



Robotic-Assisted Laparoscopic Redo Nissen Fundoplication. Does it Offer Advantages in Children?



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Abstract

Objective: The experience in RALRNF and its advantages in children is presented.

Materials and Methods: A prospective, observational, and longitudinal study from March 2015 to March 2019, in children treated with RALRNF. Parameters examined: demographic data, diagnoses, surgical technique, recurrence of our PRF, previous surgical approach, time of console surgery, TO surgical findings, bleeding, hemotransfusions, complications, conversions, PO stay, and follow-up. Surgical system used was "da Vinci model, Si versión" (Intuitive Surgical, Inc., Sunnyvale, CA. U.S.A). Measures of central tendency were used. Research Ethics Committee of Hospital approved the study.

Results: In 4 years, 19 RALRNF cases were performed in children; 66.16% were male; averages in age was 10.3 years, stature 135.2cm, and weight was 36.3kg. Previous funduplications was 10 open, 6 laparoscopic and 3 robotic. Recurrence rate of our PRF cases was 6%. TO findings: HH and wrap dehiscence 52.63% and only wrap dehiscence 47.37%. Average time of console surgery was 280 min. Conversion rate and hemotransfusion was 5.2%. TO complications occurred in 21% and not alter PO evolution, PO complications and mortality 0%. A RALRNF failure occurred (5.2%). Averages PO stay was 2.2 days, and follow-up 24.1 months.

Conclusion: The failed fundoplication is frequent, and RF is complex, difficult and laborious technique. With the RALRNF we achieved low risk of conversion, no complications, few hemotransfusion, short TO stay and low recurrence rate for our patients. The RALRNF if offers advantages to the children. Only expert pediatric surgeons solve them, by conventional laparoscopy. There are few publications of RALRNF in children.

Keywords: Robotic assisted; Robotic surgery; Laparoscopic surgery; Pediatric surgery; Robotic gastrointestinal surgery; Redo fundoplication; Redo minimally invasive surgery; Children

Abbreviations: RALRNF: Robotic-Assisted Laparoscopic Redo Nissen Fundoplication; PRF: Primary Robotic Fundoplication; TO: Transoperative; PO: postoperative; HH: Hiatal Hernia; LPNF: Laparoscopic Primary Nissen Fundoplication; RF: Redo Fundoplication; GERD: Gastroesophageal Reflux Disease; LRNF: Laparoscopic Redo Nissen fundoplication; RRNF: Robotic Redo Nissen Fundoplication; GI: Gastrointestinal

Introduction

Gastroesophageal reflux is very common in children and can often leads to reflux-esophagitis, peptic esophageal strictures, Barrett's esophagus. If the conservative treatment fails a patient needs surgical treatment as well as those who suffer from complications and HH [1,2]. Fundoplication is considered a mainstay in the surgical treatment of gastro-esophageal reflux [3]. The most popular operation is laparoscopic primary Nissen fundoplication (LPNF) with the efficiency of more than 80%, and there are authors who refer to this procedure as the gold standard [1, 4].

Pediatric endoscopic surgery in children dates from 1971, the first case of laparoscopy in pediatric surgery was reported by Stephen Gans in this year, in his landmark publication, "Advances in Endoscopy of Infants and Children," as a peritoneoscopy. The term peritoneoscopy was soon replaced by Pediatric Laparoscopy [5,6]. But the first publications of laparoscopic fundoplication in children date from the early nineties [7-9].

On the other hand, the first minimally invasive robot-assisted surgery in children was the fundoplication technique, were carried out by Meininger et al. [10] in July 2000 and reported in

April 2001 [10,11]. The fundoplication is a leading application of robotic surgery in children in GI area, since then [12,13].

