



UNIVERSITÀ DEGLI STUDI DI NAPOLI
“ FEDERICO II ”
FACOLTÀ DI MEDICINA E CHIRURGIA

DOTTORATO DI RICERCA IN

**SCIENZE CHIRURGICHE E TECNOLOGIE
DIAGNOSTICO-TERAPUETICHE AVANZATE**

Coordinatore: Prof. Michele Santangelo

XXVIII CLICLO

***Chirurgia Robotica del Cancro del Colon Destro:
Curva di Apprendimento ed Analisi dei Costi***

Relatori

Prof. Nicola Carlomagno

Prof. Francesco Brunetti

Dottorando

Dott. Nicola de' Angelis

Anno Accademico: 2015-2016

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PhD PROGRAM in

**SURGICAL SCIENCES AND
ADVANCED DIAGNOSTIC-THERAPEUTIC TECHNOLOGIES**

Director: Pr Michele Santangelo

XXVIII Cycle

***Robotic Surgery for Right Colon Cancer:
Learning Curve and Cost Analysis***

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Academic Year: 2015-2016

Riassunto

Al giorno d'oggi, i pazienti richiedono sempre più di frequente un approccio chirurgico mini-invasivo, anche se solo una piccola percentuale di essi sembra avere accesso a questa chirurgia. I chirurghi, da parte loro, devono adattarsi agli sviluppi della tecnica chirurgica, soprattutto alla ridotta manovrabilità in campo operatorio e alla perdita della visione diretta. La curva di apprendimento delle procedure laparoscopiche o robotiche può essere lunga e difficile. La chirurgia robotica rappresenta la tecnologia più avanzata nel campo degli approcci minimamente invasivi. Questo lavoro prende in esame le caratteristiche generali, i vantaggi e gli svantaggi di queste tecniche chirurgiche, oltre a presentare i risultati di uno studio prospettico condotto per confrontare la curva di apprendimento del chirurgo e i costi socio-sanitari della colectomia destra eseguita per via laparoscopica o robotica. I risultati presentati in questa tesi dimostrano che le procedure laparoscopiche e robotiche hanno risultati operatori e postoperatori simili. La colectomia robotica destra sembra però avere una curva di apprendimento più veloce della laparoscopia. Per quanto riguarda i costi, una volta inclusi sia i costi operatori che la degenza ospedaliera, la laparoscopia e la chirurgia robotica sono associati a costi equivalenti. Ulteriori studi clinici sono necessari per rispondere alla domanda se l'approccio robotico potrebbe aumentare, grazie alla sua tecnologia avanzata, l'attuale bassa percentuale di pazienti sottoposti a chirurgia mini-invasiva.

Parole chiave: Chirurgia mini-invasiva; colectomia robotica destra; colectomia laparoscopica destra; curva di apprendimento; analisi dei costi.

Abstract

Nowadays, patients request minimally invasive surgical approaches if at all possible, although only a small percentage seems to benefit of it. Surgeons have to adjust to changes in the surgical techniques, especially in the maneuverability in the operative field and the loss of direct views. The learning curve of laparoscopic or robotic procedures may be steep. Robot-assisted surgery represents the most advanced technology in the field of minimally invasive approaches. The present thesis will discuss the general characteristics, advantages and pitfalls of this surgical technique, as well as presenting the results of a prospective trial designed to compare the surgeon's learning curve and the health-related costs in laparoscopic versus robotic right colectomy for colon cancer. The results presented in this thesis support that laparoscopic and robotic procedures yield similar operative and postoperative outcomes. Robotic right colectomy appears to have a faster learning curve than laparoscopy. Concerning the costs, once included both the surgical costs and the hospital stay, laparoscopy and robotic surgery are associated with equivalent costs. Further clinical trials are awaited to address the question whether the robotic approach could increase, thanks to its advanced technology, the currently small number of patients undergoing minimally invasive surgery.

Keywords : Minimally invasive surgery; robotic right colectomy; laparoscopic right colectomy; learning curve; health-related cost analysis

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Introduction

Human anatomy has not changed and the surgical manipulation of many organs has basically remained the same for centuries, however, surgical techniques have evolved in the last decades in favor of smaller incisions, videoscopic visualization, and advanced technologies allowing for a shorter hospital stay, a reduced postoperative pain, an improved cosmesis, and a quicker return to normal activities.

Nowadays, patients request minimally invasive surgical approaches if at all possible. To acquire these benefits for patients, surgeons have had to adjust to changes in maneuverability in the operative field and the loss of direct views. For many, the transition has been difficult and the learning curve steep¹. Still, several common procedures, such as cholecystectomy, are now performed by a minimally invasive approach as the gold standard, and basic laparoscopic skills have become formally incorporated into general surgery training programs².

Robot-assisted surgery represents the most advanced technology in the field of minimally invasive approaches³. The present thesis will discuss the general characteristics, advantages and pitfalls of this surgical technique, as well as presenting the results of a prospective trial on the surgeon's learning curve in robotic right colectomy for colon cancer. In addition, a health-related cost analysis concerning this emerging technology will be described.

Minimally Invasive Colorectal Surgery

Since the introduction of laparoscopic surgery, minimally invasive techniques have been broadly applied across multiple specialties for both benign and malignant conditions. The first laparoscopic colectomy was reported by Jacobs et al.⁴ in 1991, and the enthusiasm for laparoscopic colectomy grew when recovery benefits for patients became apparent. Since then, many surgeons became soon comfortable with laparoscopic colectomy for benign disease, but the application of minimally invasive surgery (MIS) to malignant colorectal disease was much slower mainly due to oncologic concerns⁵. However, during the past 20 years, a rapid evolution of techniques, technology, and experience has occurred^{6, 7}, and several randomized clinical trials have demonstrated that laparoscopic colectomy for cancer is comparable to conventional open surgery in terms of long-term oncologic outcomes⁸⁻¹⁰, allowing for safe and appropriate oncologic resections. Also for rectal cancer, recent studies demonstrated that MIS have equivalent results than open surgery¹¹. Moreover, the MIS approach was proved to offer several advantages compared to conventional open surgery, including^{9, 10, 12, 13}:

- Smaller incisions and better cosmetic results
- Less blood loss and lower rate of transfusions
- Reduced postoperative pain and thus need of narcotic pain medication
- Faster return of normal bowel function
- Faster recovery translating into shorter hospital stays
- Higher quality of life and patient's acceptance.

The Minimally Invasive Colorectal Resection Outcomes (MICRO) review identified 22 randomized controlled trials and 66 cohort series for benign and malignant colorectal disease¹⁴. The large randomized controlled trials included, such as the COST, COLOR, and CLASICC trials, clearly demonstrated the short-term benefits of laparoscopic colectomy for colon cancer^{8-10, 14}. Moreover, several studies have also identified a decreased rate of postoperative morbidity following laparoscopic colectomy including fewer wound infections¹⁴⁻¹⁶. The same trials also examined the tumor specimens and reported long-term data on recurrence and survival. The surgical specimens evaluated showed that oncologic parameters, such as the number of lymph nodes harvested, the circumferential radial margins, and the longitudinal margins were not different between laparoscopic and open colectomies^{8-10, 14, 16}. Similar recurrence patterns, wound or port site metastases, long-term disease-free and overall survival rates were also observed between laparoscopic and open colectomy. The concern that conversion from laparoscopic to open surgery in patients with colon cancer may lead to worse oncologic outcomes was not seen in the randomized controlled trials, which showed no statistical difference between these two surgical approaches^{8, 12}.

Nevertheless, despite the evidence demonstrating improved short-term outcomes by laparoscopic colectomy and equivalent oncologic results, the widespread implementation of this technique was slow. Initially, the lack of formalized training in laparoscopy and the relatively long learning curve¹⁷⁻¹⁹ likely represented the main barriers to adoption. Based on surgical parameters like the decline in operating time, intraoperative complications, and conversion rate, the learning curve for performing colorectal resections laparoscopically

was initially estimated at approximately 30-50 procedures^{18, 20-23}. More recently, a study assessing the learning curve for laparoscopic colectomy of a surgical fellow in an university colorectal unit using a structured training protocol over 100 consecutive patients indicated that laparoscopic colectomy can be safely performed by the fellow surgeon independently and without jeopardizing the clinical outcomes after 50 procedures²⁴.

As the surgeon experience increased as well as the number of studies demonstrated that laparoscopic colectomy is an acceptable alternative to open surgery for both benign and malignant diseases, the overall ratio of laparoscopic to open colectomies has progressively increased. Between 2000 and 2004, the incidence of laparoscopic colectomy raised from 3% to 6.5% in the USA²⁵. In 2011, a French survey estimated that laparoscopy accounted for up to 29% of colorectal cancer surgeries²⁶. However, these data should be attentively analyzed in the light of the fact that after more than 20 years from its introduction, laparoscopy is still reserved to few (less than one third) surgical cases. Various socioeconomic factors, technical limitations and the steep learning curve have been advocated as the possible causes hampering the widespread of laparoscopy²⁷.

