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Is early anvil placement an alternative technique to reduce anastomotic leak after rectosigmoid cancer resection?

INTRODUCTION: Anastomotic leakage (AL) is one of the most disastrous complications after rectosigmoid cancer operations. The aim of this study is to investigate the effect of the insertion time of circular stapler anvil on assessing the blood supply of the proximal colon segment, and thus to evaluate the prevention of early anastomotic leaks.

MATERIAL METHODS: A total of 57 patients were included in the study, 25 patients in group A and 32 patients in group B, respectively. From the beginning of the operation to the time of anvil placement in group A, it was 32.08 (\pm 7.34) minutes, and in group B it was 92.19 (\pm 16.63) minutes. None of the patients in group A had AL, and 4 patients in group B had AL.

DISCUSSION: Our study shows that the anvil must be placed at the beginning of the dissection to evaluate the anomalies that cause anastomotic leaks. We think that this method increases the reliability of the anastomosis line. Thus, the hospitalization period of the patients was shortened and they returned to their active lives faster. In addition, patients used less antibiotics and they needed less medical treatment.

KEY WORDS: Anastomotic leaks, Anvil, Rectosigmoid cancer placement, Stapler colorectal

Introduction

Colorectal cancers (CRC) are the third most frequently diagnosed cancers among both men and women¹. Tumors are mostly located in the right colon and then in the rectum and sigmoid colon. CRC is an important health problem especially in developed countries and the definitive treatment is surgery².

Surgical treatment of rectosigmoid cancer (RC) has changed significantly in recent years with development

of technology and surgical techniques. Total mesorectal excision is recommended because of low local recurrence and high survival rate³. Especially with the development of stapler technology, rectal anastomosis formation has become faster and easier to apply and has become widespread⁴.

Low anterior resection and anterior resection are the preferred methods for preservation of the anal sphincter in RC surgery. Anastomotic leak (AL) is one of the major complications after RC surgery. The reported incidence of AL ranges from 3.9-19.2%⁵. Patients with an anastomotic leak have prolonged hospital stay, increased risk of infection and their mortality and morbidity risk. In addition, there are financial losses due to prolonged hospitalization and antibiotic use⁶.

AL is affected by varying factors such as gender, obesity, smoking and alcohol use plus unmodifiable factors such as tumor location^{6,7}. Although controlling blood flow, air-fluid testing or colonoscopy can evaluate anastomotic safety of stapled colorectal anastomosis, they have limited capacity to reduce leaks⁸. In addition, microcir-

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culatation methods have not yet achieved the desired success in evaluating blood flow to prevent ischemia in anastomotic leaks⁹. The use of techniques such as fluorescent angiography has been reported to reduce the risk of anastomotic leakage, especially in high-risk patients, but they have limited due to the high cost¹⁰.

Management of developing anastomotic leaks has been defined and graded according to the recommendation of the International Cancer Working Group (A: active therapeutic intervention is not required, B: active therapeutic intervention is required, but can be managed without re-laparotomy and C: re-laparotomy / laparoscopy is required)¹¹.

In our study, we evaluated the blood flow of the proximal colon segment after colon resection. Defined the difference between placing the anvil of circular staplers in the proximal colon segment at the beginning of the operation and after total mesorectal excision. In this way, we planned to prevent anastomotic leaks.

Material and Method

Patients who were diagnosed with RC in the general surgery clinic and underwent low anterior resection between 2018-2020 were included in the study. Our study was planned retrospectively. The patients were divided into two groups according to operation years. The patients who were operated in 2019-2020 and who had early stapler placed in the colon were named Group A. The patients who were operated on in 2018 and had a standard procedure were named Group B. All surgical techniques were explained to the patients. Informing consent was obtained from the patient. The patients were evaluated by an anesthesiologist before surgery and the American Society of Anesthesiologists (ASA) scores were determined. The gender, age and comorbidities of the patients were recorded.

Preoperative colonoscopy was performed in all patients. The distance of the tumor to the dentate line was measured. An open surgery procedure was applied to all patients. A single dose of antibiotics was administered before surgery. The enema was done the day before the surgery. Additional bowel cleansing was not performed on any patient.

