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Review article

Current state of digestive system robotic surgery in the light of evidence based medicine

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ABSTRACT

The incorporation of robotics in minimally invasive surgery has had mixed reception in the different fields of digestive surgery. Nowadays we are exposed to a continuous stream of publications on robotic approach techniques and outcomes, which do not always provide objective criteria and whose value, through scientific evidence analysis, is sometimes arguable.

With the aim of shedding light on current knowledge on digestive robotic surgery and giving an update of its possibilities, the authors analyse the abundant literature available on the different digestive robotic surgery procedures, and sum up their own experience.

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Presente y futuro del trasplante de islotes pancreáticos en el tratamiento de la diabetes mellitus

RESUMEN

La introducción de la asistencia robótica a la cirugía mínimamente invasiva ha tenido una aceptación desigual en los diferentes ámbitos de la cirugía digestiva. En la actualidad se están produciendo continuamente publicaciones sobre técnicas y resultados del abordaje robótico que no siempre aportan un criterio objetivo y cuyo valor, tras un análisis basado en la evidencia científica, en ocasiones puede resultar cuestionable.

Con el fin de arrojar luz sobre los conocimientos actuales en cirugía robótica digestiva y llevar a cabo una puesta al día de las posibilidades de este abordaje, en esta revisión de conjunto los autores revisan la abundante literatura producida sobre los diversos procedimientos de la cirugía robótica digestiva y suman a ella el testimonio de su propia experiencia.

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Introduction

On the 3rd of March, 1997, took place the first laparoscopic cholecystectomy assisted by a robot in history. It was done in the St. Blasius Hospital, Dendermonde, Belgium. J. Himpens, G. Leman, and G.B. Cadière were the surgeons involved. The robot used was the "Mona" from Surgical Intuitive, Mountain View, California, United States.¹ The fundamental conclusion after this intervention was that there were many more advantages derived from using the robot than the possibility to perform interventions from a distance from the patient. Among them:

- Increase in the level of freedom in the extremities of the instruments
- Elimination of the physiological tremor
- Ergonomic position and a sensation of going into the surgical field in depth
- Movements more precise and safer for the patient

The so-called "robotic surgery" started to be generalized after its approval by the United States Food and Drug Administration of the Da Vinci robot (Intuitive Surgical), that improved the possibilities of the Mona, in year 2000. The use of the robot was quickly extended to surgical specialties such as urology and gynaecology, and although less, also in digestive surgery. In these 8 years, different groups in the entire world have acquired robotic technology and many of them have reported their experiences to scientific literature. We began this fascinating adventure in July 2006 in San Carlos Clinical Hospital, Madrid, which was the first hospital of the Spanish public health network to incorporate the equipment and make it available to the different surgical specialties.²

The incorporation of any advanced technology to the surgical routine of a hospital entails organizational changes that affect every link of the surgical chain and, therefore, the collaboration of all of those involved is necessary to obtain good results³. To assimilate any change takes time, and everyone knows that a quality scientific production also requires time. The systematic review of the literature related with robotic surgery in the area of general and digestive surgery only recently began to produce interesting studies, with honourable exceptions.

Biliary surgery

The cholecystectomy is the chosen procedure to begin the experiment by the majority of groups. To do so, there are several publications since 2001 of a series of cases of this technique that demonstrate its feasibility. Many studies present series of cholecystectomies together with a series of other procedures.⁴⁻¹¹ Others present only the cholecystectomy.¹²⁻¹⁵ The longest series is that of Giulianotti et al,⁶ totalling 66 cases in 2003. All of the studies claim a low incidence of intraoperative complications and of conversions and a postoperative morbidity similar to that

of the laparoscopy. They also tend to reference the short learning curve that is required and the elevated cost of the intervention.

