

Extracorporeal versus intracorporeal anastomosis after laparoscopic right hemicolectomy: cost-effectiveness analysis



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Extracorporeal versus intracorporeal anastomosis after laparoscopic right hemicolectomy: cost-effectiveness analysis

AIM: The cost effectiveness of the laparoscopic right hemicolectomy is still debated, and the current literature does not allow to be drawn certain conclusion. Our study compared direct clinical costs and outcomes for laparoscopic right hemicolectomy with the two most used type of anastomosis, such as ExtraCorporeal Anastomosis (ECA) and IntraCorporeal Anastomosis (ICA).

MATERIAL AND METHODS: In this retrospective study, all patients who underwent laparoscopic right hemicolectomy with intracorporeal and extracorporeal anastomosis between January 2016 and April 2018 were evaluated. Patients were divided into two groups according to the type of anastomosis: ECA or ICA.

RESULTS: Thirty ECA and twenty-nine ICA patients were included in the study. Operative time was significantly longer in ICA group than ECA group ($p < 0.001$). No significant differences between the groups were seen in terms of time-to-first flatus, postoperative complications and re-admission rate. ICA group showed a shorter hospitalization (5 vs 6; $p < 0.022$). In the ICA group, considering only the surgical tools were more expensive than in ECA (1435.6 € vs 72 €). Nevertheless, the total cost of the two procedures in similar (14451.36 € in ECA group vs 14631.04 € in ICA group).

CONCLUSION: ECA and ICA are comparable in terms of postoperative outcomes. ICA requires much more expensive charges, compared to a minor hospitalization. The ECA seems to be less expensive in terms of surgical supplies but the longer recovery determines an increase in the total cost resulting in a non-inferiority of one compared to the other technique.

KEY WORDS: Cost-analysis, ExtraCorporeal Anastomosis, IntraCorporeal Anastomosis, Laparoscopy, Right Hemicolectomy

Introduction

Laparoscopic surgery benefits, compared to open surgery, are well-known: faster recovery in the return of normal

bowel functions, a shorter length of hospital stay and lower postoperative morbidity with similar oncological outcomes ^{1,2}.

Nevertheless, a surgical standardization is lacking, and various techniques are described: laparoscopic facilitated, laparoscopic assisted and total laparoscopic ³.

The first two procedures provide for an extracorporeal ileocolic anastomosis completed with the gut's exteriorization through a limited laparotomy. Only in the last one it is performed intracorporeally ⁴. This technique allows to avoid a possible twisting of the mesentery and

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bowel during the anastomosis construction and the opportunity for the surgeon to select the optimal bowel extraction site reducing the risk of incisional hernia ^{5,6}. The aims of the present study are not purely to evaluate the differences between the intra and extracorporeal anastomosis in terms of days of clinical outcomes but, based on this assessment, to try to quantify the charges of the two techniques analyzing their direct costs.

Material and Method

This is a retrospective study about intracorporeal anastomosis (ICA) and extracorporeal anastomosis (ECA) in reconstruction after laparoscopic right hemicolectomy. Fifty nine patients, registered in a retrospective database of our Surgical Oncology units - University Hospital of Chieti-Pescara from January 2016 to April 2018, were evaluated. Institutional ethics review board approval and a written consent from the patients were not required by our retrospective study. Twenty-nine and thirty patients are included in group ICA and ECA, respectively.

The primary outcome of this study was to perform a cost analysis based on the abovementioned comparison, on the price of the surgical equipment used during the two methods of anastomosis construction and on the expenditures for the operation and for the hospitalization per day in order to discriminate which technique was not only more feasible but also more affordable. In addition we also compare the performance of the two anastomotic techniques (analyzing data about the operation, the hospitalization, the short and long terms outcomes).

Data on patients' demographics, disease-related characteristics, operative characteristics, complications and long-term outcomes were retrospectively recorded.

Patient demographics such as age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) score, comorbidities, and history of previous abdominal surgery were obtained. Regarding operative variables, type of operation (right hemicolectomy or extended right hemicolectomy), operative time, conversion from laparoscopy to open and specimen extraction site were considered. As short-term outcomes, post-operative day of first flatus, hospitalization and medical and surgical perioperative complications were investigated.

The main medical complications recorded were pneumonia, pleural effusions, hyperpyrexia, anemia and transient ischemic attack. The surgical complications included: paralytic ileus, anastomotic leak and intraabdominal bleeding.