In this perspective, and considering the large acceptance of MIS procedures by both patients and surgeons, many surgical innovators and industry were pushed to develop new technologies with the goal of even less invasive and easier approaches. The introduction in colorectal surgery of robotics, which was already popular in other specialties such as urology, aimed to overcome the drawbacks and limitations of laparoscopy in the confined working space of the pelvis^{27, 28}. The robotic approach appeared to offers all the advantages of MIS but with a learning curve relatively short¹. The results of robotic surgery in terms of oncologic outcome and anastomotic leakage are presently comparable to laparoscopy, but

with longer operating times and greater costs²⁹. Nonetheless, in high volume and experienced centers, robotic surgery may be indicated for difficult cases where open surgery would most likely be preferred or in cases where laparoscopy would have a high risk of conversion³⁰.

Right hemicolectomy has been proposed as the training procedure in order to gain surgical experience with the robotic technology²⁹.

Brief History of Robotic Surgery

The application of minimally invasive surgery to complex operations has been facilitated by the development of telemanipulation systems, also referred to as robots⁶. The first robotic system approved for intra-abdominal surgery in the United States by the Food and Drug Administration (FDA) was the AESOP (*Automated Endoscopic System for Optimal Position*) system in 1993. AESOP (Computer Motion, Goleta, California) is a computerized robotic camera assistant for laparoscopic surgery. It has gone through several modifications since then and is still available today as a voice-activated, surgeon-controlled, camera assistant. AESOP offers a stable camera platform but has no arm for direct manipulation or dissection of the tissues.

More dexterous robots have been designed by the US Department of Defense for the purpose of allowing surgeons to operate on patients in remote or unsafe locations. Since these systems restore pitch and yaw at the end of the instruments, the two degrees of freedom lost with the use of traditional laparoscopic instruments, and also add benefits such

as tremor reduction, motion scaling, surgeon camera control, comfortable ergonomics, and three-dimensional optics, it is no surprise the technology has found its way into conventional operating environments. *Intuitive Surgical's DaVinci* robotic system has been used in Europe since 1997, and in 2000 the FDA approved use in USA. DaVinci has three or four arms that allow tissue manipulation and retraction as well as camera control (Figure 1). The first robot-assisted colectomies were reported in 2002³¹. Numerous papers since then have shown robotic colectomy to be safe and feasible^{7, 32-37}.



Figure 1. Intuitive Surgical's DaVinci® Robotic System.

(Source: Google Images)

Technical Aspects of Robotic Surgery

Robotic surgery provides several technological improvements compared to laparoscopy, including:

- Three-dimensional (3D) view of the operating field
- Seven-degrees-of-freedom motion with wristed instruments
- Absence of fulcrum effect
- Absence of surgeon tremor
- Greater ergonomics and comfort for the surgeon.

Moreover, the two-headed robotic platforms represent an exceptional teaching tool whereby residents in training can achieve optimal anatomical knowledge and surgical skills, by following the intervention and practicing on the mentoring console.

The current literature has most often focused on comparing the surgical and clinical advantages of robotics versus laparoscopy, but this may not be the clue of the problem. Indeed, we should be able to look further and analyze the advantages of robotic surgery in terms of advanced technology that could increase the currently small number of patients undergoing MIS also for complex procedures that might be too challenging for laparoscopy and are still approached by open surgery. Indeed, the recent results of the randomized controlled trial COLOR II showed that laparoscopy is as safe and effective as open surgery for rectal cancer resections but this approach remains technically demanding and associated with high conversion rates (estimated at 17%)¹¹. On the other hand, the available literature shows that robotic surgery provides all advantages of the MIS approach but it may allow performing complex procedures, such as rectal resections, with greater ease, lower

conversion rate, less pelvic autonomic nerve damage and a reduced learning curve³⁰.

³⁸. However, it remains unclear, to date, whether these advantages translate into significant clinical benefits that may justify the increased costs associated to the application of robotic surgery³.

Petrucciani et al.³⁹ recently conducted a meta-analysis comparing the robotic versus laparoscopic approach and focusing only on right colectomies. They included a total of six studies with a limited sample size (total of 168 patients in the robotic group and 348 in the laparoscopic group). The meta-analysis showed no differences between the robotic and laparoscopic approach in the analyzed peri-operative and postoperative outcomes, except for a longer operative time for robotic right colectomy. The authors did not perform sensitivity or subgroup analysis, but concluded that robotic right colectomy is a feasible, safe, and effective in selected patients³⁹. Another systematic review and meta-analysis mainly based on observational studies that was published by Trastulli et al.⁴⁰ in 2015 showed that robotic colectomy is more time-consuming and expensive than laparoscopic colectomy but it results in faster recovery of bowel function, a shorter hospital stay, less blood loss and lower rates of both overall postoperative complications and wound infections⁴⁰. These results appear highly promising and support the implementation of robotic platforms in surgical units as well as the introduction of robotic training for fellow surgeons.

Robotic Right Colectomy

The detailed description of a robotic right colectomy include the patient positioning, port placement, robot docking, and the step-by-step description of the procedure.

Patient Positioning

For a right colectomy, the patient is lying supine on a bean bag. The bag is positioned flush with the patient's right side, allowing excess bag on the left side with which to wrap the left side of the patient. The chest is secured circumferentially to the table with heavy tape at the level of the clavicles. The legs are secured at the thigh and calf with straps. Patient's iliac crest is positioned over the mid-point joint of the table. Patient's arms are alongside the body to lessen possibility of shoulder injury. A urinary catheter is placed, along with optional nasogastric or orogastric tube, if used. After positioning, padding, securing and preparing the patient in the supine position, the table is then placed in 10-15° reverse Trendelenburg and rolled to the left 10-15°. Then the table is flexed at kidney rest (10-15°) to lower the patient's legs and prevent external collisions with the patient cart arms. Final table adjustments should be made during the initial exposure step (Figure 2).



Figure 2. Patient positioning (Source: *DaVinci Technical Manual*).

Establishment of pneumoperitoneum, trocar placement, and initial exploration are performed with the patient in the supine position. The tattooed lesion or pathology is located and the planned point of transverse mesocolic division is marked based on the location of the right branch of the middle colic artery. The table is then tilted to the left to allow the small intestine to fall away from the midline. The robot is then brought in over the right upper quadrant to dock with the camera port periumbilically, as well as the right lower and left upper quadrant ports. The robot is brought in from the right side and the bedside assistant and the scrub nurse are situated to the patient's left side. Once the robot is docked, there can be no change to the patient's position or the robot's position, without first undocking the robotic arms (Figure 3).

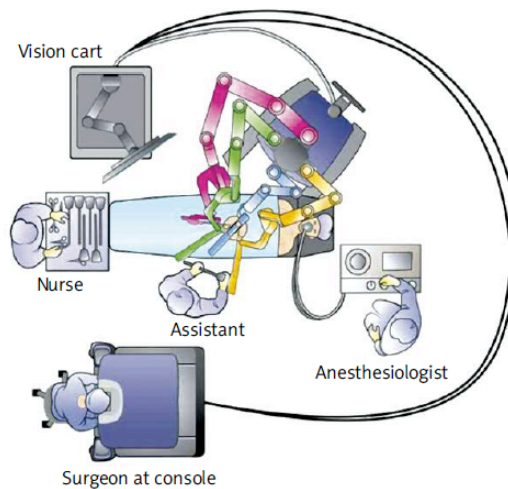


Figure 3. Patient and Robotic Positioning. (Source: Witkiewicz W et al. ⁴¹)

Port Placement

Port placement for the robotic procedure closely resembles the port configuration for laparoscopic right hemicolectomy. Three robotic working arms are usually used along with a camera. One assistant laparoscopic port is added for additional retraction, as well as an energy device or an endostapler. The following principles should be respected while positioning the robotic ports for distal lesions (Figure 4):

- Maintain remote center at level of the peritoneum
- Maintain 8-10 cm between all da Vinci ports
- Placement of camera port should be consistent
- Instrument arm ports need to shift based on patient size and anatomy
- The camera port (12 mm) should be placed ~1 cm inferior to the spinoumbilical line (SUL) and ~3-4 cm medial to the mid-clavicular line (MCL) in the left lower quadrant
- Instrument Arm Port 1 (8 mm) should be placed 1 cm lateral to the MCL, approximately halfway between the costal margin and SUL in the left upper quadrant
- Distance to the camera should be at least 8-10 cm
- Instrument Arm Port 2 (8 mm) should be placed on the midline, ~6-8 cm inferior to the umbilicus.
- Instrument Arm Port 3 (8 mm) should be placed 1 cm lateral to the MCL and 2 cm inferior to the SUL in the lower right quadrant. Distance from other

instrument ports and the camera should be at least 8-10 cm while allowing for at least 2 cm between port and anterior superior iliac spine (ASIS).

- The assistant port (12 mm) should be triangulated between ports 1 and 2 and ~3-5 cm lateral to the MCL and ~1 cm inferior to umbilicus in the left lower quadrant. Distance from surrounding ports should be a minimum of 5 cm.
- All measurements should be made AFTER insufflation.