Age, gender, body mass index, tumor size, distance of the tumor to the dentate line, operation time, time between the beginning of the operation and anvil placement, ASA score, anastomotic leaks, time to detect anastomotic leaks, complications, reoperation, morbidity and mortality were compared.

STATISTICAL ANALYSIS

Descriptive statistics were used to present demographic characteristics of the study population. Differences

between these groups were tested using the Pearson's chi-square test or Fisher's exact test for categorical variables, the independent variables t-test, and the Mann Whitney U test for continuous variables. All analyzes were performed using IBM SPSS Statistics version 24.0 (IBM Corp, Armonk, NY, USA). p-value of <0.05 was considered statistically significant.

ETHICS

All procedures involving human participants in this study conformed to the 1964 Helsinki declaration and its subsequent amendments or comparable ethical standards. Ethical consent of the study was obtained from Bakirköy Dr. Sadi Konuk Ethics committee (Registration No: 2020-227). Informed consent was obtained from all individual participants in the study. The authors also declare that they have no competing financial interests and no conflict of interest.

SURGICAL TECHNIQUE

In Group A, the operation started with abdominal exploration. The soft tissue around the abdominal aorta was opened. After the inferior mesenteric artery (IMA) was found, it was ligated with the aorta where it branches off. The inferior mesenteric vein (IMV) under the duodenum was found and ligated. After IMA and IMV were cut, the colon was separated from the splenic flexure. The left colonic meso was freed and the colonic loop was cut at the appropriate place. Circular stapler anvil was placed in the proximal colon segment (Fig. 1). Continuing the dissection, the sigmoid colon and rectum were advanced up to the clear border under the tumor. Total mesorectal excision was performed. The distal part of the tumor was closed with the help of a linear stapler. It was observed that an average of 60 minutes elapsed since the anvil was placed in the proximal

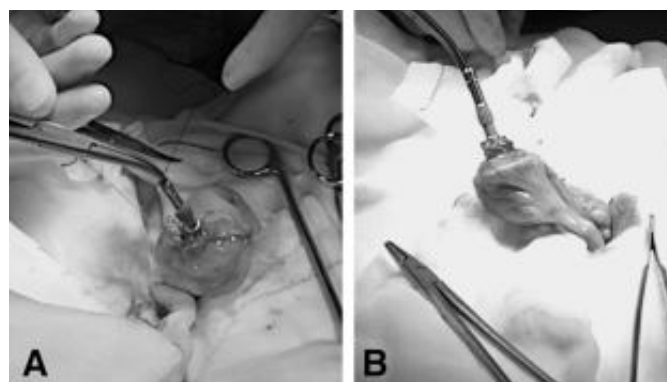


Fig. 1: Circular stapler (Premium plus CEEA, 31mm; United States Surgical Cooperation, Norwalk, CT, USA) anvil was placed in the proximal colon segment.

colon loop. The color of the proximal segment in which anvil was placed was evaluated. The blood supply and color of the colon segment was examined. In patients who were thought to be ischemic on macroscopic examination, the proximal colon was cut at the intact margin and the anvil was reinserted. We waited an additional 15 minutes. Colon and rectum, which seemed to be free of color change and bleeding disorder, were anastomosed with a circular stapler.

In Group B, the operation started with abdominal exploration. IMA and IMV were found, they were tied with non-absorbable suture and cut. The rectum was explored until a healthy border of the tumor was obtained. Total mesorectal excision was completed. The rectum was closed from the distal part of the tumor using linear stapler. The colon was separated from the splenic flexure. The left colonic meso was freed and the colonic loop was cut at the appropriate place. Circular stapler anvil was placed in the proximal colon segment. Colorectal anastomosis was performed using a circular stapler.

After anastomosis was performed in both groups, the pelvis was filled with isotonic (0.9% NaCl saline) solution and air was given from the anus with a 250-cc injector. Sutures were placed to strengthen the anastomosis lines of the patients whose air-liquid test was positive and air-liquid test was performed again. It was seen that the test became negative. A diverting ileostomy was performed in all patients. Linear stapler (75 mm, Ethicon Endo- Surgery, Inc., Cincinnati, OH, USA) was used for colon resection and a intraluminal circular stapler (Premium plus CEEA, 31mm; United States Surgical Cooperation, Norwalk, CT, USA) was used for anastomosis.

