

Robotic Laparoscopic Transdiaphragmatic Repair of Large Hiatal Hernias

Farid Gharagozloo*, Mark Meyer

University of Central Florida, Orlando, USA Email: *GharagozlooF@aol.com

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Abstract

Introduction: Although laparoscopic Nissen fundoplication is the most common procedure for the repair for hiatal hernia (HH) repair, HH recurrence due to breakdown of the hiatoplasty has been reported as a common mechanism of failure after primary repair. Left transthoracic anatomic and physiologic repair (AFR) of HH is associated with lower incidence of leak and reoperation but greater morbidity. Adopting the transthoracic approach to a robotic laparoscopic platform may represent the ideal approach to the repair of HH. This study reviews the results of this technique. Methods: A retrospective review was performed on patients who had robotic AFR (RAFR) of large HH. All patients received the previously validated Gastroesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQL) questionnaire preoperatively and postoperatively. Objectively, symptoms were graded using the Visick Scale. Recurrence was defined as greater than 2 cm or 10% of the stomach above the diaphragm detected by either CT, esophagogram or endoscopy. The preoperative data was compared to the results at 2 years. Results: 396 patients underwent RAPR. The Median GERD-HRQL score was 42 (range 38 - 45) preoperatively and 6 (range 0 - 14) at two years (p < 0.05). Preoperatively 87% of patients were graded as Visick IV. At two years, 95% were graded as Visick I. HH recurrence occurred in 4/396 patients (1%). Conclusion: RAFR of HH is associated with excellent symptom relief and low recurrence rate. RAFR should be considered when deciding on what operation to perform in patients with large paraesophageal hiatal hernias.

Keywords

Robotic, Hiatal Hernia, Recurrence

1. Introduction

The most commonly performed surgical procedure for the treatment of hiatal

hernia (HH) is the laparoscopic Nissen fundoplication (LNF). The laparoscopic approach offers several advantages compared with its open counterparts, accounting for its increased use [1] [2] [3]. These include shorter hospital stay, reduced postoperative pain, and reproducibility of results compared with transthoracic Belsey Mark IV (BM-IV) fundoplication. However, after LNF, HH recurrence due to breakdown of the hiatoplasty has been reported as a common mechanism of failure [4] [5]. In addition, with a recurrent hiatal hernia, the fundoplication "slips" above the diaphragm and results in new series of symptoms that are related to esophageal obstruction, and cardiac and pulmonary dysfunction. In a recent meta-analysis, based on 13 eligible studies and 995 patients who participated in radiological follow-up, the mean recurrence rate was 25% [6]. Interestingly, even with the implementation of different surgical techniques for closure of the diaphragmatic crura, the problem of recurrence of the HH has remained unsolved.

The rate of recurrence of HH is higher in patients who have larger hiatal defects. In a case series of patients with large HH, Dallemagne reported that radiographic recurrence was observed in 66% of the patients after a median follow-up of 99 months. The authors concluded that tailored lengthening gastroplasty based on an objective intraoperative evaluation combining endoscopy and laparoscopy might help resolve hernia recurrence [7]. Furthermore, Lugaresi and colleagues have reported that in patients with a larger HH, the HH is associated with a true short esophagus in more than 50% of cases; and have suggested that a dedicated treatment of this condition might be appropriate to reduce the recurrence rate of the HH [8].

A transthoracic anatomic and physiologic reconstruction of the hiatus using the Belsey Mark IV technique has been shown to be associated with lower incidence of esophageal leak and recurrence [9]. In addition, BM-IV allows a barrier to reflux while maintaining normal swallowing, belching, and vomiting, extensive mobilization of the esophagus, and concomitant procedures to the chest wall, lung, and esophagus. However, in the modern era, little attention has been directed toward the BM-IV as a means of primary repair for patients with large HH. The two main factors are that the transthoracic approach is mainly performed by thoracic surgeons, and BM-IV is associated with the morbidity of a thoracotomy.

One of the advantages of the robotic surgical systems is the ability to erase the traditional boundary between the chest and the abdomen which is delineated by the diaphragm. The robot can be introduced laparoscopically and be used to perform an intrathoracic procedure through a diaphragmatic opening. In addition, the high-resolution three-dimensional visualization and greater instrument dexterity provided by the robotic platform facilitate the necessary complex anatomic reconstruction using minimally invasive techniques.

We have used robotic laparoscopic transdiaphragmatic approach to accomplish the anatomic and physiologic reconstruction of the HH which has traditionally been performed by a thoracotomy.

We present a case series of patients who underwent robotic anatomic and physiologic repair of hiatal hernias.

2. Methods

In a prospective cohort study, we evaluated patients undergoing RRHH with at least a 2-year follow-up. All patients undergoing elective (RRHH) were identified preoperatively and enrolled prospectively in this study. Surgical therapy was determined based strict parameters, severe symptomatic disease, and/or Type II-IV HH (**Figure 1**). Exclusion criteria included previous repair of HH, previous fundoplication, esophageal surgery for a malignant disease process, any subject unwilling to provide informed consent, or any individual who was unwilling to undergo the required follow-up studies.

Preoperative characteristics, medical comorbidities, and clinical information were all recorded prospectively by trained research personnel and recorded into a secure surgical outcomes database.