In children, the current alternatives for fundoplication are the approaches: open, laparoscopic and robotic for fundoplication, and the main challenge is to redo fundoplications (RF) in patients who fail the primary procedure, this occurs in a wide range between 2.6% to 42%. [1,3,14-16]. On the other hand, the recurrence of gastroesophageal reflux disease (GERD) after surgical treatment can be presented independently of the surgical approach used, as evidenced by Ru W et al., [17] in a systematic review and a meta-analysis of patients undergoing laparoscopic or open primary Nissen fundoplication, they did not find a significant difference in the recurrence [17]. Other study by Thomas JF, et al, they compare recurrence of GERD in children through a study randomized, laparoscopic (44 patients) VS open primary Nissen fundoplication (43 patients), with the main outcome measure was recurrence of GERD. The results where, significantly more patients that undergoing LPNF (37%) experienced recurrence of GERD, compared with only 7% to those undergoing open primary Nissen fundoplication [18], also with the robotic approach, failures of primary fundoplication occur between 2% to 4.7 % [19-21]. So, we can say that the recurrence of GERD after surgical treatment is frequent.

The most used approaches to perform the Nissen fundoplication in the world are the open and the laparoscopic. The robot-assisted has only been slowly adopted for use in children and in particular with the technique of the primary Nissen fundoplication, there is special controversy between laparoscopy and robotic approach, because pediatric surgeons experts in laparoscopy and several published studies, comparing both approaches, no significant advantages are observed with the use of the robotic approach, but yes, a big drawback, that robotic surgery increases costs [3,22,23]. However, robotic surgery offers advantages for the patient and for the surgeon, which means that procedures for the patient are safer.

It's important to mention in relation to the experience in the world of conventional laparo-thoroscopic surgery in children, that the application of this, have at least a decade more experience that the robotic surgery and a significant number of publications compare conventional laparoscopic results with robotic surgery, and where in the latter they include the learning curve of surgeons, what can influence the results and skew the conclusions, as to time of console surgery, complications, and conversions [22,24].

For example, Rothenberg with his vast experience in minimally invasive surgery in children, in his report on LPNF for a 20-years period and procedures realized were 2008, your results are: average operative time dropped from 109 minutes for the first 30 cases to 35 minutes for the last 30 cases. In redo surgery, of the 283 procedures that were RF, the complications rates were intraoperative 2.2% and PO 4.2%, The overall wrap failure rate for primary fundoplications was 4.6% and was highest in the <6-month age group. Based on the results presented, the

author states that LPNF should be considered the gold standard for antireflux procedures. But, even with the author's experience, the failure rate in the group of the laparoscopic redo Nissen fundoplication (LRNF), was 6.8% [4].

If conventional laparoscopy is used, the reconstructive and complex procedures are very challenging, and long periods of time are necessary to acquire the appropriate skills and confidence, vs. robotic surgery, the learning curve is shorter [25-28].

There are hospital centers in the world that reoperate the GERD, through open redo Nissen fundoplication, even having with minimal invasion, and in other studies they do not mention the option of laparoscopy [29-32] of what is inferred, the complexity of the surgical technique and probably the lack of experience in minimally invasive surgery.

Open redo Nissen Fundoplication or LRNF has a variable failure rate 6% to 42%, [4,16,33-35], what translates the high complexity of this pathology.

The robotic surgery enables more refined hand-eye coordination, superior suturing skills, better dexterity, and precise dissection. It is achieved by the characteristics of robotic surgical platforms that include motion scaling, greater optical magnification, 3D and stereoscopic vision, increased articulated instrument tip dexterity, tremor filtration, operator-controlled camera movement, and elimination of the fulcrum effect [36-39], and all of this translates into greater safety for patients and advantages for the surgeon.

Robotic surgery is one technology that has gained an enormous surge in use on adults. The general surgical applications have been quite varied in adults [40-43].

There have been few reports that have been published for robotic general pediatric surgery [44-53]. Numerous case reports, case series, and comparative studies have unequivocally demonstrated that robotic surgery in children is safe [54].