Results

A total of 57 patients were included in the study, 25 patients in group A and 32 patients in group B, respectively. 30 of the patients were male and 27 were female. The average age was 63.14 (\pm 9.11). The mean age of the patients in group A was 62.96 (\pm 6.82), and the mean age of group B patients was 63.28 (\pm 10.66).

Comorbidities, body mass indexes and ASA scores of the patients are shown in Table I.

Total operation time was 111.8 (\pm 19.91) minutes in Group A and 121.34 (\pm 18.81) minutes in Group B. While there was 32.08 (\pm 7.34) minutes between the onset of surgery and the time of anvil placement in group A, it was 92.19 (\pm 16.63) minutes in group B (Fig. 2). In the pre-operative colonoscopy, the mean distance between the tumor and the dentate line was 10.28 (\pm 3.09) cm in Group A and 11.09 (\pm 3.97) cm in Group B. The proximal segment (with anvil placed) was re-evaluated after pelvic dissection was completed in Group A. Color change (bruising) was observed in the colon segment of 4 patients and ischemia was considered. In these patients, the anvil was removed and the part of the colon with discoloration was excised. The anvil was placed again and we waited an additional 15 minutes. Color change and bleeding disorder were not detected. Proximal and distal loops were anastomosed with a circular stapler.

Wound infection was observed in 4 patients in Group A and intraabdominal abscess was observed in one patient. Wound infection was observed in 5 patients in Group B. Antibiotic treatment was applied to these patients and no additional intervention was required.

TABLE I - Demographic data, comorbidities and ASA (American Society of Anesthesiologists) scores of the patients are shown.

| | Group A (n:25) | Group B (n:32) | Total (n:57) | p value |
|-------------------|-------------------------------|------------------------------|-----------------------------|---------|
| Gender | | | | |
| Female | 12 (48%) | 15 (47%) | 27 (47%) | 0.932 |
| Male | 13 (52%) | 17 (53%) | 30 (53%) | |
| Age (year) | 62,96 (\pm 6,82, 49, 74,9) | 63,28 (\pm 10,66, 39, 85) | 63,14 (\pm 9,11, 39, 85) | 0.891 |
| Body Mass Index | 31,91 (\pm 5,23, 25, 39) | 32,27 (\pm 3,91, 23, 39) | 32,11 (\pm 4,49, 23, 39) | 0,73 |
| Comorbidity | | | | |
| Diabetes Mellitus | 6 | 3 | 9 | 0,187 |
| Hypertension | 8 | 12 | 20 | 0,09 |
| Pulmonary Disease | 1 | N/A | 1 | N/A |
| Endocrine Disease | 2 | 3 | 5 | 0,369 |
| Others* | 2 | 3 | 5 | 0,369 |
| ASA** | | | | |
| I | 1 (4%) | 0 | 1 (1,8%) | 0.18 |
| II | 8 (32%) | 11 (34%) | 19 (33%) | |
| III | 12 (48%) | 18 (56%) | 30 (53%) | |
| IV | 4 (16%) | 3 (9%) | 7 (12%) | |

*Other includes breast cancer, chronic renal failure, Parkinson's disease, heart failure, and systemic lupus erythematosus;

**ASA: American Society of Anesthesiologists;

Gender and ASA n (percentile %), Others average (\pm standard deviation, minimum, maximum)