Anastomotic leak was diagnosed by clinical symptoms, as well as change in characteristics of fluids in the drains and abscess seen at abdominal CT scans. Intraabdominal bleeding was detected by progressive anemia, blood in the drains and hemoperitoneum at the CT scans. In addition, we investigated the number of patients who

required further surgical second look due to the above-mentioned complications.

Long-term outcomes and mortality were collected by 18 months follow-up and consisted in any of the following: wound infections, abdominal incisional hernia, pain at discharge day (evaluated by VAS score), days of recovery and readmissions or reoperations due to pathological conditions related to previous surgery (such as bowel obstruction, adhesions, persistent diarrhea, vomiting) or for relapse of colic cancer. All patients were contacted by telephone and no one was lost during follow-up. Days of recovery were defined as time required by patients to go back to work or to return to normal social life if already retired.

Lastly, we reported the prices of every tool used to perform extracorporeal and intracorporeal anastomosis, the cost of the surgical procedure and the hospital staying.

SURGICAL TECHNIQUE

All procedures were performed by four surgeons fully trained in laparoscopic colorectal surgery (FFDM, TG, PDS and NDB). Both techniques employed were always a medial-to-lateral dissection with ligation of blood vessels at their origin. In the ECA group, the mobilized right colon was extracted, through a wound protector (Alexis® Wound Protector/Retractor, Applied Medical), by creation of a subcostal right-sided incision in the major part of the cases and only in three cases by an extension of the incision of the umbilical port. After the manual transection of bowel edges, the surgeon performed an end-to-end handsewn (interrupted suture in single extramucosal layer with 3-0 Vicryl) ileocolic anastomosis.

In the ICA group, the transection of the bowel was performed intracorporeally using 60 mm linear tri-staple device (Ethicon endosurgery Echelon-flex™ or Medtronic Signa™). Then, the surgeon made a side-to-side ileocolic anastomosis with a 60mm laparoscopic tri-staple device (Ethicon endosurgery Echelon-flex™ or Medtronic Signa™).

The entero-colotomy was closed using a running 3-0 V-lock suture in double layer. In the end, the specimen was extracted preferably by transverse suprapubic (Pfannestiel) incision. Only in five cases an enlargement of umbilical incision was fashioned. The abdominal gap was always covered by a commercial dual ring wound protector (Alexis® Wound Protector/Retractor, Applied Medical).

Perioperative care was identical for both two groups: single shot antibiotic prophylaxis and nasogastric tube was removed with extubation. All patients were mobilized as soon as possible and included in a similar fast track program. Criteria for discharge included adequate pain control, passage of flatus and good wound healing.

STATISTICAL ANALYSIS

The quantitative variables were summarized as mean and standard deviation (SD) or median and interquartile range (IQR) according to their distribution. The qualitative variables were summarized as frequency and percentage. Shapiro-Wilk's test was performed to evaluate the departures from normality distribution for each variable. Chi Square's test or Fisher exact Test was assessed to evaluate differences in qualitative variables between study groups. Student's T-test or Mann-Whitney U-test was performed to evaluate differences in continuous variables between study groups. Alpha error was evaluated at 0.05. Statistical analysis was performed using IBM® Spss® Statistics v20.0 software (SPSS Inc. Chicago, Illinois, USA; © Copyright IBM Corporation 1989, 2011)

Results

The ECA group was older by a median of 4 years than the ICA one but it is not statically significant. The gender and BMI distributions were almost identical.

The ASA score was similar between both cohorts with at least 80% of patients having an ASA class of II or III. More than 50% of patient in both groups had previous abdominal surgery (such as appendectomy, cholecystectomy, caesarian section, inguinal hernia repair or hysteroneomyectomy); 62.1% and 56.7% in ICA and ECA group, respectively.

In ECA group the tumor was mainly located in the cecum and in the ascending colon, 33.3% and 36.7%, respectively. Only in two cases there was a double localization. The most frequent tumor site in ICA group was the cecum (55.2%). Regarding cancer stage, in the ICA group the predominant stage, according to AJCC staging, was II (31%) while in the ECA group was III (36.7%). In addition, we recorded 4 cases of adenoma with dysplasia. In ICA group two specimens were negative for cancer because of previous radical endoscopic polypectomy (pT0). Comorbidities were statistically more frequent in the ECA groups (18% vs 27%, $P=0.012$). Mean operative time was longer in the ICA group compared to the ECA groups (180 vs 112.5 min, $P<0.001$). Laparoscopic extended right hemicolectomy was performed in two cases only in the ECA group and this was related to the double localization of the cancer. In both cohorts all procedures were completed by laparoscopy. The sites of incision for the mobilized right colon extraction were transverse suprapubic in 82.8% of the ICA procedures and right subcostal in 90% of the ECA procedures. A periumbilical incision was performed in 5 and 3 cases, respectively. Incision size was significantly smaller for the ICA group [median = 4 cm (range 3.2 to 6cm)] than for the ECA group [median = 5 cm (range 4 to 7.5 cm)].