The only comparative study of cases and controls published on the cholecystectomy is very recent.¹⁶ It analyses 50 robotic cholecystectomies comparing them with 50 controls by laparoscopy. No conversion is reported, however, 1 serious complication was reported in each group. The intervention time and hospital stay were similar, but the total hospital expenses were greater for the robotic group.

We have performed 182 procedures in 169 patients over a 2 year period (July 2006 to July 2008). Of these, half are cholecystectomies (n=91)¹⁷ and 2 were biliary tract procedures for choledocholithiasis (a choledochotomy with Kehr insertion and a choledochoduodenostomy).¹⁸ The first published robotic choledochotomy¹⁹ is from 2004. The advantages of the robot become more evident for the surgeon when practicing any derivative procedure of the biliary tract by laparoscopy.

Gastroesophageal union (antireflux and Heller surgery)

The first 2 Nissen robotics procedures reported are from the Cadière group (CHU St. Pierre, Brussels, Belgium), with the Mona robot, in 1998.²⁰ The first Nissen robotic with Da Vinci was published by the Chapman group in 2001 (North Carolina University, United States).²¹ The first robotic Heller myotomy was published by the Melvin group in the same year (Ohio State University Medical Centre, Ohio, United States).²²

Similar to the case of the cholecystectomy, numerous series of cases of the Nissen robot have been published to demonstrate its feasibility, sometimes included in experiments of various procedures⁴⁻¹¹ and other times including only antireflux surgery.²³⁻²⁵ The most recent of these publications is the longest (n=118 antireflux surgeries with a robot)²⁵ and it defends that the dissection of the gastroesophageal union is technically superior using the robot. Unlike the cholecystectomy, the fundoplication has encouraged the creation of comparative studies with pure laparoscopic procedures from the beginning: the first randomized prospective study was published by the Cadière group²⁶ in 2001, where it compared 10 Nissen robotics (with the Mona robot) to 11 laparoscopies. They concluded that the results were similar but that the robot lengthened the time in surgery.

There are series that compare it with the pure laparoscopic procedures in a retrospective manner^{6,27-29} or in a non-randomized prospective manner.³⁰ The study done by Giulianotti et al⁶ reports a surgical time and a conversion incidence that are similar, but they report a lower morbidity rate and shorter hospital stay in the robotic group. Furthermore, the Melvin group³⁰ concludes that the robotic surgical time is longer, but that patients have a less frequent need of antisecretion medication in the postoperative period.

The strongest evidence comes from the studies that compare in a prospective and randomized manner, and from the meta-analysis and systematic reviews of these studies (level 1 of evidence). Currently there are various randomized

controlled trials (RCT) that compare robotic antireflux surgery with pure laparoscopy. Aside from the abovementioned²⁶ referring to the Mona robot, 3 RCT have been published that compare the Nissen robotic with the laparoscopy: one from the Morino group, with 25 Nissen robotics compared with 25 laparoscopies,³¹ another from Nakadi et al,³² with 9 robotics and 11 laparoscopies, and another from Müller-Stitch et al³³ with 20 in each group. All of them found similar results, but with a higher cost for the robotic group. There is no consensus about the lengthening of time in surgery. Some groups claim that the time in surgery is less with the robot.

Also, there is a very interesting collective review from 2003 about that published until this moment about fundoplication³⁴ and 2 other more general reviews from 2004³⁵ and 2006.³⁶ Their conclusions, in spite of the technical advantages reported by the authors, point to the fact that no clear benefit for the patient has been obviously demonstrated concerning the robotic assistance in antireflux surgery compared to the traditional laparoscopy, and by contrast its cost is higher.

This is different in the case of achalasia surgery. The Heller myotomy has been one of the chosen procedures for robotic interventions since the beginning by certain groups that have acquired a great amount of experience, such as Horgan et al.³⁷ The longest series published on a Heller procedure with a partial fundoplication by robotic laparoscopic surgery is a multicentric study published in 2005³⁸ that illustrates great results after 16 months of follow-up in 104 cases, without any cases of intraoperative oesophageal perforation. In the same year, a retrospective comparative study³⁹ of the same technique with its homologue by conventional laparoscopy (also from the S. Horgan group), reports an incidence of intraoperative oesophageal perforation of 16% with laparoscopy and none with the robot, with similar postoperative results.

