



Current Status of the Robotic Fundoplication: Case Series and Literature Review

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Abstract

Introduction: For many years, open fundoplication was the standard for the surgical management of Gastroesophageal Reflux Disease (GERD). In the last two decades, laparoscopic surgery has displaced the open approach by achieving similar results, with a faster convalescence and less postoperative pain. Robotic technology was recently introduced as an evolution of the conventional laparoscopic, whose role is still to be validated.

Material and Methods: We describe a retrospective analysis of the initial experience in Nissen floppy-type fundoplication performed by a robot assisted approach in the Zumpango's High Specialty Regional Hospital.

Results: A total of 18 cases were found from June 2014 to December 2017. The total surgical time was 146 minutes (120 min to 203 min), docking time 10.2 minutes (5 min to 20 min) and console time 108.2 minutes (60 min to 153 min). The hospital stay was 39.4 hrs (18 hr to 192 hr), the perioperative morbidity 11.1%, conversion 5.5%, reoperations 5.5% and death 0%. At 19.4 months of follow-up, 84.6% presented remission or improvement of the initial symptoms of GERD (Visick I, II), 15.4% reported no changes (Visick III), and no patient reported increased symptoms (Visick IV). The morbidity and conversion of the first 9 cases was 22.2% and 11.1% respectively, while in the following 9 cases it was 0% and 0%.

Discussion: Our initial experience with robot-assisted fundoplication shows comparable results with the reported standards in the medical literature for any approach. The probability of conversion and the incidence of complications are inversely proportional to the accumulated experience, due to the robotic approach requires an aggregate learning curve.

Keywords: Reflux; Gastroesophageal; GERD; Robotic; Fundoplication

Introduction

GERD is defined as a condition that result from abnormal and recurrent exposition of the esophagus and/or the respiratory tract to gastric contents which generates symptoms or complications, among which are included esophagitis, peptic stenosis, Barrett's esophagus and a diverse number of conditions in the respiratory tract [1,2]. It's estimated that in the USA 44% of the population shows symptoms of pyrosis once per month, 7% experience it daily, and 20% of esophagitis is complicated [3].

The management is initially pharmacological in all cases, based on Proton-Pump Inhibitors (PPI), H2 antagonist or anti acids. In relation to tolerance, effectiveness, costs and individual characteristics of each patient, eventually it can be considered a surgical approach, which consists on the making of a gastric plication and represents the therapeutical option with the best long term results and with a higher satisfaction for the patient [2,4-6].

In 1956 Dr Rudolph Nissen published his procedure designate "fundoplication" [3], later named Nissen fundoplication, which soon would become the standard surgical procedure for the GERD; later Dallemagne et al. [7] performed the first fundoplication by a laparoscopic approach with functional similar results to open surgery, but with a faster convalescence and less post-surgery pain displacing this way the open approach [6,8]. Nevertheless, the laparoscopic manipulation is hindered by the use of rigid not articulated instruments and a two-dimensional image, besides; the physiological tremors of the surgeon are easily transmitted to the surgical field, which makes dissections and delicate sutures difficult.

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Figure 1: Docking of the da Vinci surgical system.

Facing this limitations, robotic technology has recently introduced in the clinical laparoscopic practice with the objective of improving surgical performance by eliminating tremors and fatigue, offering a ergonomical pose to the surgeon, allow a tri-dimensional view of the surgery field, granting optic control to the surgeon overcoming the need to coordinate with an assistant, significantly improving the approaching of stitch in complicated places and allowing better maneuverability of the instruments [6].

The performance of robotic assisted funduplications has proved to be a feasible and safe alternative [9,10], with long term results comparable to conventional laparoscopy [6,8,11], although the high cost and surgical time for docking are a challenge for this technology.

Materials and Methods

This is a series of cases that aims to report the initial experience of funduplications performed by robot-assisted laparoscopic approach in the Zumpango's Regional Hospital of High Specialty and compare the results with those reported in the medical literature.

We retrospectively analyzed the files of all patients undergoing any robot-assisted funduplication since the acquisition of the robotic surgical system (Da Vinci Si), in a period of time between January 2014 and December 2017. 3 surgeons participated in the performance of the surgeries. The diagnosis of GERD was based on the criteria proposed by the Society of Gastrointestinal and Endoscopic Surgeons of the United States "SAGES" [1].

In all patients with clinical suspicion of GERD a high endoscopy was performed, in case of erosive esophagitis, the diagnosis was concluded without another diagnostic approach. In cases with high clinical suspicion but negative endoscopy, atypical clinical symptoms (dysphagia, odynophagia, weight loss and respiratory conditions) or diagnostic doubt with esophageal motor disorder, pH-metrics and manometry were performed.

The indications for antireflux surgery were patients with good response to management with PPI but reoccurrence of symptoms upon discontinuation, complications of GERD (Barrett's esophagus or peptic stenosis), extra esophageal manifestations of the disease, adequate control of the disease with pharmacological therapy but increased dose or progression of the disease, and some patients with poor response to PPI, particularly those with severe uncontrolled regurgitation or with respiratory symptoms.