Using multivariate analysis to compare ECA cases against ICA cases, there was no difference in the occurrence of post-operative complications between the two groups. In the ECA group more patients had paralytic ileus (30% vs 20.7%, $P=0.412$) however this data is not statistically significant. No significant differences in the time of first flatus are found.

Similarly, the occurrence of pathological medical conditions (such as pneumonia, pleural effusions, anemia and transient ischemic attack) after surgery was more frequent, even if not significantly, in ECA group (30% vs 20.7%, $P=0.412$).

In ICA group there was one case of intraabdominal bleeding and one case of anastomotic leak. Only the patient with anastomotic leak underwent second look operation with ileostomy meanwhile bleeding was treated conservatively. In contrast, in the ECA group we found 2 anastomotic leak and one post-operative bleeding that were all treated with surgical revision. No significant differences were found on the statistical evaluation (10% vs 3.4%, $P=0.317$). Short-term outcomes are scheduled in Table I.

The median length of hospital stay resulted statistically significant longer in ECA group: patients undergoing to video-assisted right hemicolectomy have been discharged one day later compared to patients undergoing to totally laparoscopic procedure (5 vs 6 days; $P=0.022$).

ICA patients were found a slightly increase in wound infections compared to ECA counterpart, however this was not statistically significant (13.8% vs 6.7%, $P=0.338$).

Post-operative pain after the discharge was similar in both groups. Patients required from 30 to 25 day in median (ICA and ECA group, respectively) to recover comple-

TABLE I - Short-term outcomes - a. Mann-Whitney U-test; b. Pearson's Chi-Square.

	ICA 29	ECA 30	p value
Time to first flatus (days) median (IQR)	3(2-3)	2.5(2-4)	0.521a
Paralytic ileus	6(20.7)	9(30.0)	0.412b
Anastomotic leak	1(3.4)	2(6.7)	0.574b
Post-operative bleeding	1(3.4)	1(3.3)	0.981b
Medical Complications	6(20.7)	9(30.0)	0.412b
Second look	1(3.4)	3(10.0)	0.317b
Length of hospital stays median (IQR)	5(4-7)	6(5-8)	0.022a

TABLE II - Long-term outcomes and mortality - a. Mann-Whitney U-test; b. Pearson's Chi-Square.

	ICA 29	ECA 30	p value
Wound infection %	4(13.8)	2(6.7)	0.338a
Incisional hernia %	4(13.8)	4(13.3)	0.612a
Pain at discharge (VAS) median (IQR)	4(2-6)	3(1-4.3)	0.074b
Days of recovery median (IQR)	30(15-32)	25(14-30)	0.582b
Death	-	1(3.3)	0.321a

TABLE III - Equipment for intracorporeal anastomosis (ICA group).

Tools	Price €	Total amount €
Wound protector	56	56
V-loc (2)	24,80 x 2	49,6
Vicryl (2)	4 x 2	8
Cartridge (3)	264 x 3	792
Tristaple device	530	530
		1435,6

TABLE IV - Equipment for extracorporeal anastomosis (ECA group).

Tools	Price €	Total Amount €
Wound protector	56	56
Vicryl (4)	4 x 4	16
		72

TABLE V - Comparison of the costs between ECA and ICA groups.

Variables	ECA groups' Cost €	ICA groups' Cost €
Cost of operation	6945.84	6945.84
Cost of supplies	72	1435,6
Total Cost		
of hospitalization	1249.92 x 6= 7499.52	1249,92 x 5= 6249.6
Total	14451.36	14631.04

tely. In terms of incisional hernia, the percentage is the same in the two groups.

No patient needed further surgical operation in the next years or was readmitted to the hospital for conditions related to previous right hemicolectomy. Post-operative mortality was nil.

The mortality during 18 months of follow-up was 3.3% in the ECA group (1 case) and 0% in ICA group. Long-term results are summarized in Table II.

Table III shows that intracorporeal anastomosis required some expensive instruments such as tri-staple device. Meanwhile, only Vicryl suture is necessary to perform the extracorporeal technique because the bowel resection is manual, as summarized in Table IV.

The total amount spent by our institution is provided by the sum of the costs for the surgical tools including the operating room with the cumulative expenditure due to each day of hospital stay.

