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Laparoscopic gastroesophageal dissociation in neurologically impaired children with gastroesophageal reflux disease☆

Jonathan H. DeAntonio, Dan W. Parrish, Shannon F. Rosati, Claudio Oiticica, David A. Lanning *

Children's Hospital of Richmond at Virginia Commonwealth University (CHOR at VCU)

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ABSTRACT

Purpose: Neurologically impaired children with severe gastroesophageal reflux disease (GERD) are a challenging group of patients. We theorized that a laparoscopic gastroesophageal dissociation (LGED) may decrease reflux-related readmissions and healthcare visits, and improve quality of life (QOL) for them and their caregivers.
Methods: A retrospective review was performed on our pediatric patients that underwent an LGED along with a caregiver survey from 2013 to 2017.
Results: Twenty-two neurologically impaired patients (14 months–17 years) with severe GERD underwent an LGED. Patients weighed 7.9-57 kg (avg = 23.8 kg), length of stay ranged from 5 to 20 days (avg = 12 days), estimated blood loss ranged from $<5cm^3$ to $450cm^3$ (avg = 66 cm^3, median = 25 cm^3), and duration of operation ranged from 299 to 641 min (avg = 462 min). One death occurred on postoperative day 19 from gram negative sepsis (30-day perioperative mortality of 4.5%). There were a modest number of minor and major complications (follow-up avg. = 13.7 months, range = 2–40 months). There was a decrease in healthcare visits for respiratory illnesses (rated 5/5 from all 13/19 survey respondents) as well as improvements in perceived QOL of the patient (avg = 4.3/5) and caregiver (avg = 4.6/5).
Conclusions: Our cohort of patients had a reduction in readmissions and healthcare visits, and improved QOL after undergoing an LGED based on the perceptions of their caregivers. In neurologically impaired patients with severe GERD, an LGED may be a viable alternative to traditional treatments.
Type of study: Retrospective case series review.
Level of evidence: Level IV evidence: case series without comparison.

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Neurologically impaired (NI) children have a significant risk of gastroesophageal reflux disease (GERD) and aspiration resulting in high numbers of yearly hospitalizations and health care visits [1–3]. These factors lead to a significant decrease in patient and caregiver overall quality of life (QOL) [2,4,5]. In the United States, those children that fail medical management are often treated with a Nissen fundoplication. Debate continues as to whether NI children have a higher fundoplication failure rate, which varies by definition, laparoscopic vs open procedure, and length of follow up [6–10]. Zaidi et al. reported a compiled fundoplication failure rate for neurologically impaired patients to be 12% to 45% for primary and 20% to 28% in redo fundoplications; others have stated 6% to 24% for primary procedures [4,6]. These failures lead to a redo fundoplication 6% to 14% of the time [2]. Most patients with severe, recurrent GERD after a failed fundoplication would have a redo fundoplication or be fed continuously via a gastrojejunal (GJ) or jejunostomy (J) tube. Neither is associated with high rates of success, and all have considerable risks, whether owing to increased operative time because of extensive lysis of adhesions, increased rate of failure for redo fundoplications [4], or the challenges of continuous feeds compared to gastric bolus feeds.

Gastroesophageal dissociation (GED), originally termed a total esophagogastric dissociation (TEGD), was first described by Bianchi in 1997 [11]. It has been used in Europe as a redo, rescue, and even as a primary procedure for severe GERD [2,4,6,11,12]. TEGD/GED has been shown to reduce GERD and respiratory complications, improve postoperative nutrition and QOL for NI children, and improve caregiver's perception of being able to care for their child [2,4,6,12]. It has also been shown in retrospective and prospective comparisons to laparoscopic Nissen fundoplications to have lower failure rates [2,6] and equal or improved results as an antireflux procedure with less use of antireflux medications post procedure [2]. However, in these

