدل تعليمى جيد من خلال تنفيذ بروتكول عمل موحد وثابت مما ادى الى تذليل العقبات الجراحية والوصول الى الطريقة المثالية للعملية.

وقد حققنا متوسط وقت للعملية حوالى 80 دقيقة للمجموعة الثانية والتى كانت اطول فى البداية ولكن تمكننا من تحسينه مع ازدياد العمل والخبرة. ولكننا لم نحتاج الى تحويل احدى الحالات الى الفتح الجراحى.

ان متوسط الوقت للبقاء فى المستشفى كان 2.4 يوم وهو مشابه للنتائج فى الابحاث العالمية.

اما بخصوص المضاعفات الناجمة بعد العملية فقد كانت مقبولة وفى حدود الامان حيث ظهرت 6 حالات تعانى من القئ بعد العملية منها حالتين من المجموعة الاولى بنسبة (10%) واربع حالات من المجموعة الثانية بنسبة (20%) وقد تم علاجهم جميعا فى المستشفى وانتهت هذه المشكلة تماما بحلول اليوم الثالث بعد العملية . كما ظهرت حالة تلوث بسيط فى الجرح فى كلا المجموعتين وتم علاجها بالمضادات الحيوية.

اما عن المضاعفات المتأخرة فلم تظهر احداها فى كلا المجموعتين . ولم تحدث اى مضاعفات اخرى او حالات وفاة .

اما بالنسبة للنتائج من حيث انقاص الوزن فقد خرجت الاحصائيات لتظهر نتائج مشابهة فى كل من المجموعتين فى خلال عام واحد من المتابعة والارشادات المستمرة لطريقة الغذاء وهذا ايضا ما ادلت به الدراسات العالمية المشابهة لهذه الدراسة .

ولذلك فاننا ننصح بزيادة فترة المتابعة للمرضى وعمل دراسات اخرى فى هذا المجال وذلك للتاكد من نجاح عملية تكميم المعدة بالمنظار الجراحى مع تركيب حزام للمعدة فى تحقيق معدلات عالية من انقاص الوزن على المدى البعيد.

Introduction

The prevalence of obesity has increased markedly in the past 20 years, becoming a major public health issue. Many obesity-related comorbidities have been documented and account for the use of considerable medical resources worldwide. It has been found that the higher one's BMI value, the higher his or her mortality. However, although nonsurgical treatment of obesity such as behavioral and pharmacologic methods have been proved to have an effect on short-term weight loss of approximately 5 to 10% of body weight, these methods are not very effective on long-term resolution of excess body weight and its related comorbidities. Therefore, bariatric surgery plays an increasingly important role for this problem. Bariatric surgery not only helps reduce body weight and decrease comorbidities, but it also causes an improvement in patients' health-related quality of life ***(Prentice, 2006)***.

Sleeve gastrectomy was initially conceived as a restrictive component of the biliopancreatic diversion and duodenal switch. Then sleeve gastrectomy has been proposed as a step procedure in high-risk patients, followed by a second step Roux-en-Y gastric bypass or biliopancreatic diversion and duodenal switch and, recently, as a standalone bariatric approach ***(Abu-Jaish et al., 2010).***

Advances in minimally invasive surgery have revolutionized the field of bariatric surgery. All major bariatric operations are routinely performed laparoscopically, and numerous technological advancements have led to innovations that push the boundaries of defining minimally invasive surgery ***(Carlos et al., 2010).***

Laparoscopic Sleeve Gastrectomy (LSG) has recently been identified as an innovative approach to the surgical management of obesity. In this procedure, the greater curvature of the stomach is resected producing a narrow, tubular stomach with the size and shape of a banana. This

procedure has quickly attracted considerable surgical interest because it does not require a gastrointestinal anastomosis or intestinal bypass and it is considered less technically challenging than Laparoscopic Gastric Bypass . LSG also avoids implantation of an artificial device around the stomach in comparison to LAGB. Weight loss following LSG is achieved by both restriction and hormonal modulation ***(Frezza, 2007).***

A substantial part of bariatric operations contain the implantation of a band. The minimally invasive restrictive intervention of a band placed around the upper stomach to create a small proximal pouch has gained worldwide recognition as gastric banding (***Favretti*** **et al.,2002)**

Further development lead to the banded gastric bypass by Fobi, the gastroplasty modification, the Mill Magenstrase (M and M) procedure and in consequence the laparoscopic sleeve gastrectomy (LSG **(Johnston et al.,2003**).

In the latter operation the stomach is reduced to a narrow tube which dramatically reduces the volume and decreases the gastric peristaltic
'wave'. Further investigation showed that a significantly better excess weight loss (EWL) can be achieved by using a 32 F gastric tube for the sleeve resection (**Weiner et al.,2008**).