Cundy TP et al, [20] using cumulative summation analysis to define the learning curve for PRF, time-based surgical process outcomes were evaluated, as well as clinical outcomes, the authors identified numerous well-defined learning curve trends to affirm that experience confers significant temporal improvements, for the time of console surgery from procedure 34.

RF is generally more difficult because anatomic planes are obscured by adhesions from the previous surgery, whether it is open or laparoscopic and the very features that distinguish minimally invasive surgery can be the cause of concern in laparoscopic redo surgery because of adhesions. Thus, the application of laparoscopy to redo surgery, particularly in children, is controversial because of safety [33]. So complex laparoscopic surgery should be performed only by an expert pediatric surgeon, and with a high volume of surgical procedures.

Children presenting for initial or RF after feeding gastrostomy are a subset of patients that may benefit from the robotic approach.

This technique is particularly difficult in standard laparoscopy without dislodgement of the gastrostomy, particularly if there are abundant adhesions or a replaced left hepatic artery to preserve [55].

There is a scarcity of publications from Latin American countries to date that describe pediatric patients who have undergone robotic surgery [13,56,57], and in relation to the number of RALRNF publications in the world, it is also limited, including the adult and pediatric population [20,58-62]. Objective

of this study is to present our experience in RALRNF and highlight its advantages in children.

Material and Methods

This prospective, observational and longitudinal study of the robotic redo Nissen fundoplication (RRNF) performed on a pediatric population was conducted from March 24, 2015 to March 27, 2019. Our hospital is a public tertiary care facility, and the robotic surgery program include specialty of the pediatric surgery.

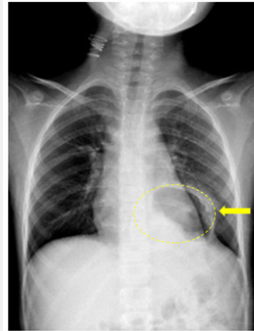


Figure 1: Male patient, 17 years old, 102kg, antecedent of LPNF, simple Rx with supradiaphragmatic radiolucency image by HH and recurrence of severe symptoms of gastroesophageal reflux (arrow and yellow circle).

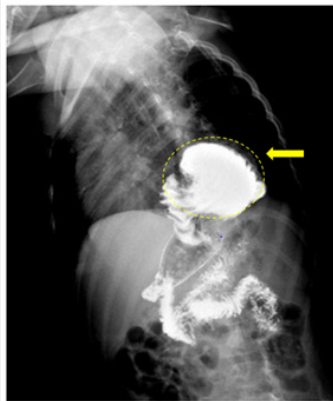


Figure 2: Patient figure 1, Rx barium study, shows important herniation of the stomach to the thorax, complex HH (arrow and yellow circle).

The diagnosis of recurrence of reflux and its complications was suspected by the presence of one or more of the following symptoms and signs: vomiting, regurgitation, heartburn, epigastric pain, dysphagia, coughing and wheezing, pneumonia, life-threatening events (apneic spells), among others, and confirmed with upper GI tract X-Ray (Figure 1 & 2), endoscopy, and in some cases impedance-pH measurement.

Non-random simples were, all pediatric patients who required RF included.

The parameters recorded were gender, age, weight, height, diagnoses, surgical technique, elapsed time of console surgery, estimated bleeding, hemotransfusion, complications, conversions,

PO hospital stay, and follow-up. The Clavien-Dindo classification of surgical complications was used [63,64].

The surgical system used was the da Vinci model, Si version (Intuitive Surgical, Inc., Sunnyvale, CA. U.S.A). We used 8mm robotic instruments and trocars, 3 robotic work arms, 8.5mm or 12mm robotic 30° lens for a three-dimensional camera, and a 5mm trocar laparoscopic for one assistant.