Other authors agree with these results. Iqbal et al⁴⁰ published in 2006 a series of 19 Heller robotics included in a series of 70 laparoscopies, and they found a total incidence of complications of 11% with 4 perforations, none of which occurred with the robot group. The only existing comparative prospective analysis of the robotic Heller technique compared with traditional laparoscopy is from the Huffman group,⁴¹ from the University of Cincinnati (Ohio, United States), that compares 37 Heller laparoscopies with 24 robotics and finds three oesophageal perforations in the laparoscopic group (8%) and none in the robotic group, and better results in the robotic group regarding the ratings of general and specific quality, although the time in surgery is longer in the robotic interventions.

Our series includes the following in the 2 specified years: 28 Nissen,^{42,43} 2 large diaphragmatic hernias, and a Heller myotomy with a Dor fundoplication.⁴⁴ From the technical point of view, this is the procedure that, in the initial experiment, most clearly shows the advantages of the robotic assistance. The dissection of the gastroesophageal union benefits greatly from the articulation of the instruments and this, together with the excellent tridimensional vision, increases the safety and control of the intervention as well as its comfort level.

Colon surgery

The first robotic colectomy was published in 2002 from the G. Ballantyne group,⁴⁵ from the University of Hackensack (New Jersey, United States). It includes a sigmoidectomy and a right haemicolectomy. In general, the studies that deal with robotic surgery of the colon are series of less than 10 cases. There are certain exceptions, such as the series of 6 paired cases with controls published by Delaney et al⁴⁶ in 2003. The study included 2 right haemicolectomies, 3 sigmoidectomies, and a rectopexy. The authors conclude that the time in surgery was longer than the time in surgery for the laparoscopy and the postoperative was similar, but they concluded that it was a viable and safe procedure. The initial series by Giulianotti et al⁶ also included 16 colorectal surgeries. A prospective series of 10 patients operated on with the Zeus robot, compared retrospectively with 10 cases of laparoscopic interventions, in the McMaster University of Ontario (Canada),⁴⁷ also found similar results but with longer intervention time with the robot.

The longest colorectal robotic surgery experiment published is from the A. D'Annibale group⁴⁸ (Ospedale di Camposampiero, Padua, Italy). This group published their results in 2004 with a series of 53 patients with benign and malignant illnesses in different locations, comparing them in a retrospective manner with traditional laparoscopic techniques. Although the results were similar, the authors concluded that the skill and flexibility that the robot provided would be useful in certain parts of the intervention.

Since 2006 there is more literature on colorectal robotic surgery. Rawlings et al⁴⁹ published the results in the same year of a prospective series of 30 consecutive cases (13 sigmoidectomies and 17 right haemicolectomies), 5 of which were oncological. Since 2006 and especially since 2007, the treatment of rectal cancer is being carried out more and more with robotic colorectal surgery: the A. Pigazzi group,⁵⁰ from the City of Hope Medical Centre, from Duarte (California, United States), published a comparative study in 2006 of lower anterior resections from cancer (6 robotics compared with 6 laparoscopies); that showed similar results and confirmed that this technique could facilitate radical minimally invasive rectal surgery. Later, the same group⁵¹ presented the results of a retrospective series of 39 consecutive patients with rectal cancer, with a morbidity of 12.8%, a 2.6% of conversions, and a 12.1% of anastomotic escapes, with no local recurrences in 13 months of follow-up.

