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Effectiveness of robotic assisted laparoscopic nissen fundoplication in neurologically impaired children with severe gastroesophageal reflux disease

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Abstract
Laparoscopic Nissen Fundoplication is still the most widely used surgical technique in the treatment of gastroesophageal reflux disease (GERD) in children. However, there are some technical and anatomical difficulties in the treatment of reflux in NIC with GERD. All these difficulties lead to the high rate of surgical failure observed in neurological impaired children (NIC). Robotic surgery provides several advantages in overcoming these difficulties. This study is the first study to evaluate the effectiveness of robotic surgery in the treatment of GERD in children with severe or moderate neurological impairments reported in Turkey. This study took place between January 2018 and February 2020. We retrospectively evaluated the records of eleven children with severe or moderate neurological problems who were treated using the robotically assisted laparoscopic Nissen fundoplication (RALNF) technique for demographic data, anesthesia time, pre-console time, console time, and postoperative complications. Nine of the patients (81.8%) had serious and two had moderate neurological problems. All of the patients applied to the emergency department at different times due to recurrent lung infections. While the first RALNF console time was 240 minutes, this study revealed that this time decreased to 45 minutes. None of the patients had complications related to the surgical procedure, but four patients required postoperative intensive care unit up to two months due to several problems related to NIC. RALNF can be safely applied to pediatric patients with GERD with severe and moderate NIC.

Keywords: fundoplication, gastroesophageal reflux, laparoscopy, neurologic disorders, robotic surgical procedures

1. Introduction

Gastroesophageal reflux disease (GERD) is a common and important gastrointestinal tract disease of childhood (1, 2). Neurologically impaired children (NIC) have an increased risk for GERD and GERD dependent comorbidities, such as recurrent upper and lower respiratory tract infections, severe feeding and growth (3). Serious neurological damages in these children result in frequent emergency service visits and persistent pulmonary problems, such as persistent coughing, asthma, apnea and apparent life-threatening situations (4). Thus, the development of progressive lung infections and chronic lung diseases is often inevitable (5). Symptomatic GERD incidence has been reported as high as 20-30% in NIC. These high rates are mostly due to several sub factors causing decreased esophageal acid clearance and increased reflux episodes. Medical treatment is the first choice in NIC with GERD. However, unsuccessful medical treatment brings surgical options to the fore. Open or laparoscopic Nissen fundoplications are the most acceptable surgical techniques in NIC with GERD. While recurrence rates after open or laparoscopic Nissen Fundoplication in non-NIC have been reported as 2-5%, they were reported as high as 45% in NIC. Therefore, surgical treatment of GERD in NIC is still a significant challenge for surgeons and patients (3, 6, 7). Laparoscopic anti-reflux surgery is still the first preferred technique in children (5). However, Laparoscopic Assisted Nissen Fundoplication (LANF) has some disadvantages, especially for surgeons, such as the need for advanced laparoscopic skills, difficulties in the exposure of the esophageal hiatus, knot tying in a very small space and dissection of the gastro esophageal junction, etc. (8).

The first cases for robotic assisted laparoscopic surgery of GERD were reported in 2001 (9). Afterwards, robotic assisted laparoscopic surgery for GERD has been widely accepted and performed. One of the reasons for the development of Robotic surgery (RS) is to overcome the difficulties present in traditional laparoscopic surgery (10). RS has some unique advantages for surgeons and patients while performing fine surgical techniques in small spaces (8, 11, 12).

Endowrist function which allows 180° articulation and 540° rotation and greater 3D optical magnification, delicate instrument motion, tremor filtration, operator controlled highly versatile camera movement, elimination of the fulcrum effect are the striking features of the Robotic Surgical system

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(Da Vinci® surgical system, Sunnyvale, CA, USA) (8, 10, 13).

There are only limited data about the effectiveness of RALNF in NIC with severe GERD.

2. Materials and Methods

This study was designed according to the Helsinki Declaration and approved by the Ethics committee of the hospital (10.03.2020/ 46418926). Between January 2018 and February 2020, we reviewed retrospectively eleven children with NIC who were operated for GERD. All of the patients were diagnosed with GERD according to Rome 4 criteria and followed by an experienced pediatric gastroenterologist. We performed RALNF on the patients who were resistant to medical treatment. We evaluated the patients' socio-demographic data, body weight, body mass index, associated disorders, intraoperative findings, operative protocols, complications and operation time and length of hospital stay.

2.1. Surgical techniques

The patients were accepted to the clinics a day before the operation. Fig. 1 shows the patient, robot and trocar positions. After fixing the patients to the table for the operation, we gave the table Trendelenburg position close to 30 degrees (10-30°). One of the main differences between LANF and RALNF is the positions of the trocars. Due to the length of the robotic arms and instruments and the thoracoabdominal deformities of the patients, trocar access sites are customized for each patient.