The docking charts for robotic surgery that are suggested for surgical techniques in adults were not applicable in infant patient, in this case, 4-5cm of separation was possible between each trocar, due to the limited space in such a small patient. The surgical technique used was Nissen Floppy fundoplication (RALRNF) (Figures 3-8).

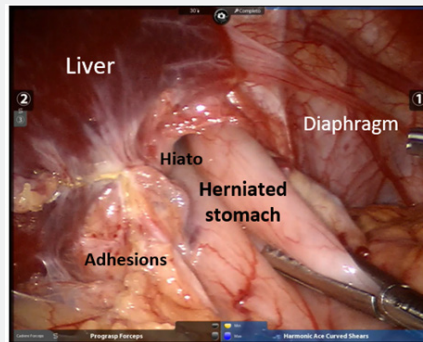


Figure 3: Patient figure 1, initial TO image, large hiatus, stomach herniated to the thorax, and dense adhesions, the RALRNF starts

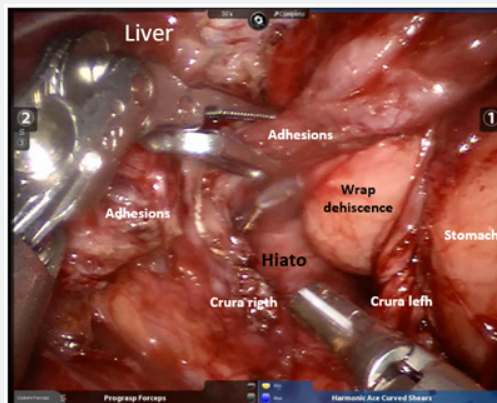


Figure 4: TO image, herniated stomach was reduced, adherensiolysis was partially performed, both pillars of the crura were identified, the hiatus is large, and the wrap is dehiscent.

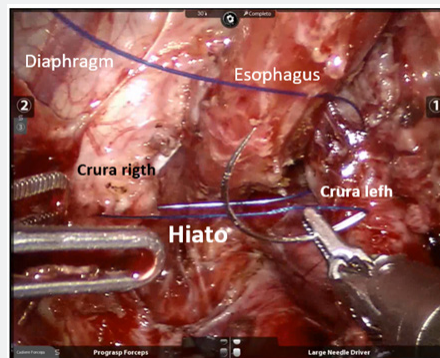


Figure 5: TO image, adherensiolysis was finished, the anatomy was completely identified, and hiatoplasty was initiated.

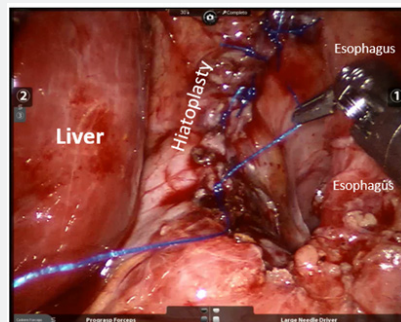


Figure 6: TO image, the hiatoplasty with nonabsorbable suture is concluded.

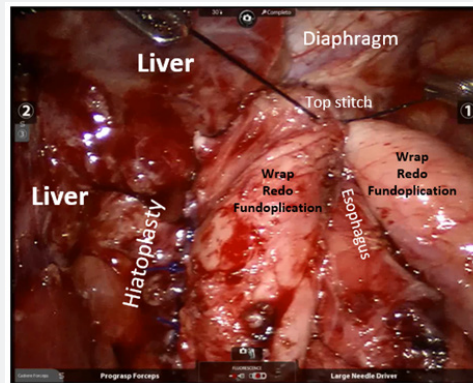


Figure 7: TO image, the RF starts, taking care of the technical details, the top stitch has been applied.