The patients were followed by surgical clinic visits, clinic visits with their gastroenterologist, and telephone consultation by specially trained Nurse Practitioners. In addition, the patients were followed by their local gastroenterologist with at least semi-annual clinic visits and endoscopy.

All patients received the previously validated Gastroesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQL) questionnaire preoperatively and at postoperative time points of 1 month and 1 year and 2 years. The questionnaire consists of 10 questions with a maximum score of 50 [10]. 6 questions relate to gastroesophageal reflux disease, 2 questions relate to swallowing, 1 question relates to bloating, and 1 for medication use). A greater score indicates a worse symptom severity.



Figure 1. A barium esophagogram showing the migration of the stomach into the mediastinum and both sides of the chest. This is representative for a patient enrolled in the study.

Objectively, symptoms were graded by an unbiased observer using the Visick Scale (I-IV) [11]. These questionnaires were administered by trained personnel during scheduled clinic visits.

Patients routinely had a barium swallow postoperatively before discharge but did not undergo a barium swallow, an endoscopy, or a CT scan study at the 1-month time point unless indicated by symptoms. At 6 months, 1 year, and yearly intervals thereafter, regardless of symptoms, all patients received a barium esophagogram and Upper GI endoscopy to ascertain the presence of a recurrence. The follow-up duration was calculated from the day of surgery to the day that the patient underwent the most recent follow-up.

Recurrence was defined as greater than 2 cm or 10% of the stomach above the diaphragm detected by either CT, esophagogram or endoscopy. Barium swallow was performed pre- and post-operatively according to a dedicated technique intended to define the relationship between the esophago-gastric (E-G) junction and the diaphragmatic hiatus in the upright and supine positions. In order to decrease observational bias, the studies were interpreted by an independent radiologist who was reminded of the study parameters and definitions but was blinded to the rest of the clinical data.

The follow-up procedures were initially developed according to "good practice criteria". The patients were informed about the rationale, advantages and disadvantages of follow-up after surgery for benign esophageal diseases, and they voluntarily accepted the proposed follow-up program.

2.1. Data Analysis

Data were exported into Excel (Microsoft Corp., Redmond, WA.). Information was obtained through hospital databases, medical records, and our prospective database. The data was prospectively accrued and retrospectively analyzed. Individual consent was waived for inclusion in this study; however, it was required and obtained to enter patient data in the prospective database. This study was reviewed by an institutional review board and determined to be exempt under 45 CFR 46.101 (b).

The data are expressed as the median values and first-third quartile (Q1 - Q3) or range, unless stated otherwise. Wilcoxon's signed-rank test was used to compare the pre- and post-operative data.

A "p-value" of <0.05 was considered to be significant. The statistical analyses were performed using the SPSS software package, version 13.0 (SPSS, Inc., Chicago, IL, USA).

2.2. Surgical Technique

Anesthesia Management:

In patients with large HHs, the pleural space is entered during the robotic dissection. In order to perform a complete dissection of the hernia sac, separate the sac and contents from the lung and the pleura, and return all the peritoneal

contents into the abdomen, it is imperative to have full exposure of the entire mediastinum and the respective pleural space. Entry into the pleural space results in loss of pneumo-peritoneum, a tension pneumothorax, downward pressure on the diaphragm, and loss of exposure at the hiatus. Consequently, in order to have full control of the exposure and to complete a perfect robotic dissection, it is important to have a mitigation plan in place. We prefer to use a double lumen endotracheal tube in patients with large hiatal defects. At the time of pleural entry, the lumen of the tube to the ipsilateral lung is clamped, thereby isolating the ipsilateral lung. This maneuver creates a large space in the chest, thereby "buying" more time before the CO₂ pressure can result in "tension" and create a tamponade physiology. After the full dissection of the peritoneal contents from the lung and the pleura, the pleural entry is closed with robotically applied clips and a member of the surgical team places a small chest tube through the 9th interspace anteriorly. Following the placement of the chest tube and evacuation of the CO₂, the ipsilateral lung is re-inflated. This strategy allows the surgeon to continue with the dissection with perfect exposure and without interruption. In cases where the pleural space must be entered and closure of the pleura is not possible, the tube thoracostomy evacuates the CO₂ and facilitates an excellent exposure of the surgical field. We use two laparoscopic insufflators in order to maintain the pneumoperitoneum at a pressure of 15 mmHg.

Port Placement:

The patient is placed in the lithotomy position. The surgeon stands between the legs. Two Laparoscopic CO_2 insufflators are used. We prefer to accurately place laparoscopic ports and introduce the robotic arms through these ports. This strategy diversifies the options for the surgeon in the event of adhesions, unexpected complications, and if the surgeon elects to use conventional laparoscopy for the repair and reconstruction phase of the procedure. We prefer to use the Visiport Instrument (Medtronic, Norwalk Conn., USA) for initial port entry into the peritoneum (**Figure 2**). Port #1 (Camera Port) is placed inferior to



Figure 2. Port placement.