In all cases, a Nissen Floppy fundoplication was performed. With general anesthesia, the patient in the supine position, the

Table 1: Preoperative Diagnosis.

| Diagnosis | n (%) |
|-------------------------------------|------------------|
| GERD without esophagitis | 4 (22.2%) |
| GERD + esophagitis* | 14 (77.7%) |
| Esophagitis A | 3 (16.6%) |
| Esophagitis B | 8 (60%) |
| Esophagitis C | 3 (16.6%) |
| GERD + esophagitis + Barrett | 4 (22.2%) |
| GERD + Hiatal hernia | 4 (22.2%) |
| Type 1 | 1 (5.5%) |
| Type 2 | 2 (11.1%) |
| Type 3 | 1 (5.5%) |

*Los Angeles Classification

pneumoperitoneum was performed through an optiview trocar of 12 mm in the umbilical scar, where the robotic arm of the camera was introduced. It changes to position in Trendelenburg inverted at 30°, trocars are placed under direct vision for two robotic arms of 10 mm (right and left), one of 5 mm subxiphoid laparoscopic conventional where Nathanson separator is inserted, and one of 5 mm in the left (conventional laparoscopic) for retraction, aspiration, irrigation, insertion and extraction of materials. The docking of the da Vinci surgical system was cephalic as shown in Figure 1.

Circumferential dissection of the esophagus was performed, short vessels were sectioned with monopolar energy and closure of the diaphragmatic pillars with two or three simple polyester 2-0 stitch, a 3 cm fundoplication was made without tension fixed with three simple knots with the same suture and the intermediate anchored to the anterior esophageal wall. Finally the robotic system moves away, materials are removed by laparoscopy and the wounds are sutured.

Three times were recorded: the total surgical time, the robotic docking, and the console time. Prophylactic antibiotic was administered with a single dose 30 minutes before the first incision and mechanical/pharmacological antithrombotic measures according to the Caprini scale. After the surgical procedure, a liquid diet was indicated in the first 4 hours with progression according to the patient's tolerance. Conditions for discharge were normal vital signs, tolerance to diet, controlled pain and no evidence of complications.

Long-term follow-up was carried out through telephone surveys using the Visick scale for symptom control and EAT-10 for dysphagia assessment.

Results

A total of 18 cases were found. The average age was 44.7 years (29 yr to 71 yr), 10 patients (55.5%) were female and 8 (45.5%) male.

77.7% of the patients presented esophagitis, being type B in the majority of cases, while 22.2% (n=4) corresponded to non-erosive GERD. 22.2% patients (n=4) presented hiatal hernia (Table 1).

The total surgical time was 146 minutes (120 min to 203 min), 10.2 minutes of docking time (5 min to 20 min) and 108.2 minutes (60 min to 153 min) of console time. The hospital stay was 39.4 hrs (18 hr to 192 hr), corresponding to 1.6 days on average.

The perioperative morbidity was 11.1% (2 patients), in one case there was high digestive tract bleeding with spontaneous remission that required transfusion of 2 erythrocyte concentrates, and the

Table 2: Visick Score.

| | |
|-------|-----------|
| I | 5 (38.4%) |
| II | 6 (46.1%) |
| III | 2 (15.4%) |
| IV | 0 |
| Total | 13 (100%) |

second case required conversion to open surgery (5.5% total incidence of conversion) due to liver injury by the Nathansson separator, with hepatic packing and subsequent reoperation for removal the compresses 48 hours later. They corresponded to a cases number 3 and 6 respectively. If the above is analyzed in 2 periods of time, morbidity and conversion rate in the first 9 cases was 22.2%/11.1% respectively, and 0%/0% for the last 9 cases.

For the follow-up, the Visick and EAT-10 scales were applied, which were achieved in 13 patients (72.2%) at 19.4 months on average after surgery. 4 patients (22.2%) were not located, and 1 patient (5.5%) refused to answer the survey. Of the patients interviewed, 84.6% (n=11) presented remission or improvement of the initial symptoms of GERD, while 15.4% (n=2) did not report differences (Table 2). On the other hand, the incidence of dysphagia was 7.7% (Table 3).

Discussion

For many years open fundoplication was the standard treatment of gastroesophageal reflux showing good results, been displaced at present by minimally invasive approaches. When a fundoplication is compared by open vs. laparoscopic approach assisted by robot, the superiority of the latter is not in doubts; an analysis carried out by the "university consortium of health systems" who evaluated a database of 12,079 patients undergoing fundoplication secondary to GERD [12], concluded that robot-assisted fundoplication was related to a lower postoperative morbidity (5.6% vs. 11%), hospital stay (6.1 days vs. 3 days) and costs of care, although the sample of patients undergoing robotic surgery only includes 339 patients.

When laparoscopic approach vs. assisted by robot are contrasted, most published series agree that robotic surgery usually consumes more surgical time [6,13-16], with total times of 86 min to 173 min for conventional laparoscopic, and 137 min to 222 min for robotic surgery [17], being maybe due to the time of docking, which has been reported from 5.3 min to 23 minutes [15,17]. However, this result has been inconstant on the experience of different authors, as the meta-analyzes of Yao et al. [18] and Cundy et al. [19] conclude, where no significant difference was found between the two approaches, or even some authors have achieved a shorter surgical time with the robotic system compared to the conventional laparoscopic, as reported by Müller et al. [20] in a randomized clinical trial (88 min vs. 102 min, p=0.03).