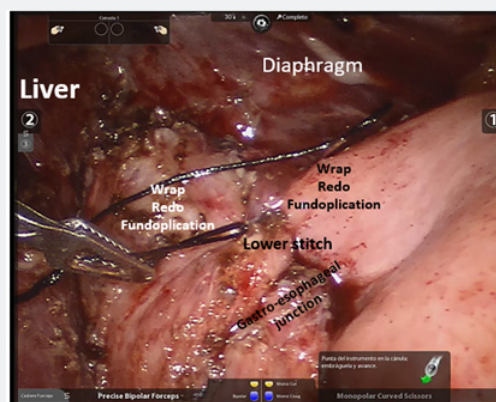


Figure 8: TO image, the redo fundoplication was completed, the wrap was stabilized, the lower stitch and esophagogastric junction were observed. The RALRNF is finished.

The PO follow-up was at 8, 30, and 90 to 120 days, and then every 6 months. Between 90 and 120 days, upper GI tract X-Ray studies were carried out to evaluate the anatomic results of the surgery.

We used measures of central tendency. The data was entered into a spreadsheet in Microsoft Office Excel 2013 version.

In relation to ethical considerations of the study, being of an observational nature, it was not necessary to consent to enter the study to the patients. The Research Ethics Committee of the Hospital evaluated and approved the study. In Mexico, robot assisted surgery complies with the records and regulations of the Mexican health authorities. In our institution, robotic surgery is routinely authorized for execution. In order to perform the medical-surgical procedures, we obtained the informed consent in writing from the parents or guardians.

Results

In a 48-months period, we performed 19 RALRNF in pediatric patients. Of the procedures, 66.16% [12] were in male, and the rest were female; the average age was 10.3 years, ranging from 7 months to 17 years. The average height was 135.2cm, and ranged from 62 to 185cm, with an average weight of 36.3kg, ranging from 5.2 to 102kg; the smallest patient was 7 months old with a height

of 62 cm and weight 5.2kg.

Our 3 most frequent GI procedures in the same period were, primary fundoplication [50], redo-fundoplication [19], and cholecystectomy [14] totaled 83 and represented 69.16% in this area, being the total 120 procedures GI, 13 of the RALRNF, they are part of the statistics of a previous publication [13].

Four patients (21%) they have neurological impairment. The previous fundoplication, in 10 (52.6%) it was open, laparoscopic in 6 (31.6%) and robotics in 3 (15.8%). One patient previously had 3 funduplications, one open and two laparoscopic. In our casuistic the failure rate of the PRF with recurrence of symptoms was 6% (3 patients), and recurrence was presented at 3.5, 11 and 24 months.

The average console surgery time in 4 cases (21%) of RF and gastrostomy procedures, including gastrostomy dismantlement, was 280min, varying the times from 235 to 328min, and in 15 cases (79%) of RF only, the average time was 185min, varying the times from 115 to 360min.

The index transoperative complications was 21% (4 casos), gastric perforations in 2, a splenic lesion and an esophageal perforation. This lesion are considered incidental, they do not alter PO evolution of patients.

The index conversion was 5.2 % and PO complications 0%. A failure of the RALRNF (5.2%), occurred at 7 months of the PO, in our patient, there are 3 risk factors for fundoplication failure: PRF at 3 months of age, neurological impairment present and prompt recurrence with RRNF at 6.5 months of age and this second recurrence to the 13.5 months of age.

The transoperative surgical findings that caused the failure were, HH and partial or total wrap dehiscence of the fundoplication 10 cases (52.63%) and only partial or total wrap dehiscence in 9 (47.37%). In addition to the above, the common transoperative findings are multiple adhesions and the liver firmly attached to the stomach, which makes it difficult to identify anatomical structures, more bleeding and predisposes to cause injuries to various anatomical structures.

Only one patient (5.2%) required hemotransfusion and conversion, his profile: a 9-year-old girl with a weight of 40kg, a fourth fundoplication, with 200ml of TO bleeding because the liver was firmly attached to the stomach, with multiple adhesions, difficult identification of its anatomy, a perforation occurred in the posterior face of the esophagus and the lack of adequate visibility of it, forced the conversion of the procedure to open.