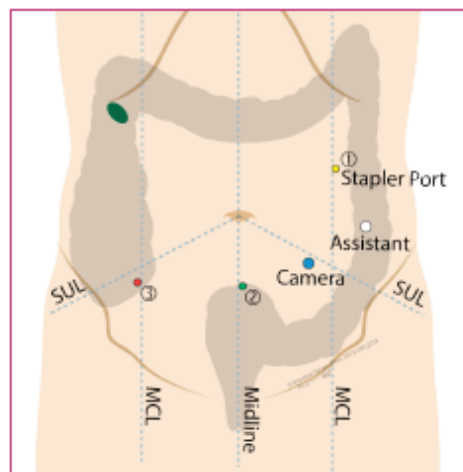


Figure 4. Robotic port positioning for distal lesions (Source: *DaVinci Technical Manual*).

The following principles should be respected while positioning the robotic ports for proximal lesions (Figure 5):

- Camera port (12 mm) should be placed ~2-3 cm lateral and slightly inferior to the umbilicus

- Instrument Arm Port 1 (8 mm) should be placed in the left upper quadrant, ~2-3 cm lateral to the MCL and ~3-4 cm inferior to the costal margin. Distance from other instrument ports and the camera should be at least 8-10 cm.
- Instrument Arm Port 2 (8 mm) should be placed on the midline, inferior to the umbilicus. Maintain ~3-4 cm distance to symphysis pubis.
- Instrument Arm Port 3 (8 mm) should be placed 2-3 cm sub-xiphoid and 4 cm to the left of midline.
- Assistant Port (12 mm) should be placed in the left-lower quadrant, ~ 4 cm inferior to the SUL and slightly lateral to the MCL. Distance from surrounding ports should be a minimum of 5 cm.
- All measurements should be made AFTER insufflation.

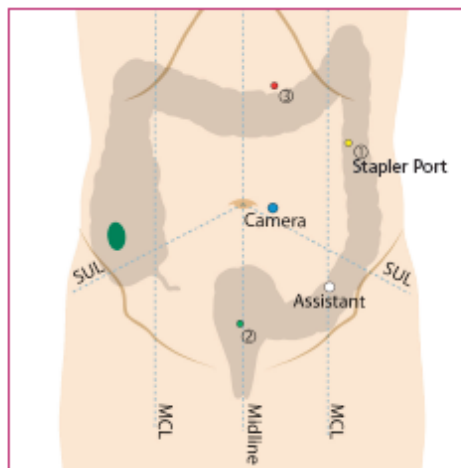


Figure 5. Robotic port positioning for proximal lesions (Source: *DaVinci Technical Manual*).

Procedure

The robotic right colectomy procedure begins with diagnostic laparoscopy. The abdomen is inspected to determine the feasibility of minimally invasive resection and to identify the extent of the disease. The patient is placed in the Trendelenburg position with the right side up. This allows for the small bowel and omentum to be displaced to the left upper quadrant, exposing the cecum and terminal ileum. The robot is then brought from the right side of the patient and docked onto the ports. Robotic monopolar scissors are on the right robotic arm (Instrument Arm Port 1) while bipolar grasp are on the left robotic arm (Instrument Arm Port 2). Depending on the surgeon's preference and anatomical variations, either a medial to lateral or lateral to medial approach can be used. However, in case of malignancy, a medial to lateral approach is preferred^{33, 42}.

The medial to lateral dissection begins by retracting the cecum anteriorly, laterally, and superiorly with the cadaver grasper (Instrument Arm Port 3). Parietal peritoneum is incised under ileocecolic mesentery identifying Gerota fascia posteriorly and Toldt fascia anteriorly. Second and third duodenal sections and pancreatic head are visualized. Ileocecolic vein and artery are isolated and sectioned with Hemolock (or linear vascular stapler) apposition at their origin. The intestinal segment to be resected is stretched with the third robotic arm, and transection of the right mesocolon is performed in a caudocranial direction, on the lateral margin of superior mesenteric axis. The right colic vessels (if present) and right branch of the middle colic pedicles are sectioned at their origins. If the tumor involves the hepatic flexure or proximal transverse colon, needing an extended colectomy, also the pedicle of middle colic vessels are sectioned at its origin. Dissection is

completed under Gerota fascia until preduodenal pancreatic fascia of Fredet. In this way, mediolateral access is concluded, and parietal peritoneal incision is continued in parietocolic sulcus along the Toldt fascia next to the cecum and ascending colon up to the previous dissection posteriorly.

Once the specimen is totally dissected, the robot is undocked and an approximately 5 cm incision is done peri-umbilically to create a small midline mini-laparotomy. The mobilized right colon is then exteriorized through this incision and resected. The standard mechanical anisoperistaltic side-to-side ileocolic anastomosis is created in open fashion.

The Rational of Robotic Learning Curve

Minimally invasive colorectal surgery has been used for inflammatory, benign and malignant disease entities and has been shown to reduce postoperative pain and length of hospital stay, provide faster recovery, and shown to be cost-effective in comparison to open surgery^{4, 10, 16, 17, 30, 43}. Among MIS techniques, laparoscopy is the most commonly applied to date.

As the demand for laparoscopic colorectal surgery increases, patient selection, case-mix, and laparoscopic outcomes such as conversion rates are expected to vary between surgeons and institutions. However, laparoscopic surgery requires a high degree of special resolution, dexterity, and technical skills. An initial training period is usually required for the majority of surgeons to become proficient in these complex procedures by continuous repetition of these tasks. As a result, to become technically proficient at laparoscopic colorectal resections, a long training period is expected. Several studies tried to assess the learning curve of specific laparoscopic colorectal procedures, and an average of 50-80 procedures appeared necessary to reach a plateau on the learning curve (Box 1).

Box 1. Summary of studies assessing the learning curve of different surgical procedures.

Reference	Surgical Procedure	Outcome	Time or number of case to reach a plateau
Meinke et al. ⁴⁴	Laparoscopic fundoplication	Complication rate, conversion rate, reoperation rate	20 cases
Tekkis et al. ¹⁹	Laparoscopic colorectal surgery	Conversion rate, complication rate, operative time	55-80 cases
Richardson et al. ⁴⁵	Laparoscopic cholecystectomy	Bile duct injury rate	3 years
Parikh et al. ⁴⁶	Gastrectomy	Morbidity, mortality, lymph node harvestes	18-24 months 15-25 cases
Sutton et al. ⁴⁷	Oesophagectomy	Operative time, blood loss, ITU stay, inpatient stay, lymph node harvested	150 cases 7 years

Despite the increasing experience with laparoscopic colorectal surgery and the continuous improvements in the available equipment and technology, laparoscopy remains associated to several disadvantages. The image projected onto the operating monitor is a 2-dimensional representation of a 3-dimensional operating field. This can result in difficulties with depth perception. The ergonomics of laparoscopy can be poor and can lead to both operator and assistant fatigue^{3, 48}. Another well-known limitation is the difficulty of obtaining a high-precision suturing, due to the fixed tips and limited dexterity of surgical laparoscopic instruments. Finally, the physiological tremor from the camera operator cannot be eliminated and may be exaggerated toward the end of a lengthy operative case.

As the most advanced technology in MIS, robotic surgery has the potential to address most of the drawbacks and limitations of laparoscopy. The robotic surgical system offers a camera system that is controlled by the operating surgeon combined with a 10-fold magnification vision, thus allowing a perfectly still and 3-dimensional visibility of the

operative field. The tips of the instruments of a robotic arm have an *EndoWrist* technology that has functions of 7 degrees of freedom, 180° articulation, and 540° rotation.

A recent systematic review of robotic surgery in the resection of rectal cancer showed that the current evidence suggests that robotic rectal surgery could potentially offer better short-term outcomes especially when applied in selected patients compared to laparoscopy⁴⁹. Obesity, male sex, preoperative radiotherapy, and tumors in the lower two-thirds of the rectum may represent selection criteria for robotic surgery to justify its increased cost related to this advanced technology. However, the role of robotics in colonic surgery is largely undefined. The results of a recent systematic review on robotic colonic surgery compared with multiport laparoscopic colonic surgery showed that the median age of patients, length of postoperative stay, and time to first bowel movement were similar between the two approaches³. The robotic colonic group showed a greater median lymph node harvest, whereas the median operative time for robotic surgery was much longer than for laparoscopic surgery. The morbidity data suggested that robotic colectomy had a favorable complication profile in comparison with multiport laparoscopic surgery. However, as the authors of the systematic review acknowledged, there were significant selection and complication reporting biases that precluded meaningful comparisons³. Nonetheless, these data supports robotic surgery as a safe and feasible procedure when undertaken in selected patients and high-volume experienced surgical centers^{3, 30, 50}.