the umbilicus. A small curvilinear incision is made under the umbilicus. A Kocker clamp is used to grasp the frenulum of the umbilicus and to elevate the anterior abdominal wall. Upward traction on the clamp provides the countertraction which is necessary for safe peritoneal entry under direction videoendoscopic guidance using the visiport instrument. Alternatively, a Veress Needle is introduced inferior to the umbilical frenulum and upon entry into the peritoneum a characteristic popping sensation is felt. Saline is introduced through the needle, and an unobstructed free peritoneal position of the needle is verified by the "hanging drop method" where the saline flows freely into the peritoneal cavity with elevation of the abdominal wall. A 10 - 12 Versiport trocar (Covidien/Medtronic Inc., Norwalk, Conn.) is introduced using the Veress Needle. A 0 degree Endoeve videoendoscope (Olympus Inc.) is used. Pneumoperitoneum is created using CO₂ gas to a maximum pressure of 15 mmHg. The table is placed in a steep Reverse Trendelenberg position. Under direct videoendoscopic guidance 5 to 6 other ports are placed. We prefer to use the 10 - 12 Versiport trocar (Medtronic Inc., Norwalk, Conn.) for all ports. These ports do not require reducer caps. An additional design advantage of these ports is that the port sites do not have to be closed. The peritoneal entry site is only 4 mm and is virtually pain free. The use of the Versiports allows for the placement of extra ports as needed, especially in patients with a high BMI or very large hiatal defects which may extend far above the diaphragm. Furthermore, the capless design of these ports enables rapid instrument change without loss of pneumoperitoneum. Port #2 is placed in the right paraumbilical region at the mammary line. An Endo-Paddle Retract retractor (Medtronic Inc., Norwalk, Conn.) is placed through Port #2 and fixed to the table using a self-retaining system (Mediflex, Velmed Inc., Wexford, Penn). The advantage of the Endopladdle retract device is that it is used to exert constant fixed upward traction onto the apex of the esophageal hiatus, and thereby, facilitates visualization and instrument maneuverability within the hiatal opening. Port #3 is placed halfway between the costal arch and the umbilicus as laterally on the right side of the abdomen as possible. This port will carry the left robotic arm. Using the videoendoscope the left and right limbs of the right crus are identified. Port #4 is placed in the subcostal region halfway between the umbilicus and the xiphoid just to the left of the midline. This port is aligned with the right limb of the right crus of the diaphragm. Port #5 is placed in the subcostal region two finger-breaths to the left and caudad to Port #4. Port #5 is aligned with the left limb of the right crus of the diaphragm. The Laparoscopic insufflator is disconnected from Port #1 and attached to port #4. A second insufflator is attached to Port #5. The use of two high flow insufflators facilitates rapid extra corporeal knot placement while preserving pneumoperitoneum and exposure of the esophageal hiatus. Port #6 is placed halfway between the costal arch and the umbilicus as laterally on the left side of the abdomen as possible. This port will carry the right robotic arm. At times a 7th port is needed to retract the contents of the hiatal defect. In such an instance Port #7 is placed in the mammary line halfway between pots #1 and #6.

Positioning and Introduction of the Robot:

The surgical robot (daVinci, Intuitive Surgical, Sunnyvale, Ca.) is docked using "side docking" technique. A 30 degree down-viewing robotic binocular camera is used, and it is introduced through Port #1. The right Robotic arm with a hook cautery instrument is introduced through Port #3. The left Robotic arm with a Debakey grasper instrument is introduced through Port #2. The entire dissection uses electrocautery and meticulous hemostasis. It is important not to use vessel sealing or other dissecting devices. The use of the hook cautery allows the surgeon to dissect along anatomic planes. Two assistants are used. A paddle retractor (Endo-paddle Retract, (Medtronic, Norwalk, Conn USA) is introduced by the Assistant #1 through Port #6. This is used to retract the tissues in a caudal direction at different points in the dissection. Assistant #2 introduces two Endo-Kittner instruments through Ports #4 and #5. The Endo-Kittner instruments are used to place lateral and upward traction on the limbs of the esophageal crus. This maneuver opens the space inside the hiatus further and allows the surgeon to have optimal exposure.

The operation is divided into 7 Steps:

Step 1. Dissection of the Right Side of the Hiatal Defect: The lesser omentum overlying the caudate lobe of the liver is opened. This allows for entry into the lesser sac and visualization of the right limb of the esophageal crus (RL) The vessels that cross over the caudate lobe and RL are dissected and elevated by the surgeon, clipped using Hem-o-lock Clips (Telleflex Inc., Morrisville, NC, USA) which are introduced through Port #4 by Assistant #2, and divided. This gives full visualization of RL. It is imperative to open the peritoneum overlying the RL. The space between the peritoneum and the muscle of RL needs to be entered. This is a natural and relatively avascular plane. Dissection in this plane allows for mobilization of the peritoneal sack and the contents of the hiatal defect with virtually no blood loss and perfect exposure. The Endo-Kittner which is introduced through Port #5 and manned by Assistant #2, is placed at the 11 o'clock position of RL and used to retract RL laterally. Next the Endopaddle retractor manned by Assistant #1 and introduced through Port #6 is placed at the 7 o'clock position of the esophageal crus and used to sweep the tissues in a caudal and leftward direction. These maneuvers allow the surgeon to grasp the peritoneum and dissect in the avascular plane between the pleura and the hiatal sac. The pleura is entered, the anesthesiologist clamps the ipsilateral lung (right), the peritoneal sac is dissected away from the plural structures. Next clips are placed to close the pleural opening, and after the completion of the dissection, a 24 French Chest tube is placed through an anterior thoracostomy. It is important to dissect the right side of the hiatal defect first. The dissection is then carried inferiorly until the posterior "V" formation between the RL and the left limb of the esophageal crus (LL) is identified. The LL is deeper than RL and is covered with fatty tissue. It is important to dissect the fatty tissue which overlies the LL until the muscle fibers are visualized. At this point the esophagus is elevated with the grasper in the left robotic hand, and the posterior aspect of the esophagus is separated from the crural "V" and the aorta. This maneuver allows for the identification and preservation of the Right (Posterior) Vagal Nerve.

