

Robotic fundoplication in children

Magnus Anderberg · Christina Clementson Kockum ·
Einar Arnbjörnsson

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Abstract Since January 2006, robotic assistance has been used for performing minimal invasive laparoscopic funduplications in children. These patients were compared with those operated on with either the open surgical technique or the laparoscopic procedure. The first six children operated on with a fundoplication using the operation robot, da Vinci[®] Surgical System from Intuitive Surgical[®], were included prospectively. As controls, data from the latest six children operated on using the open surgical procedure and the latest six children operated on using the minimal invasive laparoscopic technique were selected retrospectively. All the patients were operated on due to gastroesophageal reflux and were comparable in the De Meester score. The main outcome measures were the operating time, the use of postoperative analgesics, the duration of the postoperative hospital stay and the short-term outcome. There was no significant difference between the three groups concerning age, body weight and preoperative 24 h pH measurement. The mean operating time for the robotic group, 213 min, was the longer one, but the operating time for the latest four patients in the robotic group was similar to that for the laparoscopic group, 189 min. The postoperative hospital stay was shorter and a reduction in the use of analgesics postoperatively was noted. The reduction in the postoperative hospital stay and in the use of analgesics had been already noted with the introduction of the minimal invasive laparoscopic technique. There was no difference in short-term clinical outcome; the gastro-

esophageal reflux symptoms disappeared in all the patients. Robot-assisted laparoscopic fundoplication is comparable with the standard laparoscopic surgical procedure in terms of duration of operation, postoperative hospital stay, use of postoperative analgesics and short-term clinical outcome. The robotic surgery adds qualities to the surgical work when compared with open or laparoscopic surgery. These include better visualisation for the surgeon and greater precision in the movements of the instruments used.

Keywords Robotic surgery · Fundoplication · Children · da Vinci[®] Surgical System · Laparoscopy · Robot · Paediatric surgery

Introduction

Gastroesophageal reflux disease is a common disorder in children, and both medical and surgical treatments have shown outstanding results. Whereas proton pump inhibitors are the mainstay of the treatment, laparoscopic or open surgical fundoplication is an alternative.

There is no conclusive comparison between medical therapy and operative fundoplication. At our centre, fundoplication is performed when the medical therapy has reached its limits without satisfactorily relieving the patient's symptoms or when a spontaneous physiological improvement in the patient's situation can no longer be expected.

At our centre, the fundoplication procedure has been changed over the last 15 years from open surgical procedure to laparoscopic surgery and now to robot-assisted laparoscopic surgery.

This report compares our first paediatric funduplications using robot assistance, da Vinci[®] Surgical

M. Anderberg (✉) · C. C. Kockum · E. Arnbjörnsson
Department of Paediatric Surgery,
University Hospital, 221 85 Lund, Sweden
e-mail: magnus.anderberg@skane.se

System, with the latest funduplications using the open surgical procedure and the minimal invasive laparoscopic surgery technique.

We are not aware of any similar reports in the literature.

Patients and methods

This is a prospective study of the first six funduplications using the da Vinci[®] Surgical System operation robot from Intuitive Surgical[®] during the period January to June 2006. Retrospective data from the latest six patients operated on at our centre using the open surgical procedure and the conventional laparoscopic technique are used as controls. The fundoplication was performed by the same team and in the same way in all three groups.

The work up was the same for all the patients: endoscopy and an oesophageal biopsy, a 24 h pH measurement and an upper gastrointestinal X-ray series searching for anomalies, hiatus hernia or partial outlet obstruction. Impedance measurements were not performed in any of the patients. For 24 h pH measurements in the robotic group the BRAVO[®] (Medtronic, Shoreview, MN, USA) was used and for the patients in the open surgery group and the laparoscopy group a Synectics 24[®] antimony electrode and the Digitrapper[®] recording device (Medtronic, Salt Lake City, UT, USA). The electrodes were placed fluoroscopically two vertebrae above the diaphragm in accordance with ESPGAN criteria.

The patients were placed in the semilithotomy position after induction of general endotracheal anaesthesia. Pneumoperitoneum was induced through a 12 mm port, introduced through a minilaparotomy below the umbilicus where the camera was placed. A left and a right upper quadrant port were placed subcostally for the two robotic arms. A right upper quadrant port was placed for liver retraction. An assistant port was placed in the left lower quadrant 3 cm below the umbilicus. All the ports were introduced under direct vision. VersaStep[®] trocars from Auto Suture[™] (Manufactured by United States Health Care, a division of Tyco Healthcare group, Norwalk, CT, USA) were used.