Another group of special interest in the robotic treatment of rectal cancer is the Baik et al group, from the Severance Hospital of Seoul (Korea). After a first study that demonstrated the feasibility of the procedure in a prospective series of 9 cases,⁵² with good oncological results and without any conversions, this group is the only one that until now has published a prospective randomised study that compares the robotic treatment and the pure laparoscopic treatment in rectal cancer (18 robotics compared to 18 laparoscopies).⁵³ The results are similar in both groups, also from an oncological point of view, but the average length of hospital stay is shorter in the robotic group. The follow-up time of the study is still short.

We began the colonic surgery series in October of 2006 and in 2 years we have performed 24 interventions in the left colon (haemicolectomies, anterior resections, and amputations), 14 right haemicolectomies,⁵⁴ 4 Hartman reconstructions, and 2 rectocele repairs.

Morbid obesity surgery

The first robotic bariatric surgery was performed with the Mona robot and published⁵⁵ in 1999. The first series of cases that appeared in literature corresponded with the Cadière et al group⁵ in gastroplasties and Horgan et al³⁷ in gastric bypasses. These studies demonstrate the efficacy of these procedures as alternatives to the traditional laparoscopy.

In 2003, a comparative study with laparoscopic controls concluded that the robotic bariatric surgery was technically very simple, but it was expensive, time consuming, and there were few available instruments.⁵⁶ The broadest experiment published in this field is from four North American groups: the pioneer is Horgan et al,^{57,58} that have published excellent results in a series of 110 gastric bypasses and 32 bands. Three stenoses in the bypass group (no fistulae) and a marginal ulcer in the band group were the complications reported. The authors highlight the decrease in surgical time and morbidity after getting over the learning curve. Another group that has published a broad experiment is the Ali et al group,⁵⁹ of the University of California-Davis (Sacramento, California, United States). These authors published a prospective study in 2005 of 50 bypasses performed with the Zeus robot, and they pointed out the absence of complications from the robot. More recently, in a comparative retrospective study of 140 bypass (80 with Zeus and 60 with Da Vinci), they concluded that the changing of robot did not affect the time in surgery nor the results. There was 1 fistula present in each group.⁶⁰ Furthermore, the Curet M team, from the University of Stanford (California, United States), started publishing results of 10 robotic bypasses and comparing them retrospectively with 10 laparoscopic bypasses; they obtained shorter surgical times with the robotic group and confirmed that the procedure was viable, safe, and better than the traditional procedure.⁶¹ In the same year, these authors published a single randomized prospective trial of robotic bypasses compared with those done with laparoscopy, that is still today the only one of its kind (25 in each group).⁶² They obtained a shorter surgical time in the robotic group, above all with a body mass index (BMI) >43. The same group published a retrospective review in 2006 of 75 robotic bypasses, with an average surgical time of 140 min and no fistulae. They concluded that the robotic procedure is better than the laparoscopic procedure.⁶³ No fistulae were produced in the series of 100 cases published in 2006 by Yu et al⁶⁴ (University of Texas, Houston, United States), in spite of an average BMI of 50 and the fact that they were the first 100 cases carried out with a robot.

Not all of the authors agree in the superiority of the robotic bypass compared to its laparoscopic homologue. Artuso et al⁶⁵ published the results in 2005 of a series of 41 robotic bypasses

compared retrospectively with a laparoscopic series, and they concluded that, although the robot provided more precision when performing a gastrojejunal anastomosis, it produces the same incidence of complications as the laparoscopy (<3% of gastrojejunal fistulae in both groups) and it increases the time and cost of the intervention, and thus it does not add any benefits.