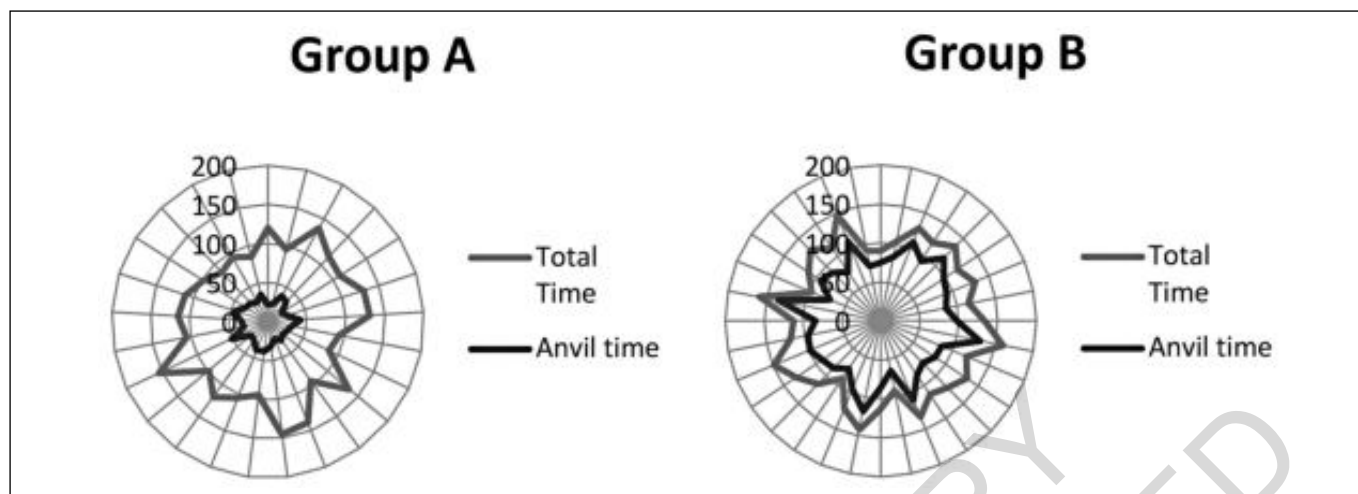


Fig. 2: Total operation time and the anvil placement time. In Group A, the anvil was placed before total mesorectal excision. In Group B, the anvil was placed after total mesorectal excision.

TABLE II - Pathological tumor size of rectosigmoid cancer, distance of the tumor to the dentate line measured colonoscopically, Operation time, duration of insertion of circular stapler anvil to proximal column, complications, length of stay in hospital, duration of hospital stay of patients with anastomotic leak.

| | Group A (n:25) | Group B (n:32) | Total (n:57) | p value |
|---|-------------------------|--------------------------|--------------------------|---------|
| Tumor Size (mm) | 32,6 (±17,16, 8, 67) | 29,38 (±11,01, 12, 61) | 30,79 (±14, 8, 67) | 0.414 |
| Dentate Line Distance (cm) | 10,28 (±3,09, 5, 16) | 11,09 (±3,97, 5, 18) | 10,74 (±3,60, 5, 18) | 0.40 |
| Operation Time (minutes) | 111,8 (±19,91, 86, 154) | 121,34 (±18,81, 88, 160) | 117,16 (±19,71, 86, 160) | 0.02 |
| Anvil Placement Time (minutes) | 32,08 (±7,34, 21, 51) | 92,19 (±16,63, 65, 134) | 65,82 (±32,89, 21, 134) | 0.01 |
| Complications | | | | |
| Anastomosis Leakage | 0 | 4 (13%) | 4 (7%) | 0.039 |
| Wound Infections | 4(16%) | 5 (16%) | 9 (15%) | 0.969 |
| Hemorrhage | 0 | 1 (3%) | 1 (1,8%) | 0.372 |
| Re-operation | 0 | 2 (6%) | 2 (3,5%) | 0.20 |
| Hospital Stay (day) | 8,32 (±2,98, 5, 16) | 11,69 (±5,52, 6, 30) | 10,21 (±4,85, 5, 30) | 0.04 |
| Anastomosis Leakage (day) (only 5 Patients) | N/A | 19 (±7,87, 12, 30) | | N/A |

Complications n (percentile%), others average(±standard deviation, minimum, maximum)

None of the patients in group A had AL. AL was seen in 4 patients in group B. Drainage catheter was placed in 2 of these patients by interventional radiology and followed up. A patient whose blood values did not regress and had abdominal pain was re-operated. The proximal segment was taken to the anterior abdominal wall as a colostomy. Endovac® (Endo-SPONGE®; B. Braun Medical, Germany) treatment was started in the other 2 patients who developed AL. A patient who received Endovac® treatment was re-operated due to presacral area bleeding after discharge and the bleeding was stopped. However, the patient was operated for the third time with bleeding from the presacral area on the 4th day during follow-up.