<u>Step 2. Dissection of the Arch of the Esophageal Hiatus</u>: Assistant #2 introduces an Endo-Kittner through Port #4. This Endo-Kittner is used to retract the right limb of the esophageal crus (RL) laterally. The surgeon uses a sweeping maneuver with the hook cautery to separate the adventitial tissue and some blood vessels from the 11 o'clock to 2 o'clock position of the hiatus. The anterior vagus nerve is deep to these tissues and is not in danger of injury.

<u>Step 3. Dissection of the Left Side of the Hiatal Defect</u>. The Endopaddle retractor is positioned at the 3 o'clock position and used to retract the tissues at the hiatus laterally to the right of the patient and in a caudal direction. The LL is identified and the tissues overlying the LL are dissected away until the muscle is visualized. The key to the hiatal dissection is to use the limbs of diaphragmatic crus as a landmark. The dissection of the LL is then carried inferiorly and laterally to the right of the patient until the "V" with the RL is identified. The left pleura is entered and the same strategy as with the right pleural entry is utilized: the left lung is deflated, the peritoneal structures are separated from the pleura and lung, the pleural defect is closed with clips, a chest tube is placed through an anterior thoracostomy, and the exposure of the hiatus and pneumoperitoneum is maintained.

<u>Step 4. Encircling the Esophagus.</u> It is important to resist the temptation of encircling the esophagus above the crural opening. In patients with large hiatal hernias, the only constant anatomic landmark is the muscle of the crus. Therefore, in order to prevent injury to the aorta or the esophagus, the esophagus must be encircled at the crus. The Endopaddle retractor is used to sweep the tissues at the hiatus to the left of the patient and caudally and the "V" formation between the RL and LL is identified. The grasper in the left robotic arm is placed behind the esophagus and used to follow the muscle of LL in an oblique sweeping motion from a cuadad to cephalad direction and toward the patient's left shoulder. Assistant #2 passes a vessel loop through Port #4, the vessel loop is retracted around the esophagus and a Hem-o-clip is used to attach the two limbs of the vessel loop together. The excess vessel loop is cut and removed. Next, Assistant #2 introduces a laparoscopic grasper through Port #4, the vessel loop just above the Hem-o-clip is grasped and the esophagus is retracted laterally to the left of the patient.

<u>Step 5. Completion of the Mediastinal Dissection.</u> In order to repair the hiatus in an anatomic fashion at a later point in the procedure, the esophagus needs to be dissected free from the mediastinal tissues. This dissection should be carried posterior to the pericardium, to the level of the inferior pulmonary vein. Complete dissection and mobilization of the esophagus facilitates a tension free primary repair and places at least 2 cm of esophagus below the hiatal reconstruction. Assistant #2 retracts the esophagus laterally to the left and then to the right, thereby facilitating exposure of the periesophageal mediastinal tissues. Esophageal dissection is continued laterally and superiorly at least to the level of the inferior pulmonary vein. All vascular and adventitial connections to the esophagus are divided such that the vessel loop can be moved freely up onto the distal esophagus. In addition, the periesophageal fat pad and migrated retroperitoneal fatty tissue is dissected away from the esophagus. Frequently retroperitoneal fat, and at times lesser sac fatty tissue, that migrates between the posterior vagus nerve and the esophagus on the right side of the hiatal defect or the lesser curve aspect of the GE junction. In addition, fatty tissue from the retroperitoneum can migrate behind and to the left of the esophagus at the greater curve aspect of the GE junction. The retroperitoneal fatty herniation results in kinking and twisting of the esophagus and will need to be dissected away. At the end of the dissection, the esophagus and the vagus nerve should be the only tissues that remain within the encircling vessel loop.

To objectively localize the position of the G-E junction and to diagnose the presence of a true short esophagus, we adopted a combined laparoscopic-endoscopic method. The objective was to place the GE junction below the diaphragmatic hiatus. This was accomplished by extensive mediastinal dissection of the esophagus and "straightening" of the esophagus or a Collis-Nissen gastroplasty was performed according to the Steichen technique.

<u>Step 6. Anatomic and Physiologic Repair of the Esophageal Hiatus.</u> The strategy is to recreate the normal anatomy of the hiatus and thereby recreate the normal gastroesophageal antireflux barrier. This step can be carried out with the use of the robot or by conventional laparoscopy. We prefer conventional laparoscopy for this step. In our experience laparoscopic suturing with extracorporeal knot tying technique is more rapid and facilitates more accurate knot placement under tension. The crucial role of the robot and its significant differential advantage to laparoscopy is in the dissection of the hernia sac, and full mobilization of the esophagus. In order to accomplish full esophageal mobilization to the level of the inferior pulmonary veins, many times the pleura needs to be entered and the esophagus needs to be dissected away from the inferior pulmonary ligament. This level of accurate and extensive dissection cannot be accomplished by laparoscopy. However, as the repair phase of the procedure is confined to the hiatus, laparoscopic or robotic repair are equivalent and are dictated by the surgeon's preference.

