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Peri-operative Morbidity of Nissen Sleeve Gastrectomy: Prospective Evaluation of a Cohort of 365 Patients, Beyond the Learning Curve

David Nocca^{1,2} · Florence Galtier^{1,3} · Sulaiman Taleb¹ · Marie-Christine Picot^{2,3,4} · Audrey Jausset⁴ · Marta Silvestris · Patrick Lefebvre¹ · Audrey de Jong¹ · Thomas Gautier⁶ · Marcelo Loureiro^{1,7} · Marius Nedelcu^{8,9}

1 CHU de Montpellier, CHU Saint Eloi 80 Av Augustin Fliche Cedex 5, 34295 Montpellier, France

2 Institut de Génomique Fonctionnelle, UMR 5203 CNRSU1191, INSERM- Univ Montpellier, Montpellier, France

3 Inserm CIC 1411, Montpellier, France

4 Clinical Research and Epidemiology Unit, CHU Montpellier, Univ Montpellier, Montpellier, France

5 Clinique Clémentville, Montpellier, France

6 Clinique Saint Jean Sud de France, Montpellier, France

7 Universidade Positivo, Curitiba, Brazil

8 ELSAN Clinique Bouchard, Marseille, France

9 ELSAN Clinique Saint Michel, Toulon, France

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Keywords

Nissen sleeve · Reflux · Sleeve · Bypass · Fundoplication · GERD

***e-mail:**

David Nocca
d-nocca@chu-montpellier.fr

Abstract

Purpose

Over the last decade, an important interest was taken to prevent the reflux following sleeve. A new variant, Nissensleeve, was described with the purpose to prevent GERD and to decrease the occurrence of leak. The current study reports the preliminary results of a prospective trial.

Materials and Methods

All consecutive patients who underwent a Nissen-Sleeve between January 2018 and September 2020 were included. Baseline characteristics including age, gender, weight, body mass index (BMI), GERD symptoms, and treatment were evaluated after 1 year. Operative time, length of stay, complication, and reoperation data were also collected.

Results

Three hundred sixty-five consecutive patients decided to undergo Nissen-sleeve: 75% females with median age of 41.2 years (+ / - 14.1) and an average BMI of 41.6 kg/m² (+ / - 5.4). There were 16 cases (4.4%) of early postoperative complications (< 30 days): six cases of acute wrap perforation (1.6%), intraabdominal bleeding for 5 patients (1.4%), one case of wrap dilatation (0.3%), one case of acute complete aphagia, one case of incarcerated umbilical hernia, and 2 cases (0.5%) of pulmonary atelectasis/pneumonia and one venous pulmonary embolism. We recorded the following complications: 16 patients (4.4%) mild dysphagia; 3 patients (0.8%) chronic dysphagia; and 2 cases of wrap perforation that have been diagnosed 8 and 9 months respectively, after the procedure due to the use of steroids not associated with PPI intake. The mean operative time was 83 min (46–125 min). The conversion and mortality rates were nil.

Conclusion

Following the initial learning curve and additional technical modifications, the Nissen-Sleeve appears to be a safe surgical technique with an acceptable early postoperative complication rate.

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Introduction

Bariatric surgery represents the gold standard of treatment for sustainable weight loss and reduction of comorbidities in morbidly obese patients. During the last decade, laparoscopic sleeve gastrectomy (LSG) has become the most performed bariatric procedure worldwide [1].

This growth can be explained by several advantages that LSG carries over laparoscopic Roux-en-Y gastric bypass, including the absence of most of the side effects of bypass procedures such as dumping syndrome, marginal ulcers, malabsorption, small bowel obstruction, and internal hernia, and also by the fact that it can offer a better quality of life (QoL) compared with gastric banding [2, 3].

The identification of some form of gastroesophageal reflux disease (GERD) preoperatively (clinical, endoscopy, bariatric procedure to be performed). The effects of the laparoscopic sleeve gastrectomy on GERD can be contradictory. LSG induces alteration of the angle of His due to the surgery itself, hypotony of the LES after the division of the muscular sling fibers, decrease of the gastric volume, and consequent increased intragastric pressure, decrease of the ghrelin level, hence dysmotility. All these factors contribute to expose the patient to the risk of increasing GERD and PPI dependency or developing de novo GERD [4] with the development of Barrett's esophagus (BE). Recent studies [5–7] have reported the occurrence of BE in 15–20% of the patients with long-term endoscopic monitoring. Thus, GERD can adversely affect the quality of life resulting in long-term medical therapy, or conversion to Roux-en-Y gastric bypass (RYGB) [8].