Overall, the reported conversion rate for robotic colectomies was approximately 8%. The most frequent reasons for conversion to open surgery included dense adhesions from sigmoid colon to bladder, descending colon ischemia after division of the inferior

mesenteric artery, venous bleeding around the pancreas, inability to identify the tattooed tumor, locally invasive tumors, and stapler malfunction. The most frequent reasons for conversion to laparoscopic surgery included fatty mesentery precluding safe robotic dissection, robotic malfunction³.

These results are promising, but for robotic colorectal surgery to become an accepted alternative to open or laparoscopic surgery, it needs to address several challenges that face any new emerging surgical technique. It should be safe and result in a comparable, if not better, oncological outcome when used for resection of malignant disease. It should also have a reasonable learning curve, and, ideally, the skills that the surgeon would gain during training for robotics would be transferable to other possible developments in minimally invasive colorectal surgery. Equally important, especially with the increasing financial strains on the current health care systems, robotic surgery should be cost-effective.

Unfortunately, the conclusion of many studies is that robotics is too expensive and probably not as cost-effective as laparoscopy. The real benefits of robotics, however, are difficult to quantify by means of preliminary cost-effectiveness analyses performed on the early experience of a few specialized centres^{3, 27, 51}. Thus, before discouraging the implantation of robotic platforms, further clinical trials should be designed to assess the efficacy of robotics, its learning curve, and more importantly, studies should aim to answer a specific patient-oriented questions, such as “What are the supplement benefits of robotics for those patients or procedures in which MIS still struggles to be applied?”

The Surgical Learning Curve

A learning curve is a graphical representation of the increase of learning/performance (vertical axis) with experience (horizontal axis) (Figure 6). When learning a new procedure, performance tends to improve with experience, thus clinicians inexperienced in a procedure are said to be on the early phase of their learning curve with improvements expected with increasing experience^{52, 53}.

A hypothetical plot of an ideal learning curve has four main phases (Figure 6). The starting coordinate A represents commencement of training. Secondly, the curve ascends. The gradient of this ascent indicates how quickly the individuals' performance improves; this part of the curve may be a stepwise ascent as individuals learn and master stages of a complex procedure. Improvements in performance tend to be most rapid at first and then tail off, as the degree of improvement attained with each case reduces as technique is refined. Thirdly, assuming adequate aptitude, a point is reached when the procedure can be performed independently and competently (coordinate B). Additional experience improves outcomes by small amounts (coordinate C), until a plateau, or asymptote, is reached (coordinate D). Fourthly, with advancing age, manual dexterity, eyesight, memory and cognition may deteriorate, outweighing any advantage derived from long experience, leading to a fall in the level of performance (coordinate E).

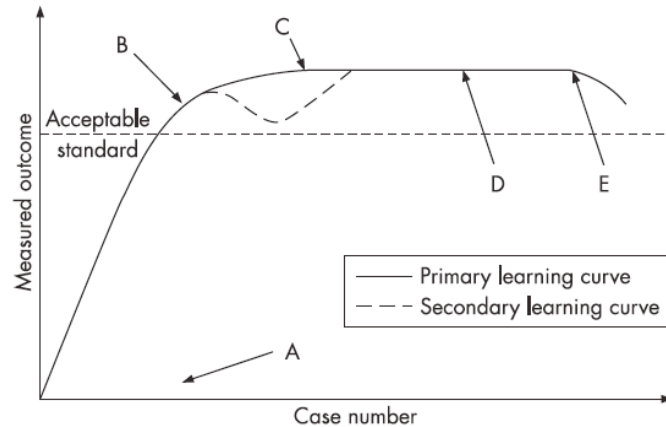


Figure 6. An idealized surgical learning curve.

The learning curve has a slope (representing the rate of learning), which may eventually plateau, suggesting that performance has reached a steady level.

A: commencement of training; **B:** tipping point when the procedure can be performed independently and competently; **C:** experience improves outcomes by only small amounts; **D:** reaching of a plateau; **E:** fall in the level of performance due to aging.

The small dotted horizontal line represents the acceptable standard. The dotted curve represents an alternative learning curve between the points B and C described as a temporary performance deterioration after technical competence has been achieved. The reasons postulated for this scenario are case mix effect (undertaking more difficult cases), or over confidence resulting in lapses in technique or judgment. (Source: Hopper A et al. 2007⁵²)

The concept of the learning curve applies across the full spectrum of medical specialities and procedures; however, with the advent of technically demanding minimally invasive techniques, it is surgery in particular where there are specific and important implications. The learning curve is indeed particularly interesting in surgery where a constant stream of new skills must be acquired safely and efficiently. It would thus be useful to know how many procedures a surgeon may have to carry out before reaching a safe and competent level of performance autonomously. Knowledge about the specific learning curve of a surgical procedure could also enhance the surgical training program. A surgeon may have to perform a procedure a certain number of times under supervision or in

a simulated environment before performing it independently. Training programs could use the learning curve data to map progress of trainee surgeons. Furthermore, an understanding of the learning curve is crucial in randomized control trials comparing new procedures with older interventions.

The effect of the learning curve of acquiring the new procedure must be considered in order to reach valid conclusions. However, on which variable the learning curve should be measured on is still a matter of debate⁵³.

By measuring specific outcomes it is possible to estimate the location of an individual on a learning curve. Measures of learning related to a surgical technique fall into two categories: measures of surgical process, and measures of patient outcome. Surgical process measures include operative factors such as operative time, blood loss, and technical adequacy of resection for cancer surgery—margin involvement and lymph node yield. Patient outcomes include postoperative factors such as analgesia requirement, transfusion requirement, length of stay in intensive care, length of stay in hospital, morbidity rates, mortality rates, and cumulative survival.

Surgical process outcomes are generally easier to analyze and therefore more commonly used, though they are only indirectly related to patient outcomes. However, when considering outcomes of cancer surgery, improvements in case adjusted long-term survival probably represent the best measure of performance. Indeed, it is possible to plot curves based on long-term survival related to progression within a case series.

It is also worth noting that in many studies on surgical learning curves the definition of the variables used to assess it are often different (e.g. operative time, rate of complications), which makes harder to compare the learning curve between studies on the same procedure. Moreover, the choice of the measurement must be carefully evaluated, since not all variables are reliable measures of learning. For example, it is easier to measure and statistically analyze data on operating time than patient complications. Yet, a learning curve based on operating time alone may not be the best indicator of good practice⁵⁴. Also, variables should be tailored to the type of procedure. For example, operative mortality may not be a good indicator in low-risk procedures where patient satisfaction and quality-of-life measures may be more important. In cancer surgery, it may be more meaningful to measure long-term survival.

Finally, confounding factors must be minimized to draw valid conclusions. Organizational factors (facilities, equipment), surgical team (experience, co-operation), case mix, complexity of cases and surgeon's characteristics (previous experience, natural abilities, motivation etc.) can all affect the learning curve of a procedure⁵³. Surgeon's previous experience is often difficult to assess and poorly defined in many studies.

Statistical Analyses to Quantify the Learning Curve

There are many different methods to assess the learning curve. The most common is the graphical representation on a simple plot. However, there is much variation and no particular rationale in the type of regression analysis or curve fitting model used (e.g. least-

squares regression, logarithmic or negative exponential curves etc.). Another method includes chronologically dividing the case number into consecutive groups to compare learning with increasing time and experience, for example dividing into quartiles and comparing performance in each quartile over time. This method is ideal for comparison between large case numbers, but the size of groups may hinder the learning curve interpretation.

Finally, another statistical method that is gaining popularity within the learning curve literature is the cumulative sum (CUSUM) analysis⁵⁵. This is a very useful sequential analysis method that detects change in the individual surgeon's performance. The trend in outcome is graphically represented as a straight line with acceptable performance and an upward slope with less than optimum performance. A trainee surgeon is expected to show a rising curve (the rate of learning), which may eventually plateau when performance stabilizes. Although, this is an excellent statistical method for detecting change and the possibility of adverse events, it is less good for comparing inter-operator differences⁵³.

Factors Affecting the Learning Curve

A complex hierarchy of factors can affect the surgical learning curve. At the bottom, factors like guidelines, protocols and standards for clinical governance agreed upon by the medical fraternity are vital. Next the Institutional policies and cost effectiveness are contributory. Needless to say the surgical team, the case mix and public awareness are relevant. The final level in the hierarchy that can influence individual learning is the

characteristics of the surgeon such as attitude, capacity for acquiring new skills and previous experience⁵³.

Training in Robotic Surgery

The learning curve of robotic colorectal surgery is claimed to be reduced in comparison to laparoscopic colorectal surgery. The estimated number of cases required to be proficient and achieve competence is of only 15 to 25 procedures¹.

The robotic learning curve has some peculiar characteristics that can be categorized into 3 phases: the phase 1, which entails adaptation to the loss of tactile and tensile feedback, the phase 2, which is the understanding of the spatial relationship of the robotic instruments with the patient's body, and the phase 3, which involves the ability to operate from the console without direct visualization of the patient. It is highly debated whether the previous surgeon's experience in MIS techniques can reduce the length of the learning curve in robotic surgery. However, if the learning curve of robotic surgery is indeed proven to be reduced compared to laparoscopy, then this may facilitate the dissemination of robotic platforms even to surgeons who perform open surgery and who have not adopted laparoscopy into their clinical practice.