The LSG has been described as the first stage of the two-step gastric bypass procedure (laparoscopic Roux-en-Y gastric bypass; LRYGB) or biliopancreatic diversion with duodenal switch (BPD-DS) in morbidly obese patients (**Hess et al.,2005**).

There is a hybrid operation between sleeve gastrectomy and VGB named banded sleeve gastrectomy, using the GaBP Ring Autolock™

Recently, other authors have published their initial experiences with the banded sleeve gastrectomy using other banding materials (**Agrawal et al., 2010).**

The dilatation of the gastric sleeve created in LSG can progress in time and may be a potential source of therapy failure. Placing a silastic ring at the outlet of the pouch to prevent dilatation of the gastric pouch in LRYGB procedure already shows promising results (**fobi et al., 2005**).

Studies describing the incidence of gastric tube dilatation and Methods to prevent this unfavorable course after LSG are lacking (**Langer et al., 2006)**

It was approved that about one fifth of patients who regain weight after Sleeve gastrectomy have a sleeve volume >300 ml when assessed by 3D-CT with gastric volumetry [**Karcz et al., 2009**].

The sleeve gastrectomy with implantation of a siliastic ring for prevention of lower gastric sleeve dilatation . GaBP Ring Autolock™ System is made of silicone, has a locking mechanism and is available in various sizes. It is currently pending approval from the FDA but has the CE certification for the European market where it is also used for banded gastric bypass operations(**karcz et al.,2011**).

The hypothesis of possible superiority of banded over conventional LSG will be evaluated in this prospective randomized trial. t

Aim of the Work

A prospective study compares laparoscopic Sleeve gastrectomy and laparoscopic banded sleeve gastrectomy as regard the operative technique and postoperative outcomes.

Chapter (I): Obesity

The typical definition of obesity, a body mass index (BMI) of over 30 obscures the heterogeneity among that group. Severely obese individuals who are 100 or 200 pounds (45–90 kg) or more overweight have on average far more complex health issues and encounter very different challenges in the health care system than the majority of (moderately) obese individuals (BMI 30–35). Physician offices and hospitals require additional resources for severely obese patients. It also affects health care personnel and the National Institute for Occupational Safety and Health started a program in 2009 to identify evidence-based best practices for handling severely obese patients to reduce occupational injuries ***(Galinsky et al., 2010).***

Demographic Distribution:

Obesity is now considered an epidemic disease; projections of the World Health Organization (WHO) indicate that, in 2006, at least 400 million adults were obese. According to recent studies, the US has the highest mean BMI among high income countries, resulting in 1 in 3 adults having a BMI over 30 based on objective Measurement or 1 in 4 adults based on self-reported height and weight. In Europe, the prevalence of obesity has increased by threefold in the last two decades. Fifty percent of adults and 20% of children are overweight; of these overweight individuals, one-third are obese, and the rates are increasing rapidly ***(Flegal et al., 2012).***

In Arab countries, the prevalence of obesity has increased at alarming rate during the last three decades and this appears to be more pronounced in women. The prevalence of obesity parallels increased industrial development, which in the Arabian Gulf related to the significant growths in incomes resulting from the rich deposits of oil reserves and the resultant impact on rapid urbanization and improved living conditions. For Kuwait, 30% of males and 55% of females over the age of 15 were classified as obese, making Kuwait the country with the highest prevalence of obesity in the Arabic-speaking countries ***(Ono et al., 2010).***

Measurements of Obesity:

Contribute to varying degrees. The simple explanation is that weight gain is caused by consuming more calories than the body expends with excess calories stored as adipose tissue. (***Galinsky et al., 2010***)

1- Body Mass Index (BMI):

Body mass index (BMI) is the most widely accepted classification of weight status. To calculate an individual's BMI, the body weight in kilograms is divided by height in meters squared. Charts and online sites are available for rapid calculation of BMI. BMI is not only used to diagnose and classify obesity, but it also can estimate health risk.

Morbidity and mortality will increase proportionately to an individual's BMI (Table 1) ***(ASBS, 2005).***

However, obesity-related health risk is also influenced by the distribution of body fat. Patients who exhibit central obesity (the "apple" shape) are at increased risk for cardiovascular disease and diabetes. A peripheral fat distribution pattern (the "pear" shape) is associated with abdominal hernia, venous stasis disease, and degenerative joint problems.