Consequently, over the last decade, an important interest was taken to prevent the reflux following LSG and promising results of LSG and concomitant hiatal hernia repair were reported [9–11]. Accordingly, our team has developed a modification to the usual surgical technique of the LSG by adding a Nissen fundoplication in order to minimize both leaks and GERD. Following encouraging initial results of the preliminary study [12] and overcoming the initial phase of the learning curve with some technical modifications, a prospective trial was set up to assess the feasibility, safety, and effectiveness of this new technique in a wider spectrum of indications. The current study is reporting the preliminary results of this trial in terms of safety, bringing out at the same time the evolution of some technical key points.

Methods

All consecutive patients who underwent a standardized Nissen sleeve gastrectomy procedure between January 2018 and September 2020 were included in the present study. Baseline characteristics including age, gender, weight, body mass index (BMI), GERD symptoms, and treatment were evaluated through a standardized clinical questionnaire. It was applied before surgery and at 1 month postoperatively and during subsequent follow-up visits. The evaluation of the efficacy was considered in function of the resolution of GERD symptoms and PPIs use cessation.

Operative time, length of stay, complication, and reoperation data were also collected. Weight loss in the first month was measured using % excess weight loss (the ideal body weight was considered a BMI of 25 kg/m²). Complications and reoperations were assessed through a systematic review of patients' electronic medical records and the hospital discharge database.

Patients with clear symptoms of GERD (heartburn and or regurgitation at least weekly) or a diagnosed hiatal hernia were included. Furthermore, patients who decided to undergo Nissen sleeve gastrectomy to prevent post-operative GERD were included as well. All the patients had a previous multidisciplinary evaluation for bariatric surgery and were informed about the experimental character of this new technique and signed an informed consent. Contra-indications were represented by previous bariatric surgery and BMI > 50 kg/m². The clinical trial number of the prospective evaluation (Bareval) was NCT02310178.

Surgical Technique

All operations were performed under general anesthesia and by a laparoscopic approach using the French technique (the surgeon standing between the patient's legs). Each procedure required 5 trocars. Pneumoperitoneum was induced through a primary trocar (12 mm) inserted in the umbilicus by the open technique (Hasson technique). The trocars' placement was identical to that of the standard LSG described by our team (12). The greater curvature of the stomach was dissected from the short gastric vessels and the gastrocolic ligament downward up to 6 cm from the pylorus, to preserve the distal antrum, by means of an impedance coagulator Harmonic Ace® (Ethicon Endo-surgery, Johnson-Johnson Inc. 2010, USA). A careful dissection was performed at the level of the gastric fundus, which is used later to perform the fundoplication, keeping an appropriate distance from the gastric wall (5 mm), thus avoiding any possible thermal injury. Complete exposure and dissection of the left crus and the gastroesophageal junction were required. When present, posterior gastric vessels were divided as well as any pancreas attachments. The fundus was completely freed and mobile to allow a retroesophageal passage without tension. Then the hepatogastric ligament was opened at its pars flaccida, with the preservation of an accessory hepatic artery if present, achieving thus the complete dissection of the right crus.

The first step of the Nissen-Sleeve technique involved the dissection and reduction within the abdominal cavity of a possible hiatal hernia, with the hernia sac and gastro-esophageal fat pad being removed. The lower esophagus was mobilized on at least 5 cm length and all the anterior and posterior esophageal space was clearly prepared, carefully preserving the posterior and anterior branches of the vagus nerve. This technique was performed for all the patients in order to fix the wrap on the lower part of the esophagus and not on the GE junction. The hiatal orifice was closed posteriorly by approaching the right and left diaphragmatic cruses with one to three 2.0 non-absorbable interrupted sutures of Ethibond® (Johnson-Johnson Inc. USA). Following, a 37F tube (Midsleeve®, Medical Innovation Development, Dardilly, France) was introduced into the stomach by the anesthesiologist. A Nissen fundoplication of 3 cm was created using a 3.0 Ethibond® suture (Johnson-Johnson Inc. USA). The wrap was designed to preserve a gastric fundus as small as possible and then the sleeve was calibrated by the Midsleeve® tube. The first two fixation points were passed between the left part of the wrap, the superficial esophageal layer, and then the right side of the wrap. The last point was passed between the two sides of the gastric wrap. Observing the initial learning curve experience, in order to perform an acceptable Nissen Sleeve two critical points are to be retained:

1. The esophagus must be adequately and systematically mobilized and the upper part of the wrap must be fixed on the lower part of the esophagus, and not at the level of esogastric junction with the entire length of the wrap covering the cardiac junction.
2. The wrap must be performed by grabbing the superior anterior part of the fundus 3 to 4 cm lower from the angle of His (Fig. 1).