☆ **Author Contributions: Jonathan H. DeAntonio, MD**: study conception and design, acquisition of data, analysis/interpretation of data, drafting of manuscript, critical revision of manuscript. **Dan W. Parrish, MD:** study conception and design, acquisition of data, analysis/interpretation of data. **Shannon F. Rosati, MD:** study conception and design, acquisition of data, analysis/interpretation of data. **Claudio Oiticica, MD:** study conception and design, acquisition of data, analysis/interpretation of data, critical revision of manuscript. **David A. Lanning, MD, PhD:** study conception and design, acquisition of data, analysis/interpretation of data, drafting of manuscript, critical revision of manuscript

* Corresponding author at: Children's Hospital of Richmond, Virginia Commonwealth University Health System, Professor of Surgery and Pediatrics, Department of Surgery/Division of Pediatric Surgery, P.O. Box 980015, Richmond, VA 23298. Tel.: +1 804 828 3500.
E-mail address: david.lanning@vcuhealth.org (D.A. Lanning).

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comparisons, GEDs have longer operating times [2,6], increased ICU care postop [2], increased length of stay (LOS) in ICU postop [2], and increased time to full feeds [2]. Interestingly, there are only limited reports of utilizing this approach in the United States [13]. There are several studies that have shown redo Nissen fundoplications can be safely and effectively done laparoscopically; however, there is limited long term follow-up, especially regarding redo Nissen fundoplications in NI children [7–10,14–16].

Our experience began in 2013 as a rescue procedure during a redo Nissen fundoplication for a patient who had two previously failed fundoplications. We then began researching TEGDs and now have developed a pilot series of a laparoscopic gastroesophageal dissociation (LGED) technique that has been performed on a total of 21 patients (22 total counting the first open procedure). We have also begun an initial, retrospective review of these procedures and surveying the caregivers for patient and caregiver QOL. We theorize that a laparoscopic gastroesophageal dissociation may decrease rates of aspiration and hospital readmissions as well as improve QOL for patients and their caregivers.

1. Methods

1.1. Selection criteria

All patients have neurologic impairment (NI) with diagnoses such as cerebral palsy, microcephaly, seizure disorders, or Down syndrome and other genetic syndromes. Each patient was determined to have moderate/severe reflux by a pediatric gastroenterologist and had failed maximal medical therapy (PPIs and/or distal feeding) prior to being referred. Most of our patients had at least one Nissen fundoplication, whereas 3 had the LGED as a primary procedure. Unfortunately, owing to the retrospective nature of this evaluation not every patient was managed by the same gastroenterologist nor did each have the same standardized work up, but all were determined to have been treated with maximum medical therapy prior to referral. Similarly, their reasons for referral also varied greatly but included recurrent aspiration events, failure to thrive, failure of GJ or J tube feeds, or documented reflux after failure of their fundoplication.

1.2. Description of procedure and postoperative care

In the initial technique for the LGED, the esophagojejunal (EJ) anastomosis was performed with the assistance of the Intuitive Surgical da Vinci Robot (5 patients), with the perception that the increased range of motion of the wristed instruments and stereoscopic visualization provided by the robot would improve the difficult dissections for the redo procedures and ease of creating an intracorporeal anastomosis. The next iteration used an End to End Anastomosis Stapler (EEA), whereas we now perform a laparoscopic hand sewn anastomosis.

Incisions are made as for a typical redo fundoplication with the addition of a 12 mm trocar in the right lower quadrant and a 5 mm trocar cephalad to the gastrostomy tube site. Please see Fig. 1 for a diagram of port placements.