In general, the series are shorter in the European groups. Certain authors published the results of robotic bariatric surgery in series of cases that include multiple robotic procedures.^{10,11} On the other hand, Parini et al⁶⁶ published in 2006 the results of 17 robotic bypasses from a total of 146 laparoscopies. They reported no complications related with the use of the robot or conversions. They concluded that the robot is safe and can be an effective alternative to the conventional laparoscopy. The only European comparative analysis published to date is very recent, and compares a group of 45 robotic bypasses retrospectively with another laparoscopic group. They reported more conversions to open surgery in the robot group because of problems related with the robot (incorrect arm position, laceration of the small intestine loops during the robotic manipulation, etc), aside from the higher cost and a learning curve of about 35 cases.⁶⁷

Splenectomy

This may be the least-explored technique regarding robotic assistance. Publications are only found between 2002 and 2005. The first ones are reports on its feasibility, of only 1 case⁶⁸ or of various cases, included in a series of multiple procedures.^{6,7,10,69,70} One of the 3 splenectomies published by Giulianotti et al⁶ was partial. A retrospective analysis to compare the first 6 robotic splenectomies with the first 6 laparoscopies, published in 2005, concluded that the intervention takes longer with the robot and that it is more expensive, and thus its use is not justified.⁷¹

Adrenalectomy

The first robotic adrenalectomy published was performed with the AESOP 2000 robot by the G. Hubens group⁷² (Antwerp, Belgium). In the same year, 1999, another adrenalectomy with the same robot was published by Piazza et al,⁷³ from Catania, Italy. Two adrenalectomies with the Da Vinci robot were published in 2002, that demonstrated the feasibility of the procedure.⁷⁴

The longest series published since then, included in studies of multiple procedures, is from the Morino group²⁷ (University of Turin, Italy) (9 cases) and from the Ayav²⁸ group (CHU of Nancy-Bravois, Vandoeuvre-les-Nancy, France) (17 cases). The results do not seem to surpass those of the laparoscopic surgery, with longer surgical times and higher costs.

Three randomized prospective trials have been published on the robotic adrenalectomy compared to the laparoscopic adrenalectomy: the first one in 2004 that includes 20 procedures (10 robotic and 10 laparoscopic).⁷⁵ They had to

convert 4 of the robotic adrenalectomies to laparoscopy and they had greater perioperative morbidity in the robotic group, aside from a higher cost. These results were very different than those from other RCT of adrenalectomies, that have recently been published: the first one, of Wu et al⁷⁶ (Urology Department, Show Wan Memorial Hospital, Changhua, Taiwan), compares 5 robotic adrenalectomies with 7 laparoscopic adrenalectomies and no perioperative complications nor conversions were reported, with a 1 year follow-up without morbidity or mortality. The other one, by Brunaud et al,⁷⁷ compares 50 robotic adrenalectomies with 59 laparoscopic adrenalectomies and concludes that the robot produces less blood loss and shortens the intervention time in patients with a BMI >30 and in large tumours, above all once the learning curve is overcome (20 cases). These authors consider that the amount of previous laparoscopic experience, expert assistance from the operating table and the side of the tumour determine the feasibility of the robotic adrenalectomy.

Oesophagectomy due to cancer

The first complete transhiatal oesophagectomy with the Da Vinci robot was published in 2003 by Horgan et al.⁷⁸ In that same year, the Giulianotti group⁶ published, in a series of 207 interventions in 193 patients, 5 oesophagectomies from cancer, 1 resection of an oesophageal diverticulum, and 1 removal of an oesophageal leiomyoma. Another 2 cases of the removal of oesophageal leiomyoma by robotic-assisted thoracoscopy were published in 2004 by Elli et al.⁷⁹

In 2005 various series were published of robotic oesophageal surgery included in studies with diverse procedures^{9,10,58} and general results. In the same year, Bodner et al⁸⁰ (Innsbruck, Austria) published an article with the results of 6 thoracoscopic oesophageal resections from malignant affection in 4 of the cases, and they concluded that the robotic treatment seemed to be ideal for the oesophagus.

Another European series, from the University Medical Centre of Utrecht, Netherlands, published in 2006, describes the results of 21 robot-assisted thoracoscopic oesophagectomies from cancer of the oesophagus.⁸¹ The authors claim that the lymphadenectomy was effective, with little blood loss, and they declared 48% of pulmonary complications and 1 death by a tracheoesophageal fistula (5%).