The National Health Service repayment system estimates an average cost of surgical procedure of 6945.84 euros, whereas it quotes an average cost of hospitalization per day of 1249.92 euros. The total cost of hospitalization was 7499.52 and 6249.6 euros in ECA group and ICA group, respectively. Total costs of supplies were

72 and 1435.6 euros in ECA group and ICA group, respectively. Total cost of the two procedures in similar (14451.36 € in ECA group vs 14631.04 € in ICA group) as shown in Table V.

Discussion

Laparoscopic colonic resections are associated with decreased postoperative pain, better pulmonary function, shorter duration of paralytic ileus, and reduced hospital stay ^{7,8}.

Moreover, its feasibility in terms of safety and oncological radicality has been proved by multiple trials with high level of evidence ³. According to Haskins et al, minimally invasive approach to right sided colon resection for colon neoplasm improves pathologic outcomes with decreased morbidity and mortality ⁹. Nowadays there is a debate about which of those two anastomosis techniques is better for laparoscopic right hemicolectomy ¹⁰.

Most surgeons performing laparoscopic right colectomy use the ECA technique; in comparison, ICA is considered more technically demanding. Our study revealed an operative time significantly shorter in ECA group as supported in current literature. Intracorporeal anastomosis requires advanced laparoscopic skills and a long learning curve is necessary ¹¹. It is indeed demonstrated that the ability in performing intracorporeal suture improves with training ⁵.

There was no conversion to open surgery in both groups and it can be mainly associated to the fact that the decision to convert is rarely related to difficulties arising during the reconstructive time but mostly during the mobilization of the colon ¹².

In our study the length of stay is significantly shorter in the ICA group and it can be related to different, even if not statistically significant, factors.

Firstly, patients of ICA groups showed a lower rate of paralytic ileus. Actually, the earlier recovery of bowel functions could be ascribed to the reduced manipulation of the abdominal organs in total laparoscopic right hemicolectomy opposed to the related tractions to the mesentery usually necessary to exteriorize the mobilized right colon through a small laparotomic incision in video-assisted procedure ¹³. Secondly, medical pathological conditions, such as respiratory diseases, are more frequent in ECA group. This finding could be related to the fact the patients of ECA group presented more comorbidities compared to patients of ICA group.

Furthermore, intracorporeal anastomosis requires a smaller incision usually located far from diaphragm muscle (such as Pfannenstiel incision) leading to less postoperative pain and consequent faster mobilization and, most of all, to a minimal pulmonary dysfunction ¹⁴.

In addition, in our retrospective study we did not find any difference in terms of anastomotic leak between ECA and ICA. Indeed, the difference in the incidence of ana-

stomotic leak reported in the current literature between the two techniques is controversial: Fabozzi's retrospective analysis of 50 patients is the only recent study to find a lower risk in intracorporeal anastomosis ($p < 0.05$) but this result is not replicated by any other retrospective analysis^{5,15}.

According to Grams et al., an explanation of the absence of anastomotic leak in his retrospective chart review could be that there is less tissue trauma in the intracorporeal technique and so a better blood supply to the bowel¹⁶.

Of interest, the incidence of anastomotic bleeding was similar as supported in Milone's et al. multicenter comparative study⁷.

We did not find any significant difference among long-term outcomes. The incidences of wound infection and of abdominal incisional hernia were similar. DeSouza et al., after an accurate analysis about the ideal extraction site for laparoscopic colorectal surgery, concluded that a Pfannestiel incision was associated with the lowest rate of incisional hernia¹⁷. Intracorporeal anastomosis, actually, offers the advantage to use any abdominal location for the extraction site⁵. This is not feasible during an extracorporeal anastomosis because the transverse mesocolon is not flexible and its anatomical characteristics makes necessary to perform the extraction incision in the proximity³. In our study, probably the surgeon's decision to prefer mostly a right subcostal incision, instead of umbilical one, permitted to avoid an elevated rate of abdominal hernia.

The pain at discharge was identical and patients got back to work and to their usual activities after a rest period almost comparable. Only one patient in ECA group died after 4 months from operation but she was the only at stage IV of disease.

Regarding our main endpoint, in literature there are some studies about the cost analysis of laparoscopic right hemicolectomy compared to the open procedure but not cost analysis comparing the two anastomotic techniques. The cost analysis comparing laparoscopic to open colorectal surgery have demonstrated that the first one not only saves money for the health care system, but it is also cost effective per quality adjusted life year¹⁸.