The truth is that the majority of robot-assisted fundoplication reports have emerged from the initial cases, and it is expected that as the experience increases, surgical time will be reduced [6], as demonstrated by Heemskerk et al. [8] in a series of 11 patients where in the first 5 cases the time interval between conventional and robot-assisted laparoscopy was 72 minutes in favor of the first, reducing to 27 minutes in the following 6 cases. In another study where the surgical times were analyzed over 2 years and 39 cases [17], it was concluded that as a greater learning curve is reached, both the docking time and the total surgical time are progressively reduced.

Table 3: EAT-10 Score.

| | |
|---------------------------|------------|
| Never presented dysphagia | 8 (61.5%) |
| Transient dysphagia* | 4 (30.8%) |
| Persistent dysphagia | 1 (7.7%)** |

*They presented postoperative dysphagia, but not currently; **6 points on the EAT-10 dysphagia scale

Although no study has been designed to specifically evaluate these learning curves, a decrease of 61% of the surgical time is estimated after the first 5 cases [21].

In the present series of cases, the total surgical time was 146 minutes, despite being an initial casuistry; the results were comparable with the averages reported in the literature for both laparoscopic and robotic surgery.

On the other hand, the average hospital stay is similar regardless of the approach, but widely variable depending on the author's preferences, with a range of 18 hrs (0.75 days) to 105.6 hrs (4.4 days) [12-20,22]. In the present series, the average hospital stay was 39.4 hrs (1.6 days), with a stay in census beds of one night in 89% of cases.

Some reports of initial experiences have concluded a greater need for conversion in patients with a robot-assisted approach, in figures as high as 11.4% [15], however, in systematic reviews and meta-analysis where more experienced series are included, there is no difference in the need for conversion between a robotic or laparoscopic approach, being generally less than 3% [16,18]. We found the need for conversion on an occasion (5.5%), corresponding to case number 3, due to a liver injury whit bleeding caused by the hepatic retractor.

On the other hand, when it comes to redo fundoplication, robotic surgery assistance has shown superiority, with lower incidence of conversions to open surgery and shorter hospital stay [16,23].

Perioperative morbidity in general has been reported from 0% to 5.6% [12,17,24]. In 3 meta-analyzes on the adult population [6,14,18] and 1 on pediatrics [19], general morbidity was reported without significant difference between conventional or robotic laparoscopic approach [6,14,16,18]. The general probability of reoperations is equivalent [6,14,16,18], requiring in 5.1% of the cases and dysphagia being the main cause followed by the recurrence of reflux symptoms [12,17].

Our experience in the first 9 cases was with a high rate of morbidity (22.2%) and conversion (11.1%), while in the following 9 cases there was no case, concluding that there is an initial learning curve that must be overcome. It is logical to think that this learning curve must be overcome for any approach, be it open, laparoscopic or robotic.

Most published series conclude that robotic surgery involves a higher cost [12-14,16,19,20], although not all authors agree with this statement, such as the meta-analyzes performed by Wang et al. [6] and Yao et al. [18] that included only prospective cohort studies where they concluded that the difference in costs between a conventional laparoscopic and robotic fundoplication does not differ significantly [6].

When the long-term results are evaluated, the most frequent postoperative complication is dysphagia, with numbers ranging from 1.8% to 10% [1,25,26], usually with a poor response to endoscopic dilation (up to 25%) [26], and without difference between robotic or laparoscopic approach [27]. The need for antisecretory medication is also similar [6,16,18] in the range of 5.6% to 62% [2,12,17,22], this

wide difference depending on the time of follow-up, being more necessary as the observation period is longer [28]; they generally have a good response to IBP (in the 89%) [22] and a good quality of life [16], with 62% to 97% satisfaction with the operation in follow-up longer than 5 years [27]; 81% to 92% referred satisfied with the procedure and willing to do it again and 90% to 92% would recommend the surgery [22,29].

The follow-up through the Visick scale has shown acceptable long-term results, with a score of I or II (resolved or improved complaints) between 73% and 90% of patients [17,30-32], being more common in order of frequency Visick II (57.4%), Visick I (21.8%), Visick III and IV (9%) [17]. Our results are comparable with 84.6% of patients with Visick I or II (remission or improvement of symptoms), without any patient Visick IV.

Robot-assisted fundoplication has been a safe and efficient alternative, where the higher cost and surgical time are frequently cited as drawbacks. These statements arise from published experiences with generally modest and initial cases [21], like this series. The function of these reports should be to determine the learning curves, and not to compare safety and efficiency profiles against other approaches, since this same learning curve represents a considerable bias. It would be expected that improved experience and technology could eventually overcome these disadvantages [33].

Conclusion

In our initial experience we observed that the probability of conversion and the incidence of complications are inversely proportional to the accumulated experience.

Despite this learning curve, our results are competitive with the experience reported in the medical literature, both conventional laparoscopic and robot-assisted approaches.

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