These aspects are also very important to support the definitive introduction of training in robotic surgery in the curriculum of the resident surgeons.

Aims of the Present Study

The present study aimed:

- 1) To compare the operative and postoperative outcomes of robotic-assisted right colectomy vs. laparoscopic right colectomy.
- 2) To evaluate and compare, by using CUSUM analysis, the learning curve of a single fellow surgeon in robotic-assisted right colectomy vs. laparoscopic right colectomy for colon cancer.
- 3) To assess the health-related cost of robotic surgery compared to laparoscopy.

Materials & Methods

Study Design

Between November 2012 and December 2015, 30 consecutive patients underwent robotic-assisted right colectomy (RRC) and 50 consecutive patients underwent laparoscopic right colectomy (LRC) for colon cancer at the Henri Mondor Hospital of Créteil (France). All procedures were performed by a fellow surgeon (NdeA), who, at the time of the study, was autonomous in general MIS training (> 75 hands-on laparoscopic cholecystectomy/appendectomy) and had assisted to > 50 laparoscopic colectomies. He had also attended training courses and simulations in robotic surgery, including periodical proctoring by an European Academy of Robotic Colorectal Surgery (EARCS) accredited surgeon. However, the fellow could be considered at the beginning of his learning curve in both RRC and LRC.

In the surgical unit of the Henri Mondor Hospital of Créteil, there is one senior surgeon (FB) highly experienced in laparoscopic and robotic colorectal surgery (> 10 years of experience). He works together with the fellow and provide team approach in MIS colorectal surgery. For this study, the senior surgeon supervised the surgical fellow in all procedures.

The study was conducted in accordance with the ethical principles ascertained in the Declaration of Helsinki.

Study Population

All consecutive patients with right colon cancer requiring surgical resection were eligible for inclusion in the study. Decision on which approach, laparoscopic or robotic one, performed was based on the patient's choice and the availability of the robotic platform, without applying any clinical contraindications. Both laparoscopic and robotic surgeries are not associated with extra costs for the patient, for whom both procedures are covered by the national assurance system at 100%.

Demographic data, intraoperative findings, operative procedures, postoperative parameters, morbidities, and outcomes were prospectively collected into the colorectal database of the surgical unit of the Henri Mondor Hospital of Créteil. To ensure patient safety and oncological clearance, bulky tumors (e.g. AJCC cT4a or cT4b) were not operated by the fellow surgeon and they were thus excluded from the study analysis.

Surgical Techniques

Preoperative preparations, operative steps, instrumentations, and postoperative care were standardized.

All patients underwent a preoperative evaluation including a physical examination, colonoscopy with tumor biopsy, and a total body computed tomography (CT) scan with contrast enhancement. In cases of suspected lymphatic packets, positron emission tomography (PET) with lymphatic biomarkers was performed for preoperative staging. Preoperative laboratory data included complete blood cell count, biochemical profile, and tumor markers (carcinoembryonic antigen, CEA). Intravenous antibiotic prophylaxis was administered according to the guidelines of the infection control committee of the hospital.

The laparoscopic right colectomy was performed as previously reported⁵⁶⁻⁵⁹. In brief, four laparoscopic ports were placed as follows:

- 12-mm umbilical, camera port for 30 degree telescope
- 12-mm left lumbar, pararectally port (right hand working)
- 5-mm right lumbar, pararectally port (assistant hand working)
- 5-mm suprapubic port (left hand working).

LCR were approached medial to lateral. First, the resectability of the mass was assessed. Then, the transverse colon was lifted up and the C of duodenum was identified. On the inferior side of duodenum, an incision over peritoneum was made with Harmonic Ace (Ethicon Endosurgery, Cincinnati). A gauze piece was passed and CO₂ itself was insufflated in to dissect duodenum and kept away from operative injury.

For carcinoma of caecum, ileocolic and right branch of middle colic vessels were clipped proximally and on specimen side and divided them with harmonic ace. All fibro fatty tissue and lymph nodes were dissected towards the specimen. Usually only right branch of middle colic vessels was clipped. The entire middle colic vessel was divided for right colon cancer near hepatic flexure or in transverse colon. The mesentery was divided completely from colon to caecum with Harmonic Ace. Then, along the white line of Toldt, the entire right colon was mobilized up to midtransverse level. The resection and anastomoses were done extra corporeally by delivering colon by enlarging the umbelical trocar incision (up to 5 cm). Extra-corporeal side-to-side anastomoses were carried on by using Linear Staplers (Ethicon). On either side of tumor, the resectional margin of colon should be at least of 5 cm. All ports and incision were closed with Vicryl and Ethilon sutures.

The robotic right colectomy procedures were performed with the robot docked as described above (see Robotic Right Colectomy Chapter, Page 16). The main surgical steps were the same of the laparoscopic right colectomy, using always a medial to lateral approach. In some cases, Energy devices (EndoWrist® Vessel Sealer) were used.

Postoperatively, diet was resumed as soon as bowel function returned clinically. Patients were discharged when they tolerated diet and regained ambulation. Patients were regarded to be suffering from prolonged ileus if they were unable to resume diet after postoperative day 4 and required parenteral nutrition supplementation. Time to ull ambulation was defined as time when the patient could walk independently in the ward without assistance. Once discharged, all patients were followed every 3 months for the first

3 years and every 6 months thereafter (French Guidelines from the Thesaurus National de Cancerologie Digestive, 2011). At the follow-up visits, physical examination, CT, and serum chemistry analysis were performed. Colonoscopy was carried out if abnormalities were detected during any follow-up visit.

Outcomes Measures

Operative time was measured from skin incision to completion of wound closure. For robotic-assisted procedures, docking time (i.e. the time required to position the robot and secure the robotic arms to the corresponding port sites) was calculated separately from the operative time. The surgeon console time was the actual time the surgeon spent at the robotic console during the procedure, and it was also calculated for the RRC. Mean operative time was used as the main outcome variable to plot the learning curve.

Conversion was defined as the shift from laparoscopic to open approach, or from robotic to laparoscopic or open approach to complete the procedure.

Postoperative morbidity and mortality were defined as events occurring during the hospital stay or within 90 days after resection. Postoperative complications were categorized by the Dindo-Clavien classification⁶⁰. All complications were assessed by a clinician and prospectively registered in the databases at discharge or during the first outpatient visit. Morbidity included postoperative medical and surgical complications such as cardiovascular, respiratory, stoma-related complications, intra-abdominal abscess, anastomotic leakage, wound infection, prolonged ileus, anastomotic hemorrhage and

reoperation. The oncological outcomes included quality of surgical resection (i.e., R0, R1), and number of lymph nodes harvested. R0 resection was defined as the macroscopically complete removal of the tumor with a microscopically free resection margin and no peritoneal spread.

Statistical Analyses

To evaluate the surgeon's learning curve in laparoscopic and robotic right colectomy, all cases were ordered chronologically, from the earliest to the latest date of surgery. The LRC and RRC groups were divided into three subgroups of patients following the chronological order without the presence of any other obvious grouping criteria. Grouping was the following: Cases 1 to 10, Cases 11 to 20, and Cases 21 and more.

The CUSUM technique was used for quantitative assessment of the learning curve. The CUSUM is the running total of differences between the individual data points and the mean of all data points. The CUSUM technique used for the 30 RRC cases and the 50 LRC was based on the operative time.

Demographic data, operative outcomes, and complications were compared between RRC and LRC groups by Pearson chi-squared test, Fisher's exact test, and Mann-Whitney U-test. Within group differences (by comparing the three subgroups of patients) were assessed by ANOVA calculations. Significant difference was defined when p value was < 0.05. Statistics were performed with SPSS (Statistical Package for Social Science, IBM SPSS Statistics, Version 23 for Macintosh; IBM Corp., Armonk, NY, USA).

Results

Data summarizing demographic and preoperative variables are shown in Table 1. The LRC and RRC did not differ significantly for any of the considered variables. No patients with ASA score IV was included. The absence of between group difference was observed when comparing the LRC vs. the RRC whole groups, as well as when comparing LRC and RRC by cases 1-10, cases 11-20, and cases 21 or more.

Data summarizing operative and postoperative outcomes of LRC and RRC groups are displayed in Table 2. As shown for the whole sample, RRC procedure were associated with significantly reduced blood loss ($p=0.012$). The mean operative time was 204.1 (26.7) min for the LRC procedures and 200.5 (29.5) min for the RRC procedures ($p=0.408$). By subgroup analysis, the LRC and RRC groups showed a trend toward statistically significant difference only in the case series 11-20, in favor to RRC ($p=0.07$). No difference was observed between the other two series of procedures.