<u>Step 6a. Posterior Crural Closure</u>. Posterior crural closure is accomplished by reapproximating the RL and LL with two or three sutures. We prefer the Endostitch Instrument (Medtronic Inc. Norwalk, Conn., USA) with O Ethibond suture. The Endostitch Instrument is an ideal suturing device for laparoscopy as it facilitates one-handed suturing thereby allowing the surgeon's left hand to provide appropriate exposure. Furthermore, when approximating the RL and LL of the right crus posteriorly, the straight needle of the Endostitch Instrument passes in a tangential plain anterior to the aorta and carries a lower risk of inadvertent aortic injury which usually is the result of deep suture placement with a curved needle. The curved needle used with a laparoscopic needle driver can pass deeper than intended and can engage the anterior wall of the aorta.

The Endopaddle retractor is placed on the medial aspect of the esophagus and used to retract the esophagus laterally and to the left. The maneuver exposes the "V" shaped posterior junction of the RL and LL of the right crus. A 1 cm squared absorbable pledget cut from Vicryl mesh (Ethicon, Inc., Sommervile, NJ, USA) is passed through Port #5. The Endostitch with O Ethibond is passed through Port #4. Intracorporeally the pledget is loaded onto the needle. The needle is passed through LL, a second pledget is loaded intracorporeally onto the needle, and the needle is passed through RL. Next, intracorporeally the needle is passed through a third vicryl pledget which is introduced with the grasper in the surgeon's left hand. The Endostich carrying the suture is withdrawn out of the entry Port #4, and extracorporeal knots are placed using a long external knot pusher. The suture is cut above the knot. This technique is repeated for all the posterior crural sutures.

Step 6b. Suspension of the Esophagus onto the Esophageal Crus: The camera is moved to Port #7. In a similar manner an O Ethibond suture on the Endostitch device is introduced through Port #4. Intracorporeally the pledget is loaded onto the needle, the needle is passed through LL at the 4 O'clock position, then through the lateral wall of the esophagus just above the GE junction at the greater curve, a second Vicryl pledget is loaded as described, and the suture is tied using extracorporeal technique. This fixes the left lateral aspect of the esophagus to the esophageal hiatus and recreates the normal attachment of the phreno-esophageal ligament. Next, an O Ethibond suture on the Endostitch device is introduced through Port #4. Intracorporeally the pledget is loaded onto the needle, the needle is passed through the medial wall of the esophagus just above the GE junction at the lesser curve, through RL at the 8 O'clock position, then, a second Vicryl pledget is loaded as described, and the suture is tied using extracorporeal technique. This fixes the right medial aspect of the esophagus to the esophageal hiatus and recreates the normal attachment of the phreno-esophageal ligament.

<u>Step 6c. Anterior Crural Closure</u>. In a similar manner to the posterior crural closure, 0 Etibond sutures on the Endostitch instrument with intracorporeally loaded pledgets of vicryl mesh are used to reapproximate the anterior portion of the crural arch. The anterior crural closure allows for the formation of an acute angle at the Gastroesophageal junction and recreates one of the important features of the normal Antireflux Barrier. The sutures are passed through Port #4, a Vicryl pledget is loaded on the suture intracorporeally and the suture is passed through the LL, a second pledget is loaded intracorporeally onto the needle, and the needle is passed through LL at the crural arch. A third Vicryl pledget is loaded intracorporeally onto the suture and the suture is tied using extracorporeal technique as outlined previously. Usually one to two anteriorly placed sutures are required. The crural closure is sized based on the passage of a 60

French Bougie into the distal esophagus.

<u>Step 6d. Creation of the Normal Gastroesophageal Valve</u>. Following crural closure, the normal gastroesophageal valve is re-created (**Figure 3**). The intussusception of the esophagus into the stomach is accomplished for the anterior 240-degrees (from RL to LL of the right crus) of the 360-degree circumference of the esophagogastric junction. The esophagus is marked 2 cm above the esophagogastric junction (EG) at the 4 o'clock position lateral to Left Vagus nerve(E1), at the 8 o'clock position just anterior to the Right Vagus nerve (E3) and halfway in between at approximately the 11 o'clock position (E2). The stomach is marked 2 cm below the GE junction at the greater curvature (G1), the Lesser curvature (G3) and at a point halfway between G1 and G3 (G2).

The Endostitch instrument with 0 Ethibond is introduced through Port #4. The first suture (G3 to E3, Lesser Curve) passes from G3 to E3 and through the diaphragm at the right crural limb, RL at 8 o'clock position. A vicryl pledget is introduced with a grasper through Port #5, and the suture is passed through the pledget. The suture is withdrawn through port #4. The suture is tied using extracorporeal knot tying technique.

The second suture (G1 to E1, Greater Curve) is passed in a similar manner from G1 to E1 and through the diaphragm at the left crural limb, LL at 4 o'clock position. A vicryl pledget is introduced with a grasper through Port #5, and the suture is passed through the pledget. This suture is withdrawn from Port #4 and tied using a knot-pusher and extracorporeal knots.