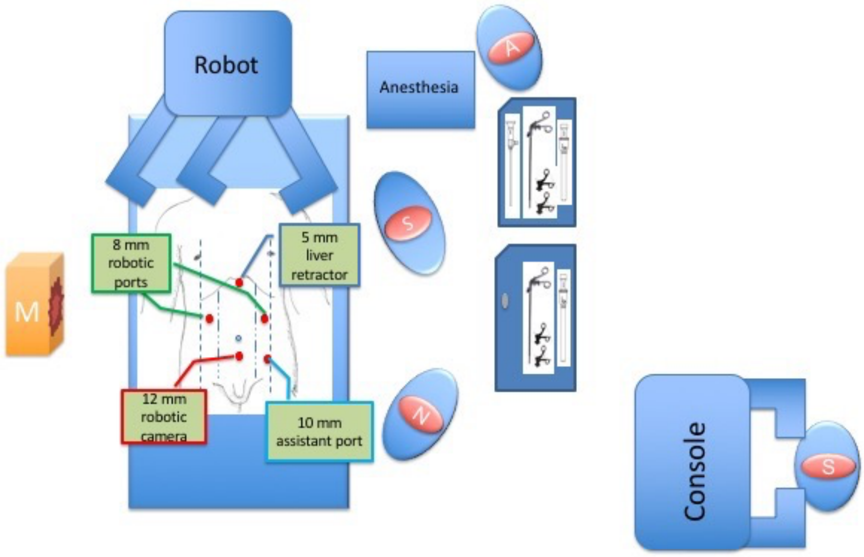

Fig.1. Operation room set up, patient, robot and trocar position during RALNF

We used the Da Vinci SI® surgical system (Intuitive Surgical, Sunnyvale, CA, USA) with a camera arm and three instrument arms. As standard, we used one camera port (12 mm), two working ports (8 mm) and 5 mm incision for liver retractor (Strong Arm™, Nathanson liver retractor system, USA), and 10 mm trocar for an assistant port (we used an additional assistant port for the use of steppes for a patient, who also underwent gastrojejunostomy). All surgical procedures were performed by two pediatric surgeons.

We selected the umbilical trocar position according to the patient's body length; the younger the child, the lower the trocar entry. We used Maryland® bipolar forceps, needle driver and the harmonic scalpel (Ultracision, Ethicon, Cincinnati, OH, USA) for robotic arms in all cases and selected hook cautery or scissors according to availability. We found hook cautery more useful due to articulation.

We drove a laparoscopic grasper through the left robotic trocar to grasp the stomach of children who required gastrostomy and performed gastrostomy under camera view on two layers using 2-3 / 0 polyglactin (YUCE, Turkey).

2.2. Definition of terms

Severe neurological impairment: Bed dependent neurological problems which result in motor and cognitive impairments.

Moderate neurological impairment: Non-bed dependent children with a lesser degree of motor and cognitive impairments (13).

Pre-console time: Starts from placing the patient on the operating table and ends with the surgeon sitting on the console

Console time: Time between the end of the pre-console time and leaving the robot

Docking: Attachment of the robotic system to the patient and trocar placement

Anesthesia time: Includes the total time that the patient was taken to and removed from the table.

3. Results

We included in the study eleven children who were followed up for GERD and underwent RALNF. Two of the patients were girls, and nine were boys. The median age of the patients was 10 (range: 25 months- 17 years). The median body weight was 19 kg (range: 8-44 kg), while the median body mass index was 16.7 kg/m^2 (range: 7.7-36.4 kg/m2). Nine of the children had cerebral palsy (CP) (81.8%), while seven had coexistent epilepsy (63.6%). One patient had pons hypoplasia with corpus callosum agenesis, while the last one had Klinefelter's syndrome with CIT gene mutation (citron rho-interacting serine/threonine kinase) and severe growth retardation (less than 1% percentile). One patient without CP had HERC2 and BCKDHA genes associated with maple syrup urine disease (MSUD) and severe respiratory insufficiency (Table 1). Two of the patients were moderate, while nine were severe NIC patients.