Our data show that surgical equipment necessary to perform an intracorporeal anastomosis, particularly Endogia stapler with its disposable components, is more expensive than tools used to make an hand-sewn extracorporeal anastomosis. Indeed, we have to remark the our ECA technique is quite uncommon and very cost-effective because it doesn't include any kind of staplers and this may represent a bias of the present study.

As mentioned before, usually the extracorporeal anastomosis includes the using of stapler, even just to cut the bowel, entailing the growing in costs.

In our study, if we consider the total amount of money spent by the cohort of patients, the difference is minimal thanks to the shorter length of stay in ICA group.

However, it's remarkable to consider the significant difference in operative times between the two groups, which affects the real costs of surgery. One hour of surgical time in operating room costs about 600 euros, and, considering that the difference between ICA and ECA groups was about 68 minutes, the right hemicolectomy with intracorporeal anastomosis costs 680 euros higher than ECA group if the anastomosis is performed without any stapler device. This supply was not considered by the National Health Service repayment system, therefore, it were not included in the cost assessment.

Some limitations of the study might be addressed. First, this was a retrospective study that depends on documentation in medical records and, therefore, there are possible abstraction errors that may have occurred. However, there is no reason to suspect that these would bias the study in any particular direction.

Second, our study comprises a small number of patients and, as a result, it could be underpowered to truly discern statistically differences in the endpoints that we analyzed.

In the end, a detailed cost assessment would have been preferable, but it was not possible in a retrospective study.

Conclusions

In conclusion, this retrospective analysis shows that intracorporeal and extracorporeal anastomotic techniques can be considered equivalent for the majority of short- and long- terms outcomes. The most important difference consists in longer hospitalization in patients who underwent extracorporeal anastomosis.

Moreover, our study reveals that the two procedures are affordable in the same way. Indeed, even if intracorporeal anastomosis requires more expensive tools, it allows a shorter length of stay and this is exactly the opposite of what extracorporeal group's cost analysis shows.

It is important to underline that the final balance is mainly due to the fact that in ECA groups there is a great saving in tools utilized in performing anastomosis. It allows to spend more money in hospitalization.

If the extracorporeal anastomosis construction procedure required any mechanical supplies, as the majority of surgeon prefer, the intracorporeal anastomosis should be more convenient.

A randomized-controlled trial and a detailed cost analysis are warranted to confirm these findings.

Riassunto

INTRODUZIONE: Il rapporto costo-efficacia dell'emicolectomia destra laparoscopica è tuttora oggetto di dibattito, ed un'analisi della letteratura attuale non consente di trarre conclusioni certe. Il nostro studio ha l'obiettivo di comparare i costi clinici diretti ed indiretti dell'emico-

lectomia destra laparoscopica mediante due tipologie di anastomosi: anastomosi extracorporea (Extra Corporeal Anastomosis) ed anastomosi intracorporea (Intra Corporeal Anastomosis).

MATERIALI E METODI: Retrospectivamente, dal Gennaio 2016 ad Aprile 2018, sono stati valutati tutti i pazienti sottoposti ad emicolectomia destra laparoscopica con anastomosi intracorporea ed extracorporea. In base al tipo di anastomosi utilizzata i pazienti sono stati divisi in due gruppi: gruppo ECA e gruppo ICA.

RESULTS: Trenta ECA e venti-nove ICA sono stati inclusi nello studio. Il tempo operatorio è risultato significativamente più lungo nel gruppo ICA rispetto al gruppo ECA ($p < 0.001$). Non ci sono state significative differenze per quanto riguarda la prima canalizzazione, le complicanze post operatorie ed il tasso di riammissione. I pazienti sottoposti ad anastomosi intracorporea (ICA) hanno avuto tempi di degenza ospedaliera ridotti se comparati ai pazienti sottoposti ad anastomosi extracorporea (5 vs 6; $p < 0.022$). Considerando i costi diretti dei soli presidi chirurgici, il gruppo ICA è risultato più dispendioso rispetto al gruppo ECA (1435.6 € vs 72 €). Tuttavia, il costo totale delle due procedure, considerando anche i costi di degenza, (14451.36 € nel gruppo ECA versus 14631.04 € nel gruppo ICA) risultano equivalenti.

CONCLUSIONI: Le anastomosi extracorporea ed intracorporea risultano comparabili in termini di costi clinici ed outcome post-operatorio. L'anastomosi intracorporea (ICA) implica costi più elevati ma una ospedalizzazione minore. L'anastomosi extracorporea sembra essere meno costosa in termini di presidi utilizzati, ma la più lunga degenza ospedaliera media determina un'aumento dei costi totali risultando in una non-inferiorità dell'una o dell'altro tecnica.

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