The third Suture (G2 to E2, midpoint) is introduced in the same manner from G2 to E2 and through the diaphragm at the midpoint of the crural arch. This suture is withdrawn from Port #4 and tied using a knot-pusher and extracorporeal knots.



Placement of the Valvuloplasty sutures results in the intussusception of the esophagus into the stomach by 2 cm for approximately 240 degrees and recreates

Figure 3. Sequence of sutures for the creation of the Gastroesophageal Valve as part of the anatomic and physiologic reconstruction of the hiatus.

the normal gastroesophageal valve.

At this point the newly created Gastroesophageal Valve is graded based on the Hill I-IV grading system using intraoperative endoscopy. Only a Grade I Valve is acceptable. Any deviations which would necessitate a Grade less than Grade I need to be corrected at this time and before removal of the ports.

<u>Step 7. Evacuation of CO_2 , and Port Closure</u>. Only the camera port needs to be closed. This trocar site is closed using a laparoscopic suture passer and 0 Vicryl (Ethicon Endo-Surgery). CO_2 is evacuated from the highest trocar by placing the patient in a steep Reverse Trendelenburg position. The other Versiport trocars are removed and the tissues are allowed to close around the introducer sheath. Subcutaneous tissues are closed with 00 Vicryl and the skin is closed with staples.

Videos of this procedure can be accessed on: https://youtu.be/7lM7Nvr6URY

3. Results

From 2008 until 2019, 809 patients underwent repair of hiatal hernias. 396 patients (median age = 67 years, $Q_1 - Q_3 = 62 - 83$) suffering from large HH (Type III-IV) HH underwent robotic anatomic and physiologic reconstruction (RAPR), 127 were male (32%) (median age = 56 years, $Q_1 - Q_3 = 57 - 82$), and 269 were female (68%) (median age = 67 years, $Q_1 - Q_3 = 62 - 83$). Two Hundred Ninety-seven patients exhibited a Type III hernia (75%) and 99 exhibited a Type IV hernia (25%). Anemia was observed in 35% of the patients; dyspnea related to the hernia was observed in 91% of the patients. The median duration of symptoms was 60 months ($Q_1 - Q_3 = 45 - 120$).

No significant difference was detected between Type III and Type IV HH with regard to age (P = 0.064), sex (P = 1.000), preoperative duration (P = 0.846) or severity of reflux symptoms (P = 0.839), dyspepsia (P = 0.919) or reflux esophagitis (P = 0.127). Significant differences in preoperative dysphagia were observed (P = 0.043) between Type III HH and Type IV HH.

Morbidity and Mortality:

There were no deaths. 59 patients (15%) experienced complications. One patient experienced vomiting, hiatal suture disruption and an esophageal leak on postoperative day 1; she was reoperated immediately and recovered completely. 58 patients experienced pleural effusion; 32 of these patients exhibited transient atrial fibrillation.

Follow-up:

All patients were followed-up for 24 months.

At the time of follow-up The Median GERD-HRQL score was 6 (range 0 - 14) compared to a preoperative score of 42 (range 38 - 45) (P < 0.05).

Preoperatively 51/396 (13%) patients were objectively graded as Visick III, and 345/396 patients (87%) were Visick IV. At the time of follow-up, 376/396 patients (95%) were graded as Visick I and 5% as Visick II.

HH recurrence occurred in 4/396 patients (1%). In 2 cases of HH recurrence,

the GE junction herniated with above the hiatus by 2 - 4 cm. In two cases, the anatomical recurrence was massive. All four patients required reoperation which per our routine were performed by a left thoracotomy.

4. Discussion

A hiatal hernia is a common clinical entity which has been the subject of great controversy for over a century. During this time, medical practitioners have been like "blind" men who have examined the different parts of an elephant and reached a conclusion based on the partial knowledge but have been unable to recognize the "whole elephant". As a result, for the first part of the twentieth century HH was treated like an abdominal wall hernia which disregarded the physiologic aspects of the GE junction at the hiatus. In turn, for the second half of the twentieth century, especially after the advent of laparoscopy, the poor symptomatic relief and high recurrence rates associated with anatomic repair, lead to the physiologic repair of HH by fundoplication. Rudolph Nissen proposed a fundoplication of the stomach via an abdominal approach in 1955 [12] [13]. Many modifications to the original Nissen procedure have been made that have brought it to its current form, including reapproximation of the hiatus, division of the short gastric vessels, and creation of a loose, floppy wrap 2 cm long. Presently, the most commonly performed surgical treatment of HH is the laparoscopic Nissen fundoplication (LNF). The laparoscopic approach offers several advantages compared with its open counterparts, accounting for its increased use [1] [2]. These include shorter hospital length of stay, reduced postoperative pain, and reproducibility of results. However, recent reports have demonstrated recurrence rates of 15% to 25% after laparoscopic repair of large hiatal hernias. With greater experience, it became evident that repair of large HHs could be a difficult operation and was rarely accomplished with the use of laparoscopic techniques. In this setting, the laparoscopic approach was associated with a high rate of recurrence and complications. The laparoscopic techniques had shortcomings in terms of two-dimensional visualization and the somewhat rudimentary instrument manoeuvrability which did not allow for complete dissection of the hernia sac and mobilization of the esophagus. These shortcomings were exacerbated when the HH extended significantly above the diaphragmatic hiatus. Consequently surgeons "settled" for incomplete mobilization of the hernia sac and relied on the "fundoplication" to keep the stomach below the diaphragm. In turn, fundoplication represented an indirect solution for the anatomic and physiologic problem which was created by the hiatal defect [14] [15]. In 2002, Stylopoulos and colleagues examined the hypothesis that elective laparoscopic repair should be routinely performed on patients with asymptomatic or minimally symptomatic paraesophageal HHs [16]. A Markov Monte Carlo decision analytic model was developed to track a hypothetical cohort of patients with asymptomatic or minimally symptomatic paraesophageal hernias and reflect the possible clinical outcomes associated with two treatment strategies: elective laparoscopic paraesophageal hernia repair (ELHR) or watchful waiting (WW). The input variables for ELHR were estimated from a pooled analysis of 20 published studies, while those for WW and emergency surgery were derived from the surgical literature published from 1964 to 2000. Outcomes for the two strategies were expressed in quality-adjusted life-years (QALYs). The mortality rate of ELHR was 1.4%. The annual probability of developing acute symptoms requiring emergency surgery with the WW strategy was 1.1%. ELHR resulted in reduction of 0.13 QALYs (10.78 vs. 10.65) compared with WW. The model predicted that "Watchful Waiting" (WW) was the optimal treatment strategy in 83% of patients and ELHR in the remaining 17%. Based on this evaluation, they concluded that WW is a reasonable alternative for the initial management of patients with asymptomatic or minimally symptomatic large HHs.