Through all these steps, the management of the fundus with the graspers must be very careful in order to avoid gastric wall damage that may lead to post-operative perforation. NB: the wrap was not sutured anymore to the right crus.

Fig. 1 Landmark for the Nissen fundoplication



During the next stage, 50 cc of saline solution was inserted in the distal balloon of the Midsleeve® (MID Company) positioned at the antrum level to define accurately the beginning of the staple line and thus avoiding an angulus stricture. A laparoscopic Echelon linear stapler with green cartridges® (Ethicon Endosurgery, USA), reinforced by Bio-Seamguard® (WL Gore, USA) was introduced into the peritoneal cavity and applied alongside the Midsleeve® (MID Company) tube positioned close to the lesser curvature. The instrument was fired and reloaded, and the procedure was repeated for an average of 6 total firings. At the end of the procedure, the Midsleeve® tube was moved backwards into the esophagus and then pushed through the wrap to control that the food will not be trapped in the posterior part of the wrap but will directly go into the remaining stomach. The gastric tube should go directly and easily into the antrum; otherwise, the fundoplication needs to be recreated or removed. Figure 2 illustrates the final laparoscopic aspect of the Nissen-Sleeve.



Fig. 2 Final laparoscopic aspect of the Nissen-Sleeve

The use of an indocyanine green (ICG) test can be useful to check the vascularization of the wrap in case of doubt (Fig. 3). We no longer systematically use the ICG test at the end of the procedure, but we strongly recommend it at the beginning of the experience or during reinterventions. The ICG test is a tool that provides additional, interesting information with no harm to the patient.

Postoperative Evaluation and Follow-Up

All patients receive peri-operative deep vein thrombosis prophylaxis using low molecular weight heparin (40 mg × 2/day) and intermittent pneumatic leg compression during the operation and recovery. Routine vital signs are recorded and notable changes, including fever > 38.5°, sustained tachycardia above 100 bpm or atypical pain are promptly evaluated for possible complications. Patients are also closely monitored for postoperative respiratory complications including hypoxemia, hypercarbia, atelectasis, and pneumonia. Postoperative management involves early oral feeding with liquids (first postoperative day) and semi-liquid diet on the second postoperative day. That same day, an upper GI series is performed (Fig. 4) to confirm a correct barium swallow. With good oral tolerance and adequate volume to maintain hydration, the patient can be discharged on day 2 or 3.

Patients normally follow a nutritional prescription consisting of protein and multivitamin supplements for the first 6 months, and then blood tests are performed for the assessment of any deficiencies and therapy is continued if necessary.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. The study was approved by the ethical board of our institution.

Fig. 3 Indocyanine green test at the end of the procedure



Results

Three hundred sixty-five consecutive patients decided to undergo Nissen-sleeve between January 1, 2018, and September 30, 2020. In 21 cases (5.7%), we did not perform Nissen fundoplication, due to the presence of a gastrointestinal stromal tumor (GIST) at the level of the fundus in 6 cases (28.6%) or technical issues as a huge size of the liver or difficulties to create the wrap in 15 cases (71.4%). In these cases, conventional sleeve gastrectomy

Considering all these, many patients opt for a N-Sleeve. The potential benefit of the technique seems evident in the treatment or prevention of postoperative GERD. The Nissen technique has been described for a long time and is recognized for treating GERD. In addition, one of the additional benefits of the Nissen-Sleeve could be to avoid gastric fistulas located at the angle of His (stapling at a distance from the angle of His due to the creation of the wrap). However, different specific complications of the Nissen-Sleeve technique have been identified in our experience. They are presented, as follows:

– Valve perforation was also described by Olmi et al. [14] in 3.5% of their patients. This was also our most important specific complication. It often appears during the first 3 post-operative days. The clinical diagnosis is suspected when presenting tachycardia (> 100/min), fever, and severe dysphagia. In this case, an opacified CT is performed because of its high sensitivity (100% in our study). The treatment is represented by emergency laparoscopy with fundus resection and drainage of the left hypochondrium. In some cases, a simple suture of the perforation and drainage may be performed. Several theories (traumatic gripping forceps, thermal lesion by ultrasound dissector) could explain this complication, but trauma to the gastric wall during the fundus dissection and fundoplication is the most likely mechanism to produce it. The nutritional recommendations for the post-operative period should be carefully discussed with the patients. It is essential to try to avoid this complication. A quick return to normal solid food can dilate the esophagus proximal to the fundoplication and significantly increase the pressure on the valve fixation points extending the risk of tearing and subsequent perforation.