Two patients (4%) in the LRC were converted to laparotomy due technical difficulties related to bleeding during the right colic artery dissection and to inadequate view. No conversion was required in the RRC group. The LRC vs. RRC groups did not differ for the other considered variables, both in the whole group analysis and by subgroups. Overall, 10 (20%) patients in the LRC group and 4 (13.2%) patients in the RRC group developed postoperative complications, which included: ileus (1), anastomotic leakage (2), intra-abdominal abscess (1), cardiopulmonary diseases (10), and urinary infections (3). Two patients (4%) in the LRC group were classified as Dindo-Clavien grade

IV and underwent reoperation (one by laparoscopy, one by laparotomy) for anastomotic leakage. Both patients had stoma diversion and peritoneal lavage.

One patient in the RRC group died at post-operative day 3 due to a suicide. The 90-day mortality was nil. The mean length of hospital stay was 8.2 (4.4) days for LRC and 7.1 (3.1) days for RRC ($p=0.133$).

Data summarizing the histological findings are shown in Table 3. No group difference was observed for any variables considered, in both the whole sample comparison and the subgroups analyses.

Table 1. Demographic data and clinical characteristics of patients treated by laparoscopic right colectomy (LRC) or robotic right colectomy (RRC) for colon cancer.

Variables	Cases 1-10*		Cases 11-20*		Cases 21 +*		All cases (n=80)		
	LRC (n=10)	RRC (n=10)	LRC (n=10)	RRC (n=10)	LRC (n=30)	RRC (n=10)	LRC (n=50)	RRC (n=30)	P value
Gender (F/M) [n]	8/2	5/5	5/5	7/3	18/12	3/7	31/19	15/15	0.353
Age (yr) [mean(SD)]	73.4 (16.73)	66.8 (10.21)	71 (13.83)	72.6 (4.47)	70.3 (11.56)	73.6 (8.85)	71.1(12.92)	71(8.50)	0.747
BMI (kg/m²) [mean(SD)]	24.27 (2.54)	25.33 (3.66)	26.1 (3.5)	27.06 (3.32)	25.3 (4.83)	26.89 (2.52)	25.26(4.19)	26.43(3.21)	0.180
Albumin Serum Level (g/L) [mean(SD)]	35.5 (5.9)	33.6 (4.5)	32.2 (5.1)	32 (4.3)	33.4 (6.25)	32.5 (4.06)	33.50(5.95)	32.7(4.18)	0.250
Diabetes [n(%)]	2 (20)	1 (10)	1 (10)	1 (10)	8 (26.7)	4 (40)	11(22)	6(21.4)	1
Cardiovascular Diseases [n(%)]	5 (50)	5 (50)	7 (70)	4 (40)	21 (70)	7 (70)	33(66)	16(53.3)	0.344
Pulmonary Disease [n(%)]	3 (30)	2 (20)	2 (20)	2 (20)	4 (13.3)	3 (30)	9(18)	7(23.3)	0.576
Previous abdominal surgery [n(%)]	7 (70)	3 (30)	5 (50)	5 (50)	14 (46.7)	4 (40)	26(52)	12(31.6)	0.358
ASA Score I/II/III [n]	1/3/6	0/7/3	3/2/5	0/5/5	0/13/17	0/3/7	4/18/28	0/15/15	0.181
Smoking [n(%)]	0	3 (30)	4 (40)	6 (60)	8 (26.7)	0	12(24)	9(33.3)	0.428
Tumor location[n(%)]									0.540
Ileo-caecal valve	1 (10)	2 (20)	2 (20)	0	5 (16.7)	0	8(16)	2(6.7)	
Caecum	3 (30)	3 (30)	3 (30)	4 (40)	9 (30)	3 (30)	15(30)	10(33.3)	
Right ascending colon	2 (20)	2 (20)	3 (30)	2 (20)	7 (23.3)	3 (30)	12(24)	7(23.3)	
Right splenic flexure	2(20)	2 (20)	2 (20)	3 (30)	5 (16.7)	4 (40)	9(18)	9(30)	
Right transverse colon	2 (20)	1 (10)	0	1 (10)	4 (13.3)	0	6(12)	2(6.7)	
TNM AJCC Stage** [n(%)]									0.609
I	5 (50)	2 (20)	3 (30)	3 (30)	10 (33.3)	3 (30)	18(36)	8(26.7)	
II	5 (50)	6 (60)	4 (40)	4 (40)	12 (40)	3 (30)	21(42)	13(43.3)	
III	0	2 (20)	3 (30)	3 (30)	8 (26.7)	4 (40)	11(22)	9(30)	

BMI stands for body mass index; ASA for American Society of Anesthesiology; TNM for tumor, nodes and metastasis score; and AJCC for American Joint Committee on Cancer.

* No statistically significant difference was noted between the LRC and RRC groups in this subset of consecutive cases.

**In the TNM AJCC categories II and III, the subcategories including T4b tumors (*i.e.*, tumors directly invading or adherent to other organs or structures) were not included.

Table 2. Operative and postoperative variables of patients treated by laparoscopic right colectomy (LRC) or robotic right colectomy (RRC) for colon cancer.

Variables	Cases 1-10*		Cases 11-20*		Cases 21 +*		All cases (n=80)		
	LRC (n=10)	RRC (n=10)	LRC (n=10)	RRC (n=10)	LRC (n=30)	RRC (n=10)	LRC (n=50)	RRC (n=30)	P value
Operative time (min) [mean(SD) and (range)]	240(26.14) (220-300)	237.8(27.07) (200-290)	214.5(12.57) (195-230) #	193.8(24.24) (168-230) #	188.6(14.73) (160-230)	180(12) (168-200)	204.1(26.7) (160-300)	200.5(29.5) (168-290)	0.408
Docking time (min) [mean(SD) and (range)]	NA	25.7 (4.8) (20-34)	NA	21.6 (1.95) (20-25)	NA	18 (4.16) (12-25)	NA	21.76(4.9) (12-34)	NA
Surgical console time (min) [mean(SD) and (range)]	NA	196.5 (13.7) (180-220)	NA	174 (26.64) (140-220)	NA	152 (8.56) (140-170)	NA	174.16(25.36) (140-220)	NA
Conversion to laparoscopy [n(%)]	0	0	0	0	0	0	NA	0	NA
Conversion to laparotomy [n(%)]	1 (10)	0	0	0	1 (3.3)	0	2(4)	0	0.525
Operative blood loss (mL) [mean(SD)]	165 (24.1)	137 (32)	170 (25.8)	147 (25.4)	160 (25.5)	162 (34.5)	164 (24.80)	148.6 (31.59)	0.012
Number of transfused patient [n(%)]	0	0	1 (10)	0	0	0	1(2)	0	1
Time to flatus [mean(SD) and (range)]	2.2(0.63) (1-3)	1.9(0.56) (1-3)	2.3(0.48) (2-3)	2.1(0.56) (1-3)	1.63(0.49) (1-2)	1.9(0.31) (1-2)	1.88(0.59) (1-3)	1.96(0.49) (1-3)	0.471
Return to regular diet [mean(SD) and (range)]	3.4(0.96) (2-5)	2.9(0.99) (2-5)	3.3(0.82) (2-5)	2.8(0.78) (2-4)	2.7(0.59) (2-4)	2.4(0.51) (2-3)	2.96(0.78) (2-5)	2.7(0.79) (2-5)	0.108
Post-operative complications [n(%)]									
Ileus	0	0	0	1(10)	0	0	0	1(3.3)	0.375
Anastomotic leakage	0	0	1(10)	0	1(3.3)	0	2(4)	0	0.525
Intra-abdominal abscess	0	0	0	0	1(3.3)	0	1(2)	0	1
Cardiopulmonary complication	2(20)	1(10)	2(20)	1(10)	3(10)	1(10)	7(14)	3(10)	0.736
Urinary infection	0	1(10)	0	0	1(3.3)	1(10)	1(2)	2(6.7)	0.553
Dindo-Clavien classification									0.499

[n(%)]									
I-II	2(20)	2(20)	1(10)	1(10)	5(16.7)	1(10)	8(16)	4(13.3)	
III-IV	0	0	1(10)	0	1(3.3)	0	2(4)	0	
Mortality within 30 days [n (%)]	0	1(10)	0	0	0	0	0	1(10)	1
Mortality within 90 days [n (%)]	0	0	0	0	0	0	0	0	NA
Length of hospital stay (days) [mean(SD) and (range)]	7.8(2.61) (5-13)	8.3(4.21) (6.20)	8.4(4.4) (5-18)	7(2.66) (5-14)	8.36(5.01) (4-30)	5.9(1.79) (4-10)	8.26(4.4) (4-30)	7.06(3.1) (4-20)	0.133

*No statistically significant difference was noted between the LRC and RRC groups in this subset of consecutive cases, if not otherwise specified.

Trend toward statistically significant difference between LRC and RRC (p=0.07).

Table 3. Histologic findings in patients treated by laparoscopic right colectomy (LRC) or robotic right colectomy (RRC) for colon cancer.