Colorectal anastomoses were evaluated by endoscopy before the diverting ileostomies of the patients were closed. Fistula holes that were not reflected to the clinic were seen in three patients in Group A and in two patients in Group B.

When the duration of hospital stay was compared, the

mean hospital stay of patients in Group A was 8.32 (± 2.98) days and the average of patients in Group B was 11.69 (± 5.52) days. All patients in Group A and B were compared with each other in terms of gender, age, BMI, ASA scores, comorbidities, tumor size, and distance of the tumor to the dentate line. There was no significant difference between the two groups Tables I and II. When AL was compared between the two groups, placing the anvil at the beginning of the surgery significantly reduced leakage (p value 0.039). When the duration of hospital stay was compared, the average hospital stay of patients in Group A was 8.32 (± 2.98) days, while the average of patients in Group B was 11.69 (± 5.52) days. It was understood that patients with AL extended this period. Average length of hospital stay in patients with AL was 19 (± 7.87) days. There was a significant difference between the two groups in terms of length of hospital stay (p value 0.04). Early placement of the anvil significantly shortened the operation time (p value 0.02) Table II.

Discussion

Although laparoscopic and robotic surgeries are preferred more frequently in RC, open surgical technique is indispensable. It is unthinkable to perform laparoscopic / robotic surgeries without specializing in open surgical technique. However, open technique is used especially in patients with lung disease, high ASA score, elderly and requiring emergency surgery^{12,13}. Despite advances in surgical technique and technology, AL is still a vital problem for RC surgery. The incidence of anastomotic leak after RC surgery varies between 1-25% in the literature¹⁴. Male gender, malnutrition, recent weight loss, important cardiovascular diseases, steroid use, high alcohol use, perioperative blood transfusion, advanced age, obesity and pelvic radiation are risk factors for anastomotic leakage¹⁵. Some of these risk factors are unmodifiable. However, the surgical technique is constantly being questioned and improved in order to reduce the rate of anastomotic leaks. In the literature, in a series of 1350 patients examining the effect of preoperative radiotherapy on AL, it has shown that there is no difference in terms of AL in direct surgery and after radiotherapy at the end of the first month¹⁶. Anastomotic leaks are known to reduce disease-free survival and 5-year survival and increase local recurrence rates¹⁷. The double stapler technique has become the standard treatment in low anterior resection surgery. The most common method used to prevent anastomotic leaks is air-fluid testing after anastomosis. However, some studies show that air fluid testing does not make a difference in preventing anastomotic leakage^{18,19}. Another method of assessing the anastomosis status is intraoperative endoscopy. The anastomosis is evaluated under direct observation by endoscopy and when there is a situation such as ischemia / perforation, the anastomosis is disrupted and re-performed. However, comparative studies show that there is no difference in anastomotic leakage between groups with or without endoscopy²⁰. The latest method used today is laser fluorescence angiography and indocyanine green test. There is no consensus in the literature. One group argues that it reduces rates of AL, other one states that it does not alter rates. It has been reported that it decreases AL especially in high risk patients (high comorbidity, elderly, ect.). However, it causes an additional cost to the patient^{21,22}.