The other 2 recently published series were North American: one from the City of Hope National Cancer Centre from Duarte (California, United States), with 14 oesophagectomies from cancer of the oesophagus or high-degree dysplasia, that obtained an illness-free survival of 87% at 17 months. The authors reported that the robot is very useful, but that it is necessary to have a nursing team that is familiar with the procedure, an experienced assistant in the operating table, an expert anaesthesiologist and a correct positioning of the trocars.⁸² The other series is from Galvani et al,⁸³ that uses the transhiatal tract for 18 oesophagectomies. They reported an average surgical time of 267 min, no conversions, an average of 12 (7-27) ganglion per piece and 11 patients illness-free at 22 months of follow-up.

Gastrectomy and pancreatectomy

The first study on the distal gastrectomy from gastric cancer assisted by a robot was by Hashisume et al⁶⁹ (University of Kyushu, Fukuoka, Japan) and it was published in 2002. Following this, the Giulianotti group⁶ included, in their well-known study of 207 interventions, 21 gastrectomies (8 subtotal and 10 total from cancer, 2 partials from an ulcer, and 1 gastrectomy in wedge from a carcinoid).

The abovementioned Japanese group reappeared in the literature in 2006 with a comparative study of the distal gastrectomy, between the Da Vinci (2 cases) and Zeus (3 cases) robots.⁸⁴ The authors concluded that both are very useful, but that the Da Vinci robot needs less intervention time and causes less blood loss. Another group that is accumulating experience in this technique is The City of Hope National Cancer Centre in Duarte (California, United States), that in 2007 published the results of 7 subtotal gastrectomies performed with a mixed laparoscopy-robotic technique⁸⁵; they obtained an average of 24 (17-30) ganglion per piece and considered that the procedure was feasible and safe. In a previous publications, the same group announced the results of 11 gastrectomies with good results in the follow-up at 9 months.⁸⁶

Regarding the pancreatectomy, aside from specific references about the Whipple⁸⁷ and a distal pancreatectomy,⁷ the only significant experience published is that from the Giulianotti group,⁶ that reported their results from 13 pancreatic surgeries in 2003. These included 8 duodenopancreatectomies (5 Whipple and 3 Transverse-Longmire) and 5 distal pancreatectomies (2 with spleen preservation and 3 with splenectomy). Recently, this author, in a personal announcement, considered that one of the laparoscopic procedures that could today benefit from robotic assistance more than others is the distal pancreatectomy with spleen preservation.⁸⁸

Consensus document

In June 2006, a conference was held in the Mount Sinai Hospital of New York on the International Consensus between the MIRA (Minimally Invasive Robotic Association) and the SAGES (Society of American Gastrointestinal and Endoscopic Surgeons) about training and certification, clinical applications of robotic surgery, the risks of said surgery and a cost-benefit analysis and research. The results of the conference were translated into one document⁸⁹ that was published in February 2008. According to this document, robotic surgery has a special application in the following general surgery procedures:

- Heller myotomy
- Paraoesophageal hernia repair
- Gastric bypass
- Gastrectomy from neoplasia
- Reconstructive biliary surgery
- Transhiatal oesophagectomy
- Transthoracic oesophageal surgery

- Distal pancreatectomy with spleen preservation
- Selected colorectal surgery procedures
- Lymphadenectomies from neoplasia

The use of simpler procedures is also mentioned such as the cholecystectomy and the fundoplication to initiate the learning curve.

The part of this document dedicated to research is very interesting as it summarizes the directions of future advances: development of "intelligent instruments," advances in vision (computer-assisted vision or microscopy in real-time), surgery integrated with imaging techniques (ultrasonography, computerized tomography, magnetic resonance), simulation of surgical procedures, miniaturising of the robots, and many other possibilities.

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