In patients with a foreshortened esophagus, an esophageal lengthening procedure (Collis gastroplasty) was added as an option to fundoplication [17] [18]. The preoperative instrumental-clinical evaluation, particularly X-ray barium swallow, offers the clinician positive elements of suspicion on the eventual complexity of the case but the diagnosis of "true" short esophagus can be performed only intraoperatively, after extensive mobilization of the mediastinal esophagus and when the intra-abdominal portion of the esophagus is shorter than 2 cm with no downward tension applied [19]. The literature still calls for the judgement of the surgeon when deciding whether to perform or not a Collis gastroplasty [18]. In fact, a subset of patients can be treated by an extended esophageal mediastinal dissection in order to obtain a tension-free, adequate abdominal segment of esophagus. Cases of elastic retraction of the esophageal muscular wall secondary to the loss of anchorage of the GE junction in the abdomen and cases of fibrotic retraction of the esophagus from panmural esophagitis secondary to GERD may have the same radiological presentation preoperative barium swallow. An elastically retracted GE junction is usually repositioned in the abdomen without any particular difficulty, because the esophagus is not irreversibly shortened, while the fibrotic, "true short esophagus" requires extensive mobilization or/and an elongation procedure to achieve a correct intra-abdominal fundoplication [20].

In contrast to patients with gastroesophageal reflux from a small hiatal hernia, symptoms from a large HH or paraesophageal HH are more related to obstruction and include chest and epigastric pain, dysphagia, shortness of breath, early satiety, and anemia secondary to bleeding from Cameron erosions. The incidence of gastroesophageal reflux disease (GERD) in large paraesophageal hernias is a debated topic. Some reports have found the incidence to be low, whereas others have found the incidence to be high and have postulated the development of large paraesophageal hernias to be a continuum of a sliding hernia.

Historically, the only symptoms considered for elective repair included severe regurgitation, aspiration, cough, anemia, or dysphagia. However, recent literature suggests that symptoms associated with HHs are much broader than just gastrointestinal issues, and due to the slow progression of disease, are present in a subtle form for a long time. Furthermore, several quality of life studies have shown that patients are severely debilitated by the extra-gastrointestinal symptoms, but due to a lack of broad appreciation among medical professionals, they are driven to attribute the symptoms to other causes. Carrott found that symptoms are wide ranging and patients with HHs are often labeled as asymptomatic or minimally symptomatic because the hernia has been present for years in an older patient, and the gradual alterations in eating and postprandial symptoms had been attributed to aging [21] [22]. In addition, symptoms such as dysphagia, early satiety, and postprandial dyspnea are often insidious and increase over the course of many years. While, historically, gastrointestinal symptoms of HHs have been the main focus of the indications for repair, pulmonary, upper aerodigestive, cardiovascular, hematologic and functional symptoms have been severely underappreciated.

The capability to perform the operation minimally invasively with greater emphasis on the anatomic and physiologic reconstruction of the hiatus as opposed to fundoplication has provided further impetus for favoring surgical repair. A more recent study from 2018, by Morrow and colleagues, has shown that surgical repair of HHs is superior to WW in terms of quality of life [23].

Clearly, the indications for surgical repair of HHs have evolved over the years. This evolution has been a function of:

1) Greater understanding of the complex three-dimensional anatomy of the esophageal hiatus.

2) The relationship of the esophageal hiatus to the gastroesophageal antireflux mechanism.

3) The importance of the esophageal hiatus in providing the "skeletal" structure onto which the which the gastroesophageal valve is suspended.

4) The non-gastrointestinal complications such as cardiac, respiratory and hematologic complications that are associated with hiatal hernias.

5) Change in the definition of symptomatic hiatal hernias.

6) Possibility of complex anatomic reconstruction using minimally invasive techniques.

7) Advances in intraoperative visualization and greater instrument dexterity provided by the robotic platform.