Almost all our patients had one or more prior operations and required extensive lysis of adhesions. The anterior and posterior vagus nerves are dissected off the distal esophagus, and attempts are made to preserve at least one of these nerves. No pyloroplasties were performed in our series of patients. Once the gastroesophageal junction (at least 2 cm of distal esophagus) is mobilized into the abdomen, the hiatal defect is closed while anchoring the esophagus to the crura at the cardinal positions. An Endo-GIA stapler is then used to transect the esophagus at the lowest healthy part. The jejunum is then transected with another Endo-GIA stapler at approximately 25 cm distal to the ligament of Treitz. The alimentary (Roux limb) is passed towards the hiatus in a retrocolic, retrogastric manner, with care taken to ensure that the limb is not twisted. In 6 of the more recent patients, the alimentary limb was passed in an antecolic, antegastric manner. An antimesenteric enterotomy is made 2 cm proximal to end of the alimentary limb and the staple line is removed from the esophagus creating an end to side, isoperistaltic anastomosis. A leak test is performed by distally occluding the jejunum with an atraumatic bowel grasper, while submerging the esophagojejunal (EJ) anastomosis under irrigation while the patient is in Trendelenburg position. An anesthesia team member instills air through nasal jejunal tube until the jejunum becomes mildly dilated and the absence of bubbles is confirmed. The alimentary limb is further anchored to the surrounding tissue and Petersen's defect is closed. A stapled side to side, functional end to side jejunojejunostomy is created approximately 30 cm distal to the EJ anastomosis. The mesenteric defect at the jejunojejunostomy is also closed with interrupted sutures. Please see Fig. 2 for a drawing of the completed LGED procedure. Lastly, drains are placed anterior and posterior to the EJ anastomosis. Postoperatively, our typical patient is extubated, admitted to the pediatric intensive care unit with a nasojejunal tube to low intermittent suction (operatively placed through the EJ anastomosis), 2 drains to bulb suction, and the gastrostomy tube to gravity drainage.

Following an early perioperative death, explained fully in the results section, our postoperative protocol has evolved to 5 days of broad spectrum intravenous antibiotics (ceftriaxone and metronidazole). Postoperatively an upper gastrointestinal (UGI) study is performed with water soluble contrast to evaluate for leaks at the anastomoses. Patients are fed and medications are given via a gastrostomy tube in the remnant stomach. Patients are also allowed to restart feeds by mouth following a negative UGI.

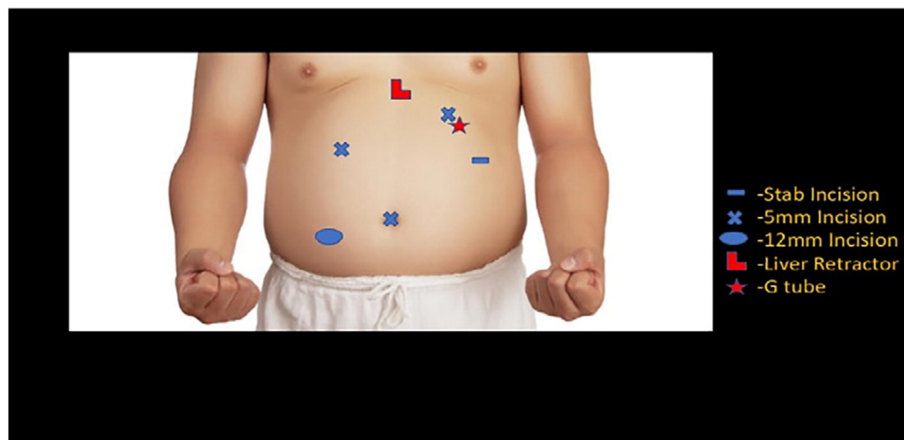

Fig. 1. Diagram of port placement for an LGED.