We need to discuss two unusual cases of wrap perforation which have occurred 9 and 10 months respectively after the initial procedure. For both patients a history of excessive use of steroids medication without PPI intake was noticed. Thus, the patients should be informed that even if they have stopped the PPI use for GERD, the PPI medication should be reintroduced in case of steroids intake, to protect the gastric mucosa.

– Another specific complication for the N-Sleeve is the dilation of the valve by food obstruction. To perform a good functional fundoplication is the most sensible part of the procedure. Should the valve be performed inadequately, the food will go directly into the fundoplication and not into the gastric tube. Its diagnosis is suspected in case of total aphagia during refeeding and it can be confirmed by an opacified CT scan. The dilation of the fundoplication can lead to necrosis of the gastric wall and peritonitis due to perforation. The treatment, which must be carried out urgently, consists of wrap resection.

Fig. 4 Postoperative barium swallow control: day 1



The operative technique evolved with several modifications during the learning curve. After the initial description of the technique and following several debates, we have decided in 2017 for a minimal mobilization of the esophagus when no hiatal hernia was found. The postoperative outcome showed us an important number of fundoplication dilation, probably due to a too low fixation of the fundoplication close to the GE junction, which imposed a subsequent modification of the technique. Starting in 2018, a systematic dissection of the last 5–6 cm of the thoracic esophagus was performed and the valve was fixed on the lower part of the esophagus but away from the GE junction. With this approach, fundoplication dilation has become rare. A systematic intraoperative test by mobilizing the Midsleeve® tube through the valve at the end of the procedure is mandatory, simulating the future passage of the food.

– Hemorrhagic complications are similar to LSG's [15]. Despite the use of seamguard (Gore)-type synthetic biomaterials, the bleeding rate found in our study is 1.4%.

– The risk of a primary necrosis of the valve (apart from its dilation) is not described in our experience. The vascular supply to the valve is provided by the gastric transmural blood circulation coming from the left gastric artery.

The analysis of our prospective study found a rate of early (< 30 days) surgical complications of 4.4%. In a recent randomized trial, Salminen et al. [16] described a major surgical complication rate of 5.8% for the LSG and 9.4% for the RYGBP. Peterli et al. [17], in a similar study, found a rate of 0.9% of major early complications for the LSG and 4.5% for the GBP (including one death). Accordingly, the Nissen- Sleeve gastrectomy could be considered safe and feasible and seems to offer a less risky alternative to GBP for patients with morbid obesity disease and severe GERD.

Conclusions

Our current experience with Nissen fundoplication associated with LSG appears to be a safe surgical technique with an acceptable early postoperative complication rate. This technique decreases the risk of staple line leak at the level of the angle of His, but on the other hand, is more technical demanding (increased risk of other specific complications) and time-consuming than the standard LSG. Particular attention should be paid, especially during the learning curve period, to specific complications (e.g., valve perforation and valve dilatation) and to valid criteria of patient selection (no revisional surgery, technical difficulties for high BMI patients). In order to prevent specific complications, adequate and systematic mobilization of the esophagus is mandatory along with repeated shifting of the calibration tube that must go into the remaining stomach and not into the fundoplication. The Nissen-Sleeve provides adequate control of the GERD symptomatology with no clear interference with the expected bariatric results of a standard LSG.

Declarations

Conflict of Interest The authors declare no competing interests.

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Key Points

- A new variant, Nissen-sleeve, was described with the purpose to prevent GERD and to decrease the occurrence of leak.
- The current study reports the preliminary results of a prospective trial 365 consecutive patients, and it brings out, at the same time, the evolution of some technical key points.
- Following the initial learning curve and additional technical modifications, the Nissen-Sleeve appears to be a safe surgical technique with an acceptable early postoperative complication rate.