Variables	Cases 1-10*		Cases 11-20*		Cases 21 +*		All cases (n=80)		
	LRC (n=10)	RRC (n=10)	LRC (n=10)	RRC (n=10)	LRC (n=30)	RRC (n=10)	LRC (n=50)	RRC (n=30)	P value
R1 resection [n(%)]	1 (10)	1 (10)	1 (10)	0	0	0	2(4)	1(3.3)	1
Number of lymph nodes harvested [n(%)]									0.739
< 12 lymph nodes	2 (20)	1 (10)	1 (10)	1 (10)	3 (10)	3 (30)	6(12)	5(16.7)	
≥ 12 lymph nodes	8 (80)	9 (90)	9 (90)	9 (90)	27 (90)	7 (70)	44(88)	25(83.3)	
Tumor size max diameter (cm) [mean(SD and range)]	4.65 (1.10) (3-6)	5.1 (0.70) (3.5-6)	5.02 (0.98) (3.5-6)	4.3 (1.31) (3-7)	5.43 (1.21) (3-8)	5.31 (0.79) (4-7)	5.2(1.2) (3-8)	4.9(1.09) (3-7)	0.261
Adenocarcinoma [n(%)]									0.517
Well differentiated	7 (70)	7 (70)	7 (70)	6 (60)	17 (56.7)	9 (90)	31(62)	22(73.3)	
Moderately differentiated	3 (30)	3 (30)	2 (20)	4 (40)	10 (33.3)	0	15(30)	7(23.3)	
Mucinous	0	0	1 (10)	0	3 (10)	1 (10)	4(8)	1(3.3)	

* No statistically significant difference was noted between the LRC and RRC groups in this subset of consecutive cases.

The operative time showed a trend towards reduction in both RRC and LRC groups (Figure 7).

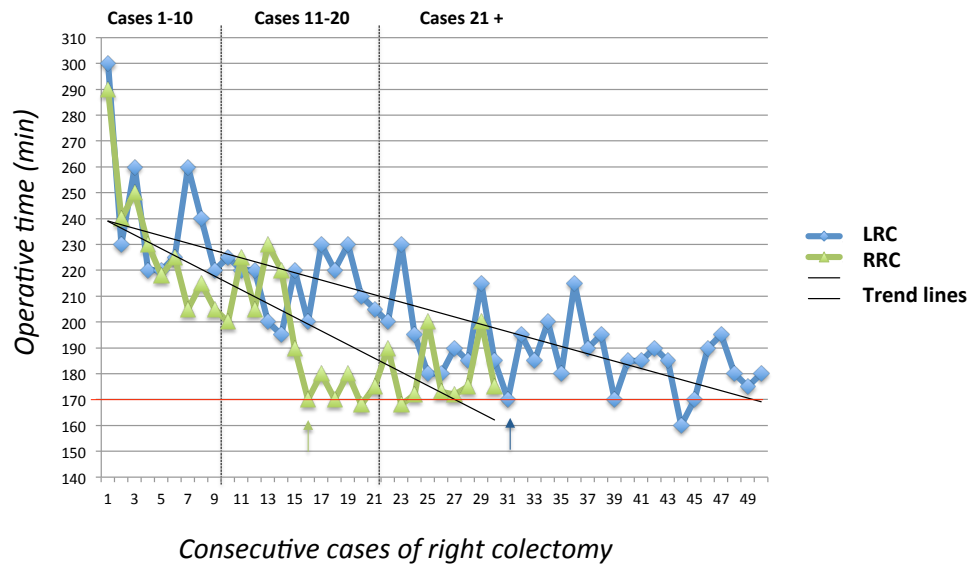


Figure 7. Plot of the operative time of LRC (blue line) and RRC (green line) procedures by consecutive patients with the respective trend lines.

In both groups, a significant reduction in the operative time was observed over time (ANOVA, for LRC $p < 0.0001$; for RRC $p < 0.0001$). Specifically, in the LRC group, a significant difference was observed between the case series 1-10 and the case series 11-20 ($p = 0.002$), and between the case series 1-10 and the case series 21+ ($p < 0.0001$), and between case series 11-20 and 21+ ($p < 0.0001$). In the RRC group, a significant difference was observed between the case series 1-10 and the case series 11-20 ($p = 0.002$), between case series 1-10 and case series 21+ ($p < 0.0001$), whereas no difference was observed between case series 11-20 and case series 21+ ($p = 0.174$). The curves showed that a drop in the operative time (≤ 170 min, red line) was observable after 31 cases of LRC (blue arrow) and after 16 cases of RRC (green arrow).

Concerning the robotic procedures, the progressive decrease in the operative time was also observed in the docking and surgeon console time, as shown in Figure 8.

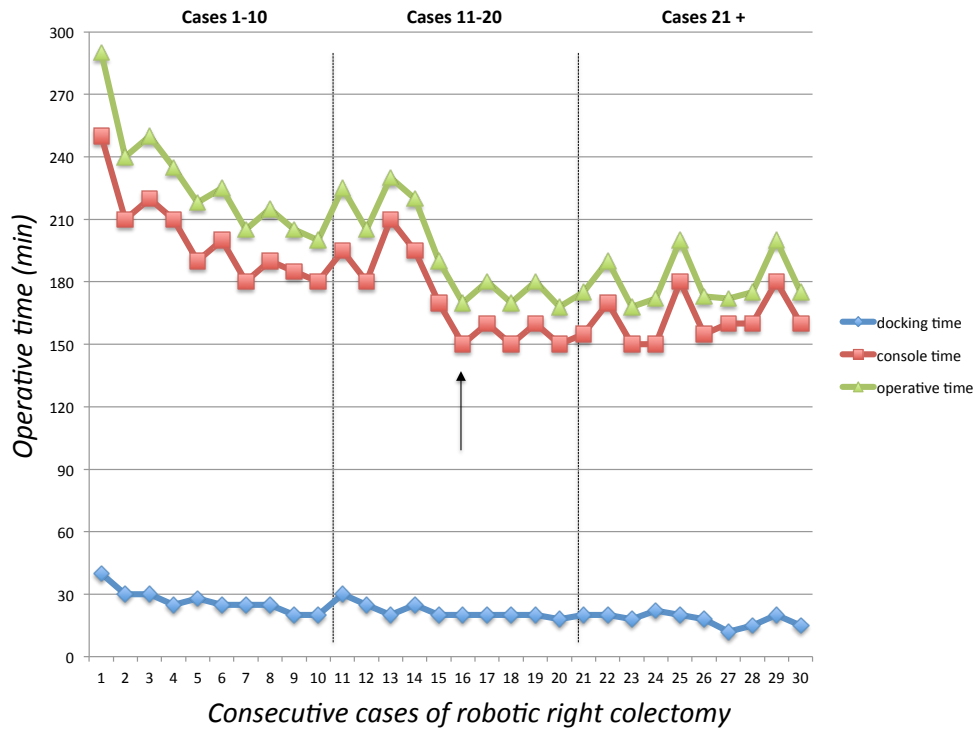


Figure 8. Plot of the operative time (green line), surgeon console time (red line), and docking time (blue line) of RRC procedures by consecutive patients.

A significant reduction over time was observed for the operative time ($p < 0.0001$), the surgeon console time ($p < 0.0001$) and the docking time ($p < 0.0001$). A drop in the operative time and console time is observable after 16 RRC cases (black arrow).

The CUSUM analyses are displayed in Figure 9 and 10 for respectively LRC and RRC procedures. As shown, the number of cases necessary to show a change in the operative time is set at 25 for LRC and 16 for RRC.

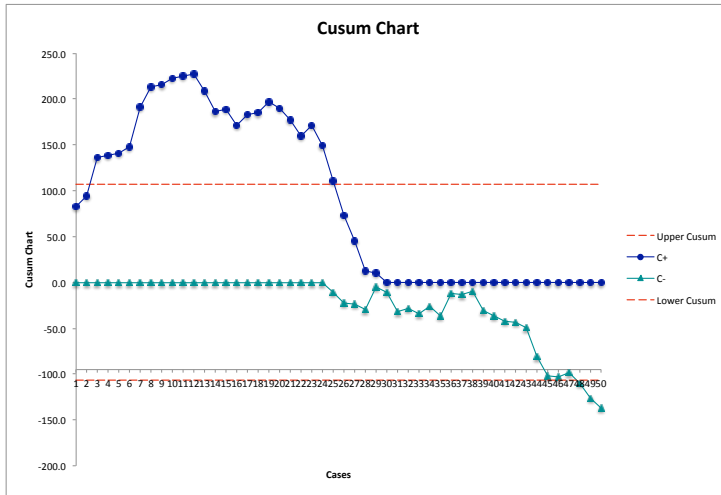


Figure 9. CUSUM analysis of LRC procedures.