The average PO hospital stay was 2.2 days, ranging from 1 to 5 days, and in 14 patients (73.7%) was 1 to 2 days.

The average follow-up was 24.1 months, with ranging from 3 to 49 months.

Discussion

Successful LRNF in adults was first reported by Frantzides and Carlson [65], followed by reports of small series of cases, some in children. As van der Zee, et al, between December 1993 and December 1998, for 100 children who underwent a laparoscopic Thal procedure, 4 of them had to undergo a LRNF. A child was found with an intrathoracic wrap and a giant HH, underwent a hernia repair and a redo-Thal, the procedure was more difficult due to a large HH and the technical limitations of the laparoscopic procedure. In two other children, the operation was relatively simple. The last child, the procedure had to be converted to open, and the authors concluded that, in children, it is feasible to LRNF after a previous laparoscopic fundoplication and does not increase morbidity [66].

Despite the increasing use of laparoscopic fundoplication, there has been relatively slow acceptance and significant criticism of its application for LRNF in children. The most major concern is that at redo surgery, adhesions are usually dense and tissue planes and gross anatomy can be distorted necessitating advanced laparoscopic skills.

Very high failure rates are reported until of 42% for RF [16]. Even though, Rothenberg insisted that in experienced hands, redo by laparoscopic is possible with good results: without conversions, under complication index, without mortality and

with a low failure rate 6% of RF [4]. In other report of children, more serious complications have been reported in relation to LRNF such as esophageal perforation or gastric leak secondary to difficult dissection, scar tissue, and adhesions from prior surgery [67]. In another report, of LRNF, there was a 21.8% incidence of visceral injury in 307 RF. Authors comment on their experience that reoperative esophageal surgery can be one of the most challenging procedures that a surgeon will face. Anatomy can be severely distorted by scarring, fundoplication herniation, and unexpected findings. Experience and knowledge of normal and abnormal anatomy is critical to not only a safe operation but also effective resolution of the patient's problems [68].

The diversity of transoperative surgical findings that caused the failure are: HH, wrap disruption, slipped wrap, crural stenosis, twisted wrap, and misplaced wrap, being the most frequent: HH, slipped wrap and misplaced wrap [68]. Our findings in relation to these, coincide with that reported in other series, HH and/or partial or total slipped wrap.

In the LRNF, it is recommended: extreme caution during dissection, because is tedious and anatomic landmarks are distorted, and successful completion of RF requires familiarity with this abnormal anatomy. In particular, younger trainees should be carefully supervised by surgeons with sufficient experience in revision surgery, for the complex and laborious of these cases, longer learning curve, in order to prevent serious complications, reduce conversions and hemotransfusions.

Total thickness perforation of the gastric and esophageal wall is common during RF and should be detected and resolved. But also during the surgical dissection can cause partial thickness visceral injuries or weakening of its walls, which we must also detect and repair, since potentially they can evolve towards the perforation in PO period, and obviously it is synonymous with abdominal catastrophe and its consequences, not detect an esophageal-gastric perforation during the transoperative period.

After an exhaustive search using the terms: robot-assisted, laparoscopic, redo, fundoplication and children, it was not possible to locate publications as or similar to ours., and if there are a good number of publications on open and laparoscopic approach of the RF, of which we have already made several considerations.

From our results the aspects that we consider transcendent are: the robotic procedures, fundoplication is surgical technique the most frecuente of robotic GI área [12], and the failure rate of the PRF (6%) and the RRNF (5.2%) are at the lower limits of what was reported in previous publications, without difference in relation to the antecedent of the primary fundoplication, with respect to those previously published, being in order of greater or lesser frequency in our casuistry, open, laparoscopic and robotic approach.