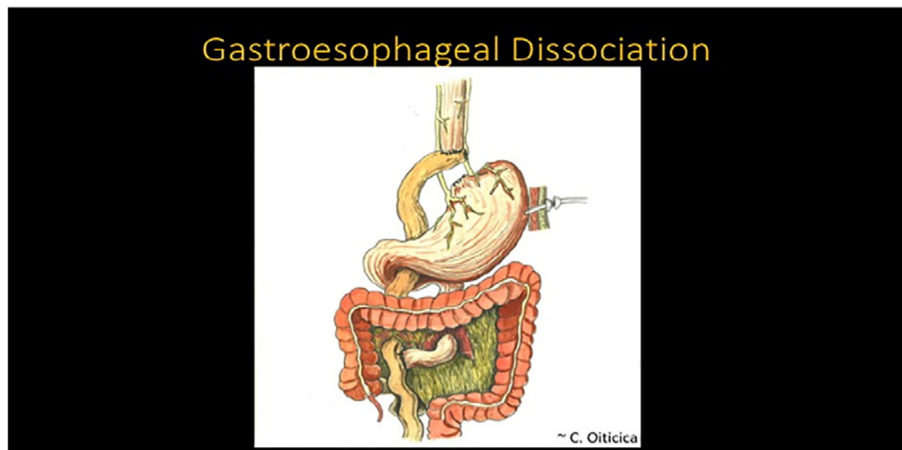

Fig. 2. Diagram of a completed LGED.

1.3. Follow-up and survey

Readmissions were evaluated by chart review at two separate time points in September of 2015 and 2016. We originally used a survey published by Zaidi et al. in 2009, to assess the QOL for NI children and their caregiver, following an esophagogastric dissociation. [4] The survey was explained and given to each patient's caregiver at a subsequent follow-up visit, or it was explained and completed over the phone. A standardized statement about the purpose of the survey and its voluntary nature, and then an explanation of Likert (1–5) scoring system were read or given to the caregivers prior to filling out the survey. The survey questions are listed below in Table 1. The caregivers were asked if they had any questions and for consent to participate. Each question was read as many times as needed in person or over the phone and the score for each was reported. Throughout the survey their comments were also reported. For the most recent 5 patients, a modified survey was created to reduce the time needed to complete it in clinic and by phone (decreased from 21 questions to 4). The original was also shortened based on our main objectives of monitoring readmissions, healthcare visits for aspiration and reflux, and quality of life for patient and caregiver. This new survey is listed in Table 2. The responses for the surveys, including the modified one, since it included questions from the original, were averaged to obtain an overall perceived QOL assessment for the patients as well as their caregivers.

2. Results

Twenty-two neurologically impaired patients (14 months to 17 years of age) with severe GERD underwent an LGED with 19 of them having had at least one prior fundoplication (max = 3). Patients weighed 7.9 to 57 kg (average = 23.8 kg), LOS ranged from 5 to 20 days (avg. = 12 days, Median = 11.5 days), and estimated blood loss ranged from <5 cm^3 to 450 cm^3 (avg. = 66 cm^3, median = 25 cm^3). The duration of operation ranged from 299 to 631 min (avg. = 462 min). The laparoscopic Nissen converted to open GED procedure required 727 min and was not included in operative duration for LGED. Primary LGED procedures (N = 3) averaged 385 min (operative times of 348, 350 and 450 min), which is not significantly different from the nonprimary cases (p-value of 2.09).

One patient died from gram-negative sepsis on postoperative day 19 (30-day perioperative mortality of 4.5%), and two others died during the follow-up period owing to unrelated causes. The patient who died during the immediate postoperative period was noted to have gram-negative bacteremia without evidence of leak on UGI study or

Table 1
Modified follow up survey from Zaidi T. [4]. QOL is quality of life.