Table 1. Demographic and clinical features of eleven children treated using the RALNF technique

#	Gender	Age (year)	Height (cm)	Weight (kg)	BMI	ASA score	Surgery procedure	Notes	TLHS (day)	Additional disease
1	W	11	150	33	14,70	II	HHR+ RALNF + G	ICU	10	CP + Epilepsy + PEG(+)
2	M	16	150	42	18,70	III	HHR+ RALNF + G	ICU	1	CP + Epilepsy
3	M	2(+1 month)	70	8	16,30	II	HHR+ RALNF + G	ICU	2	CP + Epilepsy+ Pons hypoplasia + DCCH
4	M	11	110	44	36,40	II	HHR+ RALNF		7	CP
5	M	8	100	30	30,00	III	HHR+ RALNF + G		6	CP + Epilepsy + Tracheostomy
6	M	17	130	31	18,30	II	HHR+ RALNF + G+GJ		7	CP + MMR
7	M	17	100	17	17,00	II	HHR+ RALNF + G	ICU	2	CP + Epilepsy+ MMR
8	W	6	150	19	8,40	II	HHR+ RALNF + G		6	CP + Epilepsy
9	M	4	100	12	12,00	II	HHR+ RALNF + G		4	KS+ Epilepsy + CIT gene mut + MMR
10	M	10	140	15	7,70	III	HHR+ RALNF		6	CP
11	M	2(+3 month)	98	16	16,70	III	HHR+ RALNF+ G		6	MMR + HERC2 and BCKDHA+ PEG(+)

DCCH: Diffuse corpus callosum hypoplasia; PEG: percutan endoscopic gastrostomy; G: Gastrostomy; TLHS: Total length of hospital stay; CP: cerebral palsy; ASA: American Society of Anesthesiologists risk score; RALNF: Robotic assisted laparoscopic Nissen fundoplication; KS: Klinefelter syndrome; MMR: mental motor retardation; HHR: Hiatal hernia repair; GJ: Gastrojejenostomy; ICU: intensive care unit

Two children had big hiatal hernia detected by an upper gastrointestinal contrast study.

The surgical protocols of patients were as the following: Eight children (72.7%) RALNF and gastrostomy, two children (18.1%) RALNF and one child (9%) RALNF, gastrojejunostomy and gastrostomy (Table 1).

Two patients had a previously opened percutaneous endoscopic gastrostomy tube. Gastrostomy was taken down by RS, and gastrostomy was performed again after fundoplication.

The mean total anesthesia time was 4.5±1.39 hours, while the mean pre-console time was 81.2±13.8. The mean docking time was 26.7±4.5 min, while the mean console time was 145±84.7 min (Table 2). We completed all of the RALNF procedures successfully without any need for conversion to open or laparoscopic surgery. No intraoperative complications were observed, and no need arouse to give blood for any reason. Three children were followed up in the intensive care unit due to their associated diseases. We used pethidine HCl (1 mg/kg/dose) and paracetamol (10 mg/kg/dose) for the first postoperative day and two to four days, respectively. We removed the nasogastric tube right after the operation. We started oral feeding/gastrostomy on postoperative day two and increased it gradually according to the patients' tolerance. The mean length of hospital stay was six days (range: 4-10 days). Two children, who were discharged before without any complications, were readmitted with fever to the clinic, caused by non-operative problems. The mean follow-up period was 17.5 months (range: 7-34 months). There were no major complications after RALNF. However, considering our experiences from Laparoscopic Nissen fundoplication, trocar side wound healing was better than RALNF. A patient died from an oncological problem on postoperative month eight.

Superficial and limited liver injury occurred in two patients due to liver retraction. We observed in all patients liver enzyme elevation which decreased to normal values in a short time. None of the patients had vagal nerve, spleen or esophageal injury. We observed no recurrence during the follow-up period.

Table 2. Surgical time subdivisions of the eleven children

Case no	Anesthesia time (h)	Pre-console time(min)	Docking time (min)	Console time (min)	Follow-up time (months)
1	6,50	78,00	35,00	240	34
2	7,00	88,00	30,00	300	24
3	3,00	84,00	20,00	60	22
4	3,50	75,00	22,00	90	21
5	4,50	75,00	25,00	180	17
6	6,00	90,00	30,00	240	17
7	4,50	116,00	24,00	100	15
8	4,00	80,00	25,00	90	15
9	3,50	72,00	27,00	90	12
10	3,00	65,00	24,00	45	8
11	4,50	70,00	32,00	160	8

4. Discussion

There is limited data about RALNF in NIC with GERD. The surgical treatment of NIC with GERD continues to be a challenging problem due to some difficulties unique to such patients. Severe musculoskeletal deformities (severe scoliosis, kyphosis, etc.), reduced lung reserve caused by recurrent lung infections (fig. 2), epilepsy which causes wrap dehiscence, and migration are only some of such difficulties (15, 16).