The operation started by dissection of the left and right crura using the robotic hook tip and electrocautery. The short gastric vessels were not divided. The crura were sutured in half of the patients. The antireflux procedure was then performed by a floppy fundoplication. No gastric drainage procedure was performed in this group of patients. The method used

for performing the operation was the same in all three groups, only the instruments differed.

Postoperative pain was evaluated for each patient by the registered nurse on duty according to the visual analogue scale (VAS). The reliability and validity of the VAS as a measure of pain has been established previously. Analgesics were ordered by the surgeon on call.

Follow-up included personal interviews after 1 month. The patients were scheduled for personal interviews after 6 months and endoscopy and oesophageal 24 h pH measurement 1 year after surgery. Patients were questioned specifically about heartburn, regurgitation, retrosternal pain, dysphagia and vomiting. The outcome was compared with the patient's preoperative situation.

The analysed variables were: patient age and sex, body weight, pre-operative 24 h pH data and De Meester score, operating time skin-to-skin, the number of days morphine was needed, length of postoperative hospital stay, postoperative complications and functional results 1 month after surgery. No patient was lost to follow-up. All were analysed.

This work was performed in accordance with the rules of the ethical committee at our centre and the ethical standards laid down in the 1964 Declaration of Helsinki.

Statistical analysis was performed using the Kruskal–Wallis' test. A *P* value lower than 0.05 was considered significant.

Results

The demographic data for the patient groups are summarised in Table 1. There was no significant difference (*P* = 0.05) in age or body weight. The children's symptoms and concomitant diagnoses are summarised in Table 2.

Table 1 Demographic data for the patients included as well as the two control groups

	Surgical methods			Statistics
	Open	Laparoscopic	Robotic	
Number of patients	6	6	6	
Female/male	2/4	3/3	1/5	
Age at operation (years)				
Mean	4	11	7	<i>P</i> = 0.05
Range	1–13	7–13	2–11	
Weight at operation (kg)				
Mean	13	37	22	<i>P</i> = 0.05
Range	3–25	13–66	9–37	

Table 2 Symptoms and concomitant diagnoses for the patients included as well as the two control groups

	Surgical methods		
	Open	Laparoscopic	Robotic
Number of patients	6	6	6
Symptoms			
Cough	6	6	5
Vomiting	6	6	6
Vomiting blood	3	3	6
Pulmonary infections	6	6	5
Otitis	2	3	4
Concomitant diseases			
Cerebral paresis	3	3	3
Oesophageal atresia	1		1
Hiatal and diaphragmatic hernia	1		1
Corpus callosum agenesis, microcephali or encephalopathy	1	1	1
Only GERD		2	1

The result of the pre-operative work-up is summarised in Table 3 and this shows no significant difference between the groups. The high De Meester score and the fact that the children had pH < 4 during one fifth (20%) of the measured 24 h period suggest that these children were in need of surgery for their severe gastroesophageal reflux.

The operating time, the duration of the postoperative use of morphine analgesics and the duration of hospital stay are summarised in Table 4. There were

significant differences between the groups. The post-operative hospital stay was reduced from 6 to 4 days with the two minimally invasive methods and the use of morphine showed a more than 50% reduction.

All the operations were performed without complications. No conversion to open surgery was made. There was no procedure related mortality. Blood loss was sparse in all the patients.

Six out of the 18 patients had a gastrostomy when undergoing fundoplication and 5 out of 18 received a gastrostomy when operated on with the fundoplication. These patients were distributed between the three groups as shown in Table 4.

The mean time for the robotic surgery operating procedure was longer than for the open surgery or the laparoscopic surgery. However, the operating time for the four latest robotic operations was the same as the operating time for the laparoscopic operations.

There was no difference in the short-term clinical outcome between the groups; the gastroesophageal reflux symptoms disappeared for all the children.

Discussion

Our results suggest that the robotic fundoplication in children is comparable to conventional laparoscopic surgery with regard to operating time, postoperative pain and duration of the postoperative hospital stay.

Table 3 Results of the patients' pre operative work-up including endoscopy, oesophageal biopsy and pre operative 24 h pH measurement

	Surgical methods			Statistics
	Open	Laparoscopic	Robotic	
Endoscopy: normal/oesophagitis	3/3	2/4	0/6	
PAD: normal/oesophagitis/barrets	0/3/3	2/2/2	0/2/4	
<i>24 h pH measurement</i>				
Duration of pH < 4 in % of 24 h (% time pH < 4, total time ^a)				
Mean ± SD	23 ± 10	19 ± 6	21 ± 18	<i>P</i> = 0.69
Range	8–37	9–45	5–38	
Number of reflux episodes				
Mean ± SD	228 ± 72	229 ± 45	159 ± 11	<i>P</i> = 0.15
Range	120–408	151–330	85–369	
Number of reflux episodes ≥5 min				
Mean ± SD	12 ± 5	9 ± 4	13 ± 6	<i>P</i> = 0.48
Range	4–25	3–24	1–29	
Longest reflux episode (min)				
Mean ± SD	24 ± 6	29 ± 4	57 ± 138	<i>P</i> = 0.93
Range	12–38	9–72	5–200	
DeMeester score ^b				
Mean ± SD	48 ± 37	52 ± 37	73 ± 33	<i>P</i> = 0.55
Range	24–48	27–86	31–137	

^aTotal time is used since some of the patients did not walk and some fed via a gastrostomy.