Parent/caregiver's perception of the outcome for their child (1 = worst could possibly be, 2 = poor, 3 = average, 4 = good, 5 = excellent)
1. How easy is it to feed your child?
2. Does your child get uncomfortable during feeding?
3. Does your child choke/gag during feeding?
4. Does your child vomit?
5. Is retching a problem?
6. Does your child experience constipation?
7. Does your child experience wind after feeding?
8. Does your child experience frequent chest infections not requiring hospital admission?
9. Does your child experience frequent chest infections requiring hospital admission?
10. How comfortable is your child generally?
11. How able is your child to enjoy life?
Parent/caregiver's perception of their and their child's overall Quality of Life (QOL) (1 = worst could possibly be, 2 = poor, 3 = average, 4 = good, 5 = excellent)
1. How easy is it to care for your child overall?
2. How much can you enjoy your child overall?
3. How would you rate the quality of time you spend with your child?
4. How would you rate your level of frustration when taking care of your child?
5. How worried are you about your ability to look after your child properly?
6. How do you rate your overall QOL?
7. How optimistic are you about your child's future?
8. How optimistic are you about your future?
9. How do you rate the amount of time you spend caring for your child's medical/physical needs?
10. How do you rate the frequency of visits and calls to doctors, hospitals, and other health care/social services?

Table 2
Revised Survey utilized during the last 5 patients. QOL is quality of life.

Revised Survey
(1 = worst could possibly be, 2 = poor, 3 = average, 4 = good, 5 = excellent)
1. Has your child been admitted to the hospital for reflux-related pulmonary or aspiration problems?
2. How do you rate the amount of time you spend caring for your child's medical/physical needs relating to reflux and feeding?
3. How would you rate the frequency of doctor's visits for reflux, aspiration, pulmonary problems?
4. As it relates to your child's reflux problem, how do you rate your overall QOL? Your child's QOL?

exploratory laparotomy, as well as, any abscess or other pathology on CT scan. This patient only received preoperative antibiotics. Antibiotics are now broadened (ceftriaxone and metronidazole) and extended for 5 days postoperatively as most patients require extensive adhesiolysis leading to disruption of the liver capsule, which is followed by an EJ anastomosis in this location. Another patient who previously had two lyses of adhesions and bowel resections, returned to the operating room on postop day 5 for a lysis of adhesions. An additional patient had a small, contained leak on postoperative day 3 UGI study but remained hemodynamically stable with a benign physical exam. Repeat UGI study on postoperative day 5 demonstrated that the leak had resolved. This led to a change from EEA stapler to a laparoscopic hand sewn anastomosis, along with attempts to reduce the cost of the procedure. Lastly, a patient who resides in a long-term care facility developed an internal hernia approximately 10 months following his LGED procedure. He was taken emergently for exploratory laparotomy, underwent partial small bowel resection and ultimately reanastomosis. He was eventually discharged to his long-term care facility and is currently back to his baseline status, on full enteral feeds. This patient had an antecolic, antegastric alimentary limb. Petersen's defect was not closed (only closed in retrocolic, retrogastric alimentary limbs, at the time of this operation); however, following this internal hernia, Petersen's defect is now partially closed for antecolic alimentary limbs.

During the follow-up period (avg. = 13.7 months, range 2–40 months), of the 19 living patients, there were 5 readmissions (follow-up period readmission rate = 26.3%), one for a dislodged feeding tube, two with viral illnesses, and one with pharyngeal aspiration. There was a decrease in healthcare visits for aspiration and respiratory illnesses determined by survey responses (rated 5/5 from all 13/19 survey respondents), as well as improvements in perceived QOL for the patient (avg. = 4.3/5) as well as the caregiver (avg. = 4.6/5). Caregivers were also asked for general comments about the procedure during the survey, all of which were positive and included: "Approximately 8 admissions for respiratory or aspirations the year before surgery, now none [since].", "Awesome, a God send, best I've seen him in 14 years.", "Gaining weight, doing so much better, [I] don't have to worry about aspiration of food.", and "He has never been this happy, [which] makes me happy.".