In the oncological surgical procedure, IMA is cut from the abdominal aorta where it branches off. Therefore, the blood flow of the left colon segment depends on the presence of arches between the superior mesenteric artery (SMA) and the IMA. The arches between these two arteries may appear in different variations or be absent. The largest of these arches are Drummond and Riolan arches. They ensure the safety of the anastomosis, but in the absence of these arches due to anatomical variations, can cause ischemia in the left colon after IMA is attached²³. Our study aims to detect and prevent this ischemic colon segment during surgery. After the anvil was placed

in the proximal colon loop, the prolongation of the time until the anastomosis was performed, enabled us to better evaluate the colon segment. Thus, it allowed us to excise the segment with suspected ischemia. In Group B, it was not always noticeable that the blood supply was disturbed due to the short waiting time. It was observed that necrosis developed in the anastomosis line after the surgery, especially in cases where blood flow decreased partially. Another factor questioned in the prevention of colon anastomotic leaks is the type of anastomosis. Ikeda et al. showed that the side-by-side anastomosis can withstand the highest burst pressures by comparing 5 different methods that emphasize the importance of bursting pressures in anastomotic leaks¹⁹. For this reason, all anastomoses in our study were performed using the double staple method. The effect of the selection of the ligated region of IMA on anastomotic leaks during surgery is also controversial. Prospective studies show that the close attachment of IMA to the aortic root does not increase anastomotic leaks²⁴. However, tying the IMA away from the aortic root prevents disruption of the anastomotic supply in patients without Riolan arch²³. Unfortunately, this situation causes the lymph nodes in the root of IMA not to be removed. It causes an insufficient excision in patients who undergo surgery due to malignancy²⁵. In our study, IMA was ligated and cut at the closest place in the abdominal aorta in all cases. Adhering to oncological procedures as the surgical technique in Group 1, we only placed the anvil before total mesorectal excision. The most important advantages are that early anvil placement does not bring additional cost to the patient and does not change the surgical technique. Every surgeon can apply this surgical technique without requiring additional training, just by reading this article. We think that our retrospective study can be supported by prospective randomized studies to be conducted in the future, and we consider that a revision can be made in the surgical technique. We were able to significantly reduce anastomotic leaks by changing the order in the surgical procedure.

In Conclusion, early placement of the anvil increased the reliability of the anastomosis line. It was especially helpful in the assessment of blood flow in the anastomosis line. It significantly reduced anastomotic leaks. In this way, the duration of the patients' hospital stay was shortened. Patients used less antibiotics and did not need additional medical intervention. Patients' treatment costs were decreased. With this method, the comfort of the patients are improved and they returned to their homes earlier.

Riassunto

La deiscenza anastomotica (AL) è una delle complicanze più disastrose dopo le operazioni di cancro del retto-sigma. Lo scopo di questo studio è quello di indagare l'effetto del tempo di inserimento dell'incudine della

cucitrice circolare sulla valutazione dell'afflusso di sangue del segmento prossimale del colon, e quindi valutare la prevenzione delle perdite anastomotiche precoci.

Il nostro studio è stato pianificato in modo retrospettivo. I pazienti sono stati divisi in due gruppi in base all'epoca dell'intervento. I pazienti operati nel periodo 2019-2020 e con anvil dello stapler posizionato precocemente nel moncone del colon sono stati denominati Gruppo A. I pazienti operati nel 2018 con procedura standard sono stati denominati Gruppo B.

Risultati: un totale di 57 pazienti sono stati inclusi nello studio, 25 pazienti nel gruppo A e 32 pazienti nel gruppo B, rispettivamente. Dall'inizio dell'operazione al momento del posizionamento dell'incudine nel gruppo A, sono stati 32,08 (\pm 7,34) minuti e nel gruppo B sono stati 92,19 (\pm 16,63) minuti. Nessuno dei pazienti nel gruppo A è andato incontro a deiscenza anastomotica, mentre ciò si è verificato in 4 pazienti del gruppo B.

Il nostro studio mostra che l'incudine deve essere posizionata all'inizio della dissezione per valutare le anomalie che causano perdite anastomotiche. Riteniamo che questo metodo aumenti l'affidabilità della linea di anastomosi. Pertanto, il periodo di ricovero dei pazienti è stato abbreviato e sono tornati alla loro vita attiva più velocemente. Inoltre, i pazienti usavano meno antibiotici e avevano bisogno di meno cure mediche.