^b95th percentile <14.72

Table 4 Duration of operation, usage of morphine analgesics and the duration of hospital stay

	Surgical methods:			Statistics
	Open	Laparoscopic	Robotic	
Operating time, minutes				
Mean \pm SD	121 \pm 85	189 \pm 13	213 \pm 81	$P = 0.03$
Range	73–215	140–257	150–285	
Use of morphine (days)				
Mean \pm SD	3.8 \pm 0.7	1.5 \pm 0.7	1.3 \pm 0	$P = 0.002$
Range	3–5	1–2	1–3	
Hospital stay (days)				
Mean \pm SD	6.2 \pm 0.7	3.5 \pm 0.7	4 \pm 1.4	$P = 0.01$
Range	5–8	3–4	1–7	
Gastrostomy				
Pre operative	2	1	2	
During operation	2	3	1	
None	2	2	3	

Previous studies have reported the safety and feasibility of robot-assisted antireflux surgery in children [1–6]. The first report on a randomised study [2] concluded that there was no obvious added benefit from the robotic technique compared with laparoscopic surgery. There is a recent report on a randomised clinical trial of robot-assisted versus laparoscopic Nissen fundoplication in adults [7] concluding that the current robotic system is of no significant benefit compared with routine laparoscopic surgical practice. These conclusions are in agreement with our findings reported here.

In this study, we used historical controls when comparing with our prospective follow-up of the patients operated on with the aid of the robot. It is obvious that a randomised procedure would be preferred. However, we cannot expect our Ethical Committee to allow us to compare robot-assisted laparoscopy with the conventional laparoscopic or the open surgical procedure. The benefit for the patients of the robot-assisted procedure or the routine laparoscopy are far too obvious compared to open surgery. Furthermore, the surgeon's learning curve will be delayed if the training is divided between two methods.

The parameters measured in this report do not disclose any significant difference between the robotic and the laparoscopic fundoplications in children. However, there are some details supporting the use of the operation robot:

- better sight in three dimensions in the operating field
- better access to the operating field
- more exact movements of the balanced instruments
- filtration of tremor

- the perfectly adjusted balance for each instrument used by the robot arms, which reduces tension and strain on the abdominal wall.

The use of the robotic technique can be criticised for its lack of tactile feeling. However, this is more than compensated for by the far better visibility and mobility in the operating field.

Potential complications of fundoplication are damage to the vagus nerve and perforation of the oesophagus or stomach. These complications can be minimised with the use of computer-assisted surgical devices. In contrast to conventional laparoscopy, the 3D high quality vision, the advanced instrument movements and the ergonomic position of the surgeon should enhance surgical precision. Furthermore, robotics allows the specialised laparoscopic surgeon to operate in fields previously accessible only through large abdominal incisions. Thus, robotics overcomes the limitations of the laparoscopic techniques.

Robotic surgery enables the surgeon to refine hand-eye coordination and provides the 3D views lost in laparoscopic surgery giving greater precision for advanced laparoscopic procedures. The camera controlled by the surgeon, the instruments' small-scale movements and tremor elimination provide other major advantages. Furthermore, robotic surgery offers, in our opinion, a pedagogical situation superior to the other two operating procedures.

Introducing new instruments in surgery often prolongs the operating time initially, as seen in this study. However, the learning curve for robotic surgery is steep. The operating time for our four last patients, still representing the learning curve, was similar to the mean operating time in the laparoscopic group, representing the late routinely operated patients.

The drawback of laparoscopic and robot assisted surgery is the greater expense. The cost of the operation is the highest for the robotic surgical group. Since the instruments are new, this is to be expected and the cost will decrease in time.

Our results show that robotic surgery is comparable to laparoscopic surgery and better than open surgery with regard to the use of postoperative analgesics with morphine and postoperative hospital stay. We suggest that robot-assisted surgery for performing fundoplication in children becomes the new standard. Considering all the potential benefits of the robotic instruments, we think the future will favour its use in paediatric surgery.

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