The individual's level of physical fitness is another factor that influences risk. People who are obese who are active and exhibit higher levels of fitness are at lower risk for developing cardiovascular disease or diabetes ***(Kral, 2001).***

Table (1): Classification of Obesity ***(US Department of Health and Human Services, 2000).***

Underweight	< 18.5
Normal	18.5-24.9
Overweight	25-29.9
Obesity (class I)	30 to 34.9
Obesity (class II)	35 to 39.9
Extreme obesity (class III)	40 to 49.9

Super obesity (class IV)	50 to 59.9
Super-super obesity (class V)	> 60

Different BMI cutoff points have been proposed for specific ethnic populations. Chinese, Malay, Indian, Taiwanese, and Indonesian men and women have more body fat than do Caucasians for a given BMI, which means that Asian people are at risk for chronic disease at BMIs lower than the existing cutoff point for overweight. Thus, additional BMI cutoff points are suggested with Asian populations. In some groups of Asians, a BMI of 23 rather than 25 would indicate increased risk from overweight and a BMI of 27.5 rather than 30 would indicate increased risk from obesity ***(Boardley and Pobocik, 2009).***

2- Skin Fold Thickness:

Normally most adipose tissue is in the subcutaneous layer, the thickness of which can be estimated by measuring a skin fold. Individuals differ in the proportion of fat at different subcutaneous sites, but the sum of skin fold at biceps, triceps, sub-scapular and supra-iliac sites yields an estimate of body fat ***(Jung and Cuschieri, 2000).***

Skin folds are particularly useful in the estimation of fatness in children. The method is inexpensive, but requires a skilled observer, and is not applicable to very obese people whose skin folds wouldn't fit between the jaws of the measuring caliper. Some information is obtained by comparing the subscapular skin folds with limb skin folds concerning the central distribution of fat, but this is not a reliable method for estimating intra-abdominal fat ***(Goran, 1998)***.

The point at which the skin fold is taken on the arm is measured as half the distance between the acromial and the olecranon processes. A fold of skin and subcutaneous tissue is taken by pinching the tissue between thumb and forefingers and initially placed 2 cm apart. It is essential to maintain the grip with the left hand while the right hand relaxes pressure completely on the

handle of the calipers. The biceps reading is taken in the same plane but at the front of the arm with the hand supinated. The supra-iliac measurement is also taken on the left side in the mid-axillary line just above the iliac crest ***(Garrow, 1996).***

3- Distribution of Fat:

a- Waist Circumference (WC):

The measurement of waist circumference (WC) is now widely advocated as a simple anthropometric indicator of metabolic and cardiovascular disease risk. WC is a key diagnostic criterion for the metabolic syndrome according to the US National Cholesterol Education Program and the International Diabetes Federation and has been incorporated into clinical practice guidelines for the identification and treatment of overweight and obesity in several countries, including the United States, Canada, and Australia ***(Lau et al., 2007).***

Despite the widespread use of WC measurements, there remains no uniformly accepted measurement protocol, resulting in a variety of techniques employed throughout the published literature. For example, current US National Institutes of Health guidelines specify that WC be measured directly above the superior border of the iliac crest, whereas the World Health Organization and Health Canada recommend measurement at the midpoint between the superior border of the iliac crest and the lowest rib. Measurements made at the umbilicus and at the minimal waist are also commonly used in clinical and research settings ***(Ross et al., 2007).***

b- Waist-to-Height ratio (W/Ht):

Some researchers recommend that the W/Ht ratio (calculated as WC in inches divided by the height in inches) should be used as the global indicator for health risk of obesity, because it is a simple, inexpensive measurement; it is associated with risk factors for obesity and metabolic syndrome; and it works equally well for both men and women, people in different ethnic groups, and

for children and adults. This index can identify people within the normal range of BMI who may have a higher metabolic risk associated with central obesity ***(Ashwell and Hsieh, 2005)***.

c- Waist-to-Hip ratio (WHR):

A WHR greater than 0.8 in women and greater than 0.9 in men is a predictor of increased risk of obesity complications. The WHR includes both subcutaneous and intra-abdominal adipose tissue, and it is unknown how to correct for the level of subcutaneous tissue. The WHR can be affected by postprandial status, standing position, time of day, and depth of inspiration, although the degree to which these factors can contribute to error is unknown. As with WC, there is no standardized approach for measurement. In addition to the different locations for the waist measurement, the hip measurement can vary as well, but the widest area around the hips is commonly used. Another practical difficulty is the more invasive nature of the hip measurement. Thus, the BMI in combination with WC is a better measure of obesity than WHR ***(Misra, 2006).***

d- Sagittal trunk diameter:

Sagittal trunk diameter is a less commonly used method of assessing abdominal fat. The sagittal trunk diameter is taken while subjects are in a recumbent position on an examination table and is the maximum diameter of the abdomen in the sagittal plane. When a person with an enlarged intra-abdominal adipose mass is standing, gravity pulls the fat tissue down so the WC might not be as accurate in assessing the intra-abdominal fat in those who are very obese compared with when the same person lies supine and the mass shifts causing anterior projection of the abdomen, which is measured by the sagittal diameter. Clinical judgment should be used in deciding if this method would produce better results than a WC measurement ***(Larsson, 2006).***

e- Magnetic resonance imaging (MRI) and computed tomography (CT) of the abdomen have also been used to assess visceral deposition of fat in research settings, but cost and lack of easy accessibility make them impractical for clinical use ***(Rakel et al., 2011).***

Etiology and Pathogenesis of Obesity:

There are various studies conducted to understand the main etiology of obesity from which they concluded that there are 3 main factors (genetic, environment and energy balance) involved in the pathogenesis of obesity.