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Commento e Commentary

PROF. NICOLA PICARDI

Già Ordinario di Chirurgia Generale

Le conclusioni di questo studio non sono da condividere perché considerano un aspetto sostanzialmente casuale della tecnica chirurgica: apponendo anticipatamente l'anvil nel moncone colico prossimale si ha più tempo per constatare se la vascolarizzazione del moncone del colon dà sufficiente affidamento. Si agisce con l'osservazione e non con la prevenzione. Il problema va invece impostato sulla base dell'anatomia chirurgica. La prevenzione della deiscenza anastomotica con l'uso degli stapler non è più dipendente dall'abilità manuale del chirurgo ma dalla irrorazione residua del moncone colico e di quello del retto. Se si seziona l'AMI alla sua origine dell'aorta si abolisce l'apporto arterioso diretto all'emicolon sinistro, che viene privato dell'arcata anastomotica tra AMS e AMI e resta affidato all'arteria marginale di Drummond, con una vascolarizzazione sostanzialmente precaria. Inoltre la situazione è diversa se si tratta di asportare un tumore del sigma o un tumore del retto, perché il tratto terminale del retto è vascolarizzato dalle arterie emorroidarie superiori (rami dell'AMI) e dalle arterie emorroidarie medie (arteria ipogastrica) e arterie emorroidarie inferiori (arteria pudenda). In caso di tumore del sigma bisogna fare scelte tecniche che conservino la vascolarizzazione al moncone distale del retto. Sarà allora consigliabile non allacciare l'AMI ma scheletrizzarla fino a poter conservare le arterie emorroidarie superiori per un'ottimale vascolarizzazione del moncone rettale.

Invece per conservare una adeguata irrorazione arteriosa al colon sinistro in caso di localizzazione del tumore nel retto sottoperitoneale non si può ricorrere alla tecnica appena descritta ma nemmeno in questo caso è ragionevole allacciare e sezionare l'AMI alla sua emergenza dall'aorta, ma la sua sezione deve cadere solo dopo l'emergenza dell'arteria colica sinistra, per poter sfruttare la vascolarizzazione arteriosa del moncone colico derivata dall'arcata anastomotica tra AMS e AMI, o addirittura dopo l'emergenza delle arterie sigmoidee.

Altre sono le considerazioni riguardo l'inutilità della allacciatura della vena mesenterica inferiore ai fini oncologici, per i quali valgono le considerazioni della tecnica del "no-touch" di Turnbull.

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The conclusions of this study are not to be shared because they consider a substantially random aspect of the surgical technique: by placing the anvil in advance in the proximal colonic stump you have more time to ascertain whether the vascularization of the colonic stump gives sufficient reliability. We act therefore with observation and not with prevention. The problem must instead be set on the basis of the surgical anatomy. The prevention of anastomotic dehiscence with the use of staplers is no longer dependent on the manual skill of the surgeon but on the residual arterial vascularization of the colonic stump and that of the rectum, or both. If the IMA is tied and sectioned at its origin from aorta, the direct arterial supply to the left hemicolon is abolished, deprived of the anastomotic arch between SMA and IMA and remains entrusted only to the marginal Drummond artery, with a substantially precarious vascularization. Furthermore, the situation is different if to remove a tumor of the sigma or a tumor of the rectum, because the terminal tract of the rectum is vascularized by the upper haemorrhoidal arteries (branches of the IMA), by the middle haemorrhoidal arteries (branches of hypogastric artery) and inferior haemorrhoidal arteries (branches of pudendal artery). In the case of a sigma tumor, technical choices must be made preserving to the best the arterial vascularization to the distal stump of the rectum. It will then be advisable not to section the IMA at its origin from the aorta but to skeletonize it until the origin of upper haemorrhoidal arteries to be preserved for optimal vascularization of the rectal stump. On the other hand, to maintain adequate arterial blood supply to the left colon in case of tumor localization in the subperitoneal rectum, the technique just described cannot be used, but even in this case it is not reasonable to dissect the IMA at its emergence from the aorta, but its section must fall only after the emergence of the left colic artery, in order to exploit the arterial vascularization of the colonic stump derived from the anastomotic arch between SMA and IMA, or even after the emergence of the sigmoid arteries. There are other considerations regarding the uselessness of lacing the inferior mesenteric vein for oncological purposes, for which the considerations of Turnbull's "no-touch" technique apply.

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