Therefore, there has been a resurgence of interest in the "Anatomic and Physiologic Reconstruction" of the esophageal hiatus for the purpose of obtaining normal physiologic function. The principles of the surgical repair are:

1) Complete dissection of the hernia sac.

2) Preservation of the hernia sac as opposed to resection. In larger HHs the anterior (left) vagus nerve is elevated and displaced with the phrenoesophageal ligament or the anterior sac. One of the common mistakes is to resect the sac. The hernia sac represents an extension of the peritoneum in the antero-lateral aspect of the HH. It is important to recall that a HH represents a "Sliding" HH

where the posterior aspect of the hernia is made up of the esophagus as opposed to a peritoneal sac. HHs need to be approached like a "Sliding" inguinal hernia where the hernia is reduced but the sac is not resected as it would result in damage to the cecum in the case of a "sliding" inguinal hernia. In the case of a HH, all tissues should be dissected and replaced into the abdomen. Attempts at resecting the sac result in injury to the anterior vagus or the esophagus.

3) Complete mobilization of the esophagus to the level of the inferior pulmonary vein.

4) Separation of the peritoneal structures from the lung and pleura.

5) Dissection of all periesophageal fatty tissue, the so-called Mediastinal fat pad away from the esophagus.

6) Identification and preservation of both vagus nerves.

7) Dissection and removal of the fatty tissue at the esophagogastric junction (GE fat pad).

8) Posterior Closure of the hiatal "V" by crural re-approximation in a primary fashion using absorbable buttresses (pledgets) for the sutures, without the use of nonabsorbable buttressing material or mesh.

9) Suspension of the esophagus onto the right and left limb of the crus.

10) Recreation of the esophagogastric intussusception and creation of the Gastroesophageal (GE) valve.

11) Anterior closure of the hiatus in a primary fashion over a 60 French esophageal bougie.

12) Suspension of the GE Valve onto the anterior crural closure.

Traditionally, these steps have been accomplished using a left thoracotomy. The main advantage of the transthoracic approach is the direct visualization and accessibility of the esophagus, which is essential in this procedure. Proper mobilization of the esophagus is highly correlated to the success rate of the procedure in terms of recurrence, as it ensures a tension-free repair [24] [25].

The advent of laparoscopy introduced an alternative to open procedures. However, laparoscopy has been hampered by the shortcomings of two-dimensional visualization and un-wristed instruments that pivot at the level of the trocars on the abdominal wall. Although in experienced hands, these shortcomings have been largely overcome, in common practice, the essential steps of the procedure have not been adequately accomplished.

In general practice of laparoscopic repair, surgeons have used various techniques to overcome the shortcomings relating to inadequate hiatal dissection and esophageal mobilization. These techniques have included relaxation of the diaphragmatic crura, and the use of mesh. The goal of mesh repair has been to oppose the radial tension by strengthening the hiatal orifice. While many surgeons continue to use mesh, this issue continues to be debated, as many studies have shown that mesh does not improve the success of the procedure, but it can cause severe complications, such as dislodgement and erosions requiring gastric resection [26]. In fact, a randomized controlled trial from Watson *et al.* demonstrated similar outcomes between suture and mesh repair [27].

Another area of controversy where the shortcomings of the laparo-endoscopic techniques have dictated the surgical approach to HHs has been in morbidly obese patients. The connection between obesity, and HH is well established. Wilson et al. found that individuals with a body mass index (BMI) exceeding 30 kg/m^2 were 4.2 times more likely to have a hiatal hernia than those with a BMI lower than 25 kg/m² [28]. However, a 10-year retrospective review of laparoscopic repair of HHs identified obesity as a risk factor for long-term adverse outcomes [29]. In other studies, obesity has also been shown to increase the failure rate of antireflux surgery [30]. Because of the increased risk of surgical failure in this challenging population, a sleeve gastrectomy or gastric bypass has been recommended. However aside from the many potential physiologic shortcomings of this indirect approach to the repair of HHs in patients with high BMI's, there are still several sociologic obstacles, such as patient preference and lack of insurance coverage. Many patients with a hiatal hernia do not meet Medicare requirements for bariatric surgery (BMI > 40 kg/m^2 , alone, or $35 - 40 \text{ kg/m}^2$, with significant comorbidities). Other patients may meet these requirements but may prefer not to undergo gastric bypass or are unwilling to comply with postoperative lifestyle modifications.

The advent of robotic technology, which provides enhanced minimally invasive capabilities such as three-dimensional high definition visualization, and greater and more precise instrument maneuverability in a confined space, has facilitated more extensive mediastinal dissection, full mobilization of the HH and the esophagus, and an accurate anatomic primary reconstruction of the esophageal hiatus. Robotic Repair of HHs provides for an equivalent procedure which has been heretofore performed by a thoracotomy using laparoscopic trans-hiatal techniques. With the results of robotic repair of hiatal hernias, elective repair may be a more appropriate solution in all patients (including patients with high BMI's) with HHs.

Our study showed that using the technique of robotic laparoscopic transdiaphragmatic "Anatomic and Physiologic Reconstruction" of the hiatus, there was excellent relief of symptoms and a very low recurrence rate at two-year follow-up. With greater and more widespread experience this technique may prove to be the minimally invasive procedure of choice in patients with HH.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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