3. Discussion

NI children have a high incidence of GERD owing to prolonged periods of being supine, spasticity and scoliosis causing increased intraabdominal pressures, and often having a hiatal hernia. [3] Furthermore, the treatment of severe GERD in this population is challenging, especially after failure of a Nissen fundoplication, and is often with medications and/or GJ feeds. These methods have their own well known complications and effects on QOL, such as continued aspiration, migration of jejunal portion of GJ tube back into the stomach, and having to undergo continuous instead of bolus feeds, which are labor intensive and more complex to manage for caregivers. Redo Nissen fundoplications have also been used to treat this difficult problem, especially when there is a hiatal hernia present [14–16]; however, with reported failure rates of 20%–28%, another viable option is needed. [4] Numerous publications have shown that a TEGD/GED has equal or improved results when compared to fundoplication as a primary or redo procedure, including reduced respiratory complications, lower failure rates, improved antireflux results with less postoperative medication usage, and improvements in perceived QOL for patient as well as their caregivers. [2,4,6,12]

LGED is a complex, lengthy operation that can be associated with minor and major complications, especially if done as a redo procedure after one or more failed fundoplications (19 of 22 in our series, with a max of 3 previous fundoplications). TEGD/GED has been shown to have longer operating times [2,6], increased ICU care postop [2], increased LOS in ICU postop [2], and increased time to full feeds when compared to fundoplication. [2] In our retrospective review, the 30-day perioperative mortality was 4.5% (1/22) and the readmission rate during our 14-month average follow up was 26.3% (5/19). In a meta-analysis, published in 2013, of 157 GED procedures in NI children, 105 were primary procedures and 52 were rescue procedures. There were 29 (18.5%) early complications (<30 days, i.e. EJ anastomic leak, slow gastric emptying, and small bowel obstruction) and 24 (15%) late complications (>30 days, i.e. internal hernia, paraesophageal hernia, and small bowel obstruction) with 5 (3%) deaths related to the procedure and 19 (12%) patients required reoperation during the study periods. [17] As a reference, the nonneurologically impaired group had no early complications, 4 late complications, 1 death related to procedure, and 1 reoperation. [17] However, from our experience, and that of the many European publications discussed previously, for a very specific, complex patient population, this procedure has a high likelihood of permanently treating recurrent reflux, aspiration, and improving the QOL of the patient and their caregiver by reducing respiratory healthcare visits and readmissions, and improving feeding habits.

Throughout our experience the LGED procedure and postoperative management have been refined with the goal of decreasing operative time, length of stay, and complications. We also theorize that the purely laparoscopic approach, with a hand sewn anastomosis, decreases surgical time owing to not having to dock the robot or change the instrument arms, decreases costs associated with robot and EEA stapler, and results in a more secure anastomosis in our series. We have even more recently transitioned to an antecolic, antegastric alimentary limb, as our standard of practice, to decrease operative times. We currently do not have enough patients to statistically compare each iteration of the procedure and evaluate these goals.

To the best of our knowledge, there has not been a similar laparoscopic series of patients published previously and the majority of our patients received an LGED following 1–3 previous fundoplications. There are several advantages to the laparoscopic approach. It provides excellent visualization given that these patients often have severe scoliosis or contractures, and are smaller than average size for their age. Also, when comparing our laparoscopic series to a recent publication from Manchester, England, we have a lower dehiscence rate (0% compared to 7.5%), another advantage to the laparoscopic approach. As our series is mainly redo procedures, most patients required extensive adhesiolysis and our operative times ranged from 299 to 631 min (avg. = 462 min), which are longer than those reported in the European series. [6] We attribute this longer time to a significant learning curve for a difficult operation and to extensive adhesions in our redo population. In our own primary LGED procedures (N = 3), the average was decreased to 385 min, which is not significantly different from the nonprimary cases (p-value of 2.09).

Our study is limited significantly by its retrospective nature. This requires a reliance on caregiver survey data to evaluate readmissions related to aspiration or reflux (that didn't occur in our hospital system), related healthcare visits, and perceived quality of life of patient and caregiver completing the survey. Also, our patient population is highly variable by age, overall size, causes of neurological impairment, preoperative health, and gastroenterology evaluation and medical

management prior to the procedure, leading to no consistent, objective measurement of GERD severity.