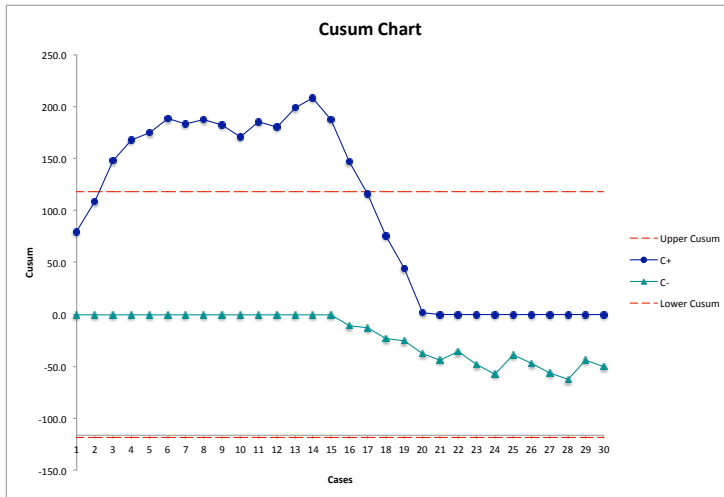


Figure 10. CUSUM analysis of RRC procedures.

In the Health Care Cost analysis, surgery-related costs of the LRC procedures resulted significantly less expensive compared with the RRL, with a mean cost of 1800 (90.9) Euros for the LRC vs. 2990 (298) Euros for the RRC ($p < 0.0001$). However, when the surgery-related costs are combined with the hospitalisation-related costs (estimated at approximately 1300 euros per day), the LRC or RRC procedures did not differ significantly ($p = 0.632$). Overall, the mean cost (surgery + hospitalisation costs) per right colectomy procedure was 12400 (5180) Euros (Figure 11).

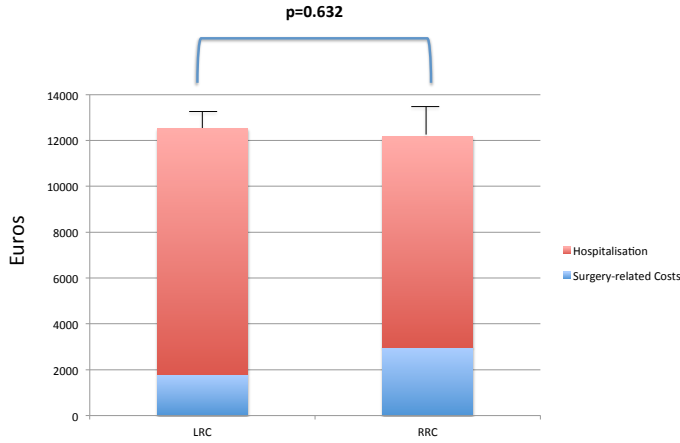


Figure 11. Health Care cost analysis for LRC and RRC procedures by taking into account the surgery-related costs and the hospitalisation.

Discussion

The present study shows that robotic right colectomy yields similar operative and postoperative outcomes of laparoscopic right colectomy performed by a fellow surgeon. The learning curve appears to be longer for LRC, whereas with only 16 robotic procedures a significant reduction in the operative time is already observable. RRC are also associated with significantly less blood loss compared to LRC. The postoperative complication rate and the histologic variables were not different between the two approaches. Interestingly, the present results also show that the health related costs are similar between LRC and RRC when considering the mean cost per procedure by adding the surgical costs (significantly more important in RRC) to the hospital stay.

Paucity of reports exists on learning curves involving robotic colonic surgery¹, while more literature is available for laparoscopic procedures^{17-19, 21, 23, 24, 44, 61}. Comparing the two techniques is also hard in the literature due to the fact that most of the time the surgeons beginning their learning curve in robotics are already experienced in laparoscopy, and this can have a direct and indirect influence on the robotic skills. In the present study, the operating surgeon was simultaneously adopting laparoscopic and robotic surgery for right colectomy procedures and he was at the beginning of his minimally invasive career. Thus, the results provide further elucidations on MIS learning curves and allows for direct comparisons. In our knowledge, only one previous study used this design to compare laparoscopy vs. robotic rectal surgery and concluded that the simultaneous development of laparoscopy and robotics provides acceptable perioperative outcomes, whereas robotics has a faster learning curve⁶². The present results confirmed those previous findings. Indeed,

robotic right colectomy appears to have a learning curve of 16 procedures whereas the laparoscopic ones of 26. In discordance with the previous literature^{40, 63}, the present study showed that the mean operative time of RRC is similar to LRC, which falls into the previously reported ranges for laparoscopic right colectomy (85-214 min^{29, 64, 65}). Moreover, the operative time decreases progressively with the number of procedures and the increasing surgeon experience for both robotic and laparoscopic approaches, but this process looked faster for robotic surgery. Indeed, after 16 RRC procedures, an improvement in the operative time is observable and appears quite stable for the following 14 procedures analyzed in this study. For LRC, the same improvement in the operative time is set at 31 procedures and it is more difficult to identify a plateau even after 30 procedures.

Previous studies reported that an operative time proficiency in robotic rectal surgery is reached in 15–25 cases¹. Another study has recently estimated that 80 robotic total mesorectal excision cases are the necessary learning curve⁶⁶, whereas the operative times did not improve during the course of the study. Thus, data in the literature are still controversial but it must be noted that the learning curve may be substantially different between right colectomy, rectal resections, or total mesorectal excision, which require various levels of difficulties and technical skills. In this regard, right colectomy appeared to be a suitable intervention to start the learning curve²⁹, and was chosen in this study as the sole procedure (performed with the same approach, i.e. medial to lateral, in both RRC and LRC) in order to limit the possible confounders in the evaluation of the learning curve.

The results presented in this study further show that the initially longer total operative time for robotic surgery improves rapidly and after only 15 cases it become faster

(trend toward significance) than that of laparoscopic surgery. Interestingly, this decrease seems to be attributed to the both the decrease in the docking time, which is finally assessed at 15-18 min, and the surgeon console time, which directly corresponds to the laparoscopic time.

Considering these data, the robotic approach can be safely chosen as an alternative approach to laparoscopy for right colectomy. The major concern will remain the costs for the Public Health System. The present results must be interpreted with caution since they refer to a specific situation of procedures performed by a fellow surgeon during the learning curve. Despite this, the present study shows that the two surgical techniques are not associated to different health related costs when combining the surgery-related costs and the hospitalization. Indeed, RRC procedures carry higher intraoperative costs in terms of surgical materials of laparoscopy, but the costs of laparoscopy per se might be higher than for experienced surgeon. Thus the gap between the two approaches may be inferior than what previously reported in the literature and is balanced out by the costs in the postoperative period. Another important point is the low incidence of complications, which can drastically influence the costs for the Health Care System. These aspects cannot be neglected and the present results cannot be generalized. However, they may suggest that the argument of cost-effectiveness or saving resources are not longer valid to discourage robotic surgery training and implementation^{27, 32, 48, 51}.

Study Limitations and Strenghts

One of the main limitations of the present study is the relative small number of cases, especially for the robotic procedures. Moreover, the learning curve was evaluated on a single surgeon experience and potential additive or even synergistic learning effects transferring from laparoscopy to robotic surgery and vice versa (which were developed simultaneously) cannot be excluded. On the other hand, the fact that this is a single surgeon experience performing both procedures at the onset of his career allows for a unique head-to-head comparison where many variables and effects stay similar for both techniques. However, the external validity of this findings is not assessed and all operative, postoperative and health costs results should be interpreted taking into account the specific situation of a fellow surgeon at the beginning of his MIS career. Points of strength include the homogeneous sample of patients undergone LRC and RRC during the same time period. The two groups were not balanced in numbers (due to the lower availability of the robotic platform compared to the laparoscopic instruments), but they did not differ for the most important demographic, clinical, and tumor-related variables.

Conclusion

Robotic right colectomy yields similar operative and postoperative outcomes of laparoscopic right colectomy once performed by a fellow surgeon during his learning curve. The advantages of MIS are observable in both robotic and laparoscopic procedures, but these latter ones appear to be associated with a longer learning curve. With increasing experience, operative time will further decrease, and it is not longer when operating with

the robotic platform. This suggest that it is reasonable and important to include robotic colorectal training for fellow surgeons, and this advanced MIS approach could be considered as safe, feasible and advisable in colorectal surgery. Moreover, the real challenge of cost-effectiveness of robotic procedures appear to be on the way of improvement. Especially in the present time characterised by important financial constraints of health care systems, robotic surgery had appeared not appropriate because not cost-effective. However, evidence are growing to support that the costs of robotic colonic surgery are reducing over time and they are projected to be further reduced in the near future because of the progressive decrease in equipment costs and consupcion, and the progressive shortening in hospital stay. It would be more and more difficult to argue that robotic surgery will not offer any potential advantage over laparoscopy, mostly in terms of further reduction of hospital stay. When analyzing the outcome of robotic surgery, too often we read the message that it is safe and feasible but too costly to be chosen over laparoscopy. Indeed, we keep answering the important clinical patient-oriented question “What are the surgical and clinical advantages of robot-assisted rectal surgery?” with a reply based on an often biased cost-effectiveness analysis. Surgeon are starting to use robotic surgery in a cost-effective way by decreasing the number of instruments used, being faster in docking and undocking and getting dedicated personnel in the robotic room. It is thus important that further clinical trials will be conducted to address the question whether the robotic approach could increase, thanks to its advanced technology, the currently small number of patients undergoing MIS.

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