✓ Genetic factor:

It is estimated about 30% to 50% of body weight gain is due to genetic factor. Study on families of obese patients had proven the existence of significant relationship of BMI between members of family among one generation.

These genetic disorders consist of monogenic and multigenic disorder:

i. Monogenic disorder:

In obesity due to single gene disorder, Body Mass Index (BMI) may reach as high as > 60 kg/m2, and usually occur since childhood. For example Prader-Willi syndrome which is caused by disappearance of material expression of paternal active genome in chromosome 15q11-13. The manifestation of the syndrome is short gesture, fat deposition in upper body, mental retardation, and hypogonadism. This disorder is very rarely found ***(Rosenbaum et al., 1997).***

ii. Multigenic disorder:

Obesity phenotype is presumed as the result of simultaneous interaction of genetic disorders and environment factor. Various genes are responsible for fat distribution, energy expenditure during activity and rest, eating habit, lipase

protein activity, basal metabolic rate, insulin induced-fat synthesis and decreased effect of thermogenic factor of the food ***(Rosenbaum et al., 1997).***

- ✓ **Environment factor:**

Environment factors that contribute to obesity are factors that cause increased food intake and decreased physical activity. Some factors suggested to promote overeating like portion size, high glycemic index of foods, accessibility of food, soft drinks, sugar, taste of food, fast foods, variety of food and low calcium & others that suggested to reduce physical activity like reduced need for physical labor in most jobs, no required physical activity in schools and reductions in physical activity required for daily living ***(Hill and Donahoo, 2002).***

- ✓ **Energy balance factor:**

Energy balance consists of intake regulation and energy expenditure of the body. If there is increased intake or decreased energy expenditure, the body would try to reduce excess energy and lower intake or increase energy expenditure. The extra energy in the long term will be stored in form of fat mass in adipose tissue. Protein and carbohydrate storage is relatively stable, thus, condition that determines the body weight in the long term is adipose tissue mass ***(Jequier and Tappy, 1999).***

i. Energy (food) intake regulation:

Physiologically, food intake is controlled by appetite which is the result of stimulus interaction of food and its inhibitors. Food stimulation is caused by increased need and expenditure of energy in the form of hunger sensation, while the inhibitory factor is in the form of satiety. Hunger is influenced by internal factors such as blood glucose, insulin, ghrelin and external factors like emotion, time, food availability and environment factors. The sense of satiety has more roles in determining food quantity and much more influenced by internal factors ***(Jequier and Tappy, 1999).***

There is feedback mechanism of food intake regulation consists of:

✓ Center of intake regulation and energy expenditure:

Hypothalamus is the center of information that receives and processes regarding energy balance status in the body through afferent signal derived from gastrointestinal tract and adipose tissue. Ventromedial hypothalamic nuclei (VHN) stimulation causes the release of neuropeptide of 'satiety' sensation. On the other hand, stimulation of lateral, dorsomedial and periventricular hypothalamic nuclei cause the release of neuropeptides of 'hunger' ***(Druce et al., 2004).***

Afferent signal of intake regulation; There are two afferent signals which are classified as hormonal and neuronal signal:

1. Hormonal signal:

This afferent signal comes from adipose tissue, gastrointestinal tract, thyroid glands, adrenal, muscles and reproductive organs where signals from the first two mentioned organs have more roles. These signals deliver information on nutritional balance and body fat mass ***(Tschop and Horvath, 2003).***

Peripheral afferent signal of gastrointestinal tract during eating and digestion process is cholecystokinin (CCK) which is released due to mechanical stimulation of gastric stretching. This hormone delivers afferent signal through vagal nerve to solitary tract nuclei (STN) which then projects it to hypothalamus, insular cortex and motor nuclei of brain stem cell resulting in signal of cessation of eating processes ***(Druce et al., 2004).***

Peripheral afferent signal of pancreas are insulin, glucagons, and amylin which are food intake regulator. If condition of excess energy exists, secretion of insulin and leptin will increase as adipose signal that gives information to hypothalamus. On the contrary, in condition of insufficient