The transoperative findings found do not differ from those published in these cases of revision antireflux surgery, generally

with dense and firm adhesions, anatomy altered and difficult to identify, risk of significant bleeding when the liver was firmly attached to the stomach. We caused gastric and esophageal perforations, and splenic lesion, only the esophageal perforation was of significance, since it forced to the only conversion to open surgery, the others did not alter the PO evolution, and no PO complications or mortality occurred, and the PO stay was brief in the majority of the patients.

Independently that we do not find similar publications in children, to have a reference in relation to our times of console surgery, we consider that they are satisfactory taking into account the complexity of the cases.

The patient who required hemotransfusion and conversion was his fourth fundoplication and found the liver firmly attached to the stomach, firm adhesions, it was difficult to identify its anatomy, it favored an incidental perforation of the esophagus, and it was not possible to visualize its exact site, which forced the conversion to open surgery.

The failures of the fundoplication are more related to patients of younger age, with ongoing retching in the PO period, extensive dissection of the hiatus in primary surgery, patients with neurological impairment and a shorter time to re-operation [30, 69]. Our patient who evolved with recurrence after the robotic fundoplication redo, meets 3 of the 5 factors mentioned above.

It is very important to perform a fundoplication with any of the 3 approaches, to reduce the risk of failure to take into account the following recommendations: minimal dissection of the hiatus, only enough mobilization of the esophagus for adequate creation of intraabdominal esophagus, creation of a tension-free and appropriate orientation, and positioning of the wrap and omission of esophagocrural sutures [4,70,71]. As well as, the use of biosynthetic mesh enhance hiatal repair, can reduce the risk of failure [72].

The need for a revision surgery after a fundoplication is a very variable event and, fundamentally, it is considered that it depends on the experience of the surgeon and the volume of surgeries depending on the center where he works, and the volume of cases (experience) per surgeon [14]. The results of published series of patients with redo, open or laparoscopic fundoplication show that the index of failure of this, is greater than in primary surgery [29,31,62,69].

Robotic surgery has special applications in complex and reconstructive surgery. In the GI area in children, RRNF with HH or not and the correction of bilio-digestive anomalies, the robotic surgery is very profitable. In these procedures, from the open technique, we jump to robotic surgery. Due to the characteristics and advantages of this technology, it overcomes the limitations of conventional laparoscopy, we achieve a lower risk of conversions, fewer complications, less hemotransfusions, short stay PO, increase patient safety and the probability of failures and other reinterventions can be reduced, as our results show with medium-

term follow-up.

Due to the limitations of conventional laparoscopic surgery, complex cases or reconstructive surgery in children can only be performed by a limited number of highly qualified surgeons, with advanced skills and sufficient experience [73].

Long-term follow-up outcomes from large prospective comparative (randomized) studies are necessary to prove these preliminary data in support of the use of robotic systems in pediatric patients with failed anti-reflux surgery.

Conclusion

The failed fundoplication is frequent, and RF is complex, difficult and laborious technique. In the redo, open or laparoscopic fundoplication, the failure rate is higher than in primary surgery and increases with other re-operations.

With the RALRNF, we achieved low risk of conversion, no complications, few hemotransfusions, short PO stay and low recurrence rate for our patients, for which we affirm that RALRNF is safe and effective and if offers advantages to the pediatric population.

There are few publications of RALRNF in children. Advantages of robotic surgery are application in complex surgeries, in small operating field, difficult access, delicate dissection, need control of hemostasis and intracorporeal sutures. Only expert pediatric surgeons solve them, by conventional laparoscopy.

Long-term follow-up outcomes from large prospective comparative (randomized) studies are necessary to prove these data's in support of the use of robotic systems in pediatric patients with failed anti-reflux surgery.

Conflict of Interest

The author declares to be Proctor of the da Vinci Surgical System and sometimes receives salary for advice to Surgeons in their first robotic procedures, from the marketing company in my country, as part of the support in the training of Surgeons by this company. But, in relation to the treatment of patients and the execution of this manuscript, no economic financing was received from commercial companies.

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