Lastly, we suspect that healthcare costs for these very complex patients would be significantly reduced over time because of decreased admissions and reductions in the cost of further care for their chronic GERD, but this series was not established to evaluate this topic. To answer more of these questions and decrease the limitations, we are actively recruiting new patients for a prospective clinical trial to compare LGED to a redo laparoscopic Nissen fundoplication.

4. Conclusion

In neurologically impaired patients with recurrent GERD, relying on long-term gastrojejunostomy feeds or redoing their fundoplication often leads to significant reflux-related problems. While associated with some minor and major complications, our cohort of patients had a reduction in readmissions for reflux-related respiratory illness, and improved patient and caregiver QOL. In neurologically impaired patients with severe GERD, an LGED may be a viable alternative to traditional treatments in this challenging patient population.

Appendix A. Discussions

Presented by Jonathan DeAntonio, Richmond VA

THOMAS INGE (Denver, CO): I wanted to applaud you for publishing this work. It is an important realization that sometimes our fundoplications are not adequate, and sometimes we have to do more. I have certainly done this operation before, too, and I rise to point out that this is really not different in principle and anatomy from what we do for morbidly obese teenagers in the form of gastric bypass, and that is an operation that certainly has consequences long term for nutrition. I guess I would just ask what nutritional protocols do you use because it really is incumbent upon us not only to do the surgery but also to manage them longer from a nutritional standpoint.

JONATHAN DE ANTONIO: Thank you. All these children, at least for our series because they are redo most of the time, already have a G-tube in their excluded stomach, so their nutrition mainly comes from that. The oral feeds basically go back to their baseline status, which for a lot of them is just comfort by mouth, and then also this is an EJ or an esophagojejunostomy, so we actually just have the excluded stomach that we can feed into.

TODD PONSKY (Akron, OH): I just want to congratulate you also. I think that every once in a while we find new paradigm changes, and I would say this is one of those. I heard John Densmore present something similar in Peru, and I think this is a total new concept for a lot of us who just keep redoing Nissens. I think this is something we have to pay close attention to because this is one of those paradigm changes that we have to take very seriously, so congratulations.

JONATHAN DE ANTONIO: Thank you very much.

SHAUN KUNISAKI (Ann Arbor MI): Very nice study on a very challenging group of patients. My question is just with regards to your experience with the open procedure. Was there any previous historical experience with the open procedure or another control group, because you know this is obviously a very technically challenging operation. I guess the mean times were eight hours for these, and so do you feel like the laparoscopic approach perhaps offers some advantages to the open approach, and is there a learning curve to this?

JONATHAN DE ANTONIO: To address your first question, the actual historical precedence for the open procedure is actually still done in Europe in an open fashion, and almost all the studies in Europe were open procedures. Of note though, they do for their longer ranges still have almost eight hours as their longest range, because especially if it is a redo fundoplication or a redo procedure, these children will have extensive lysis of adhesions, almost over two hours. Laparoscopically, we found that the typical surgeon dictum or dogma still exists. If we are not making progress, we will convert to open. Fortunately, we have not had to, but in these kids that have scoliosis and a lot of other issues, it provides we believe better visualization to have it done laparoscopically and is a better working area for us at least from our series.

HENRI FORD (Los Angeles CA): It appears that you did primary operations in people who did not have — what was the indication for that?

JONATHAN DE ANTONIO: During our prospective trial we are actually now offer the families both. They either can have a Nissen fundoplication or in some cases a redo fundoplication, but they also have the option of going along with this as an LGED, which is our procedure. The children sometimes are from family members who have either heard about the procedure or have had very significant beneficial results and have seen how it works, so they will come in and actually request it, either through social groups where they meet the mothers and parents. In Europe this is actually done as a primary procedure, so they are actually not even doing the redo as much. The most recent series had 40 cases in Europe, and 33 of them were primary procedures with only seven being redo.

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