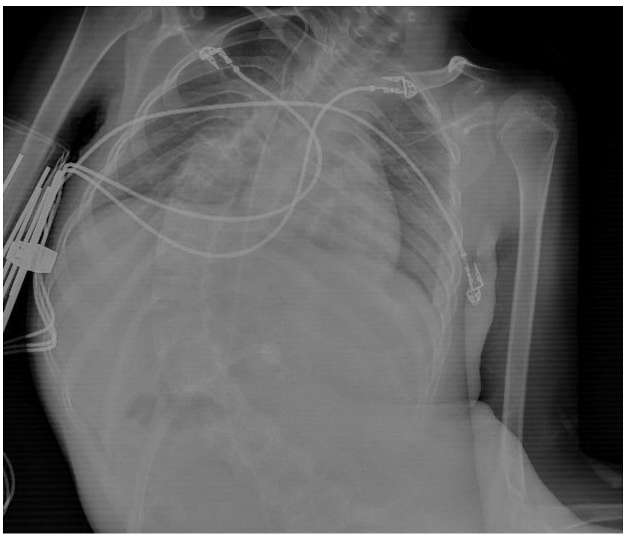

Fig. 2. Thoraco abdominal X-ray of patient #7, the patient has severe scoliosis and upper and lower extremity contractures

During open or laparoscopic Nissen fundoplication in NIC with GERD, extreme abdominal wall deformities and limb contractures are usual challenges limiting the exposure of the esophageal hiatus and the dissection of the intrathoracic esophagus essential for a successful surgical procedure. These difficulties are also responsible for the high surgical failure rates in NIC with GERD (15, 16). Robotic surgery makes significant contributions to successfully coping with these common difficulties in the surgical treatment of children with NIC with GERD.

Today, robotic surgery (RS) is frequently used by some surgical disciplines such as urology, general surgery, gynecology, cardiovascular surgery and is accepted as the gold standard for the treatment of some diseases such as prostatic cancer. However, RS has some disadvantages for routine clinical use in pediatric surgery. Some of these disadvantages are the instrument size, high cost, difficulties in reaching the robotic system due to their limited number and resistance to the new surgical technique to a certain extent. After reporting the first pediatric RALNF case in 2001 (10, 13), an increasing number of pediatric cases have been operated using robotic techniques. This study is the first pediatric RALNF case series from Turkey.

Unlike adult patients, a significant proportion of children undergoing anti-reflux procedures have neurological sequelae and serious additional pathologies (17, 18). In our series, all patients had severe or moderate neurological impairments. Serious advantages of the RS are a short learning curve thanks to articulating instruments, 3D high definition imaging, and fine surgical simulation capacity (8, 19). While the total surgical time (including pre-console and console times) was 6.5 hours in the first RALNF and gastrostomy case, it was 7.5 hours in the last two (case 1: RALNF + gastrostomy, case 2: RALNF) operated the same day. Comparison of the console time between the first and the cases revealed that the time reduced from 240 minutes to 45 minutes (Table 2). These rates are approximately similar to the learning curves specified in the literature (8, 17, 20).

Unlike LANF, re-positioning the patient after performing "docking" in RS significantly prolongs the operation time. In our cases, the most important factor causing the pre-console time to be longer was the positioning difficulties of patients with severe limb contracture. All of the patients except one had moderate to severe upper, lower or both extremity contractures, significantly extending the docking time despite increasing experience. Unfortunately, this problem persists as a challenge in either RALNF or LANF. Anderberg et al. (1) showed that robotic fundoplication in children was comparable to conventional laparoscopic surgery in terms of operative time, postoperative pain, and postoperative hospital stay. A study showed that long pre-console time in RS was compensated with faster dissection and knot tying (21).

The most common acute surgical complications of Nissen fundoplication are *N.vagus* damage, esophageal perforation, and spleen and liver injuries, which are also similar in LANF and RALNF except with different rates (22).

In our series, the length of hospital stay time was too long, especially for four patients due to severe neurological and pulmonary problems which needed intensive care unit treatment up to two months. The mean length of hospital stay was six days (range: 4-10 days) for the remaining seven patients (Table 1).

Probably the most commonly accepted disadvantages of RS are the high price of robot and robotic instruments, in addition to high annual maintenance expenses, which seriously limit the usage of robotic surgical systems (1). The average cost of a surgical procedure using two robotic arms (excluding annual maintenance costs) is about US$ 2000. Another problem in Turkey is that pediatric robotic cases can still not be billed due to the lack of appropriate procedure codes.

This study had several limitations such as small case numbers, short follow-up periods and the patient groups including only those with severe neurological and pulmonary disabilities.

The usage of the robotic surgical system in pediatric cases has some difficulties caused by their design for adults. We hope the problem will be solved with an increasing in the number of pediatric cases. RALNF could be performed safely in children with severe or moderate neurological impairments. However, low cost-effectiveness and adult size instruments are the most important problems of RS in pediatric cases. Solving such problems will lead to the RS being used more commonly in the treatment of GERD in NIC.

Conflict of interest

The authors declared no conflict of interest.

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Authors' contributions

Concept: M.U., T.A., Design: M.U., T.A., Data Collection or Processing: M.U., T.A., Analysis or Interpretation: M.U., T.A., Literature Search: M.U., T.A., Writing: M.U., T.A.

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