

The Use of Intocare™ Stapler Devices During Colon and Rectal Surgery: A Single-Center Retrospective Study with the Use of a New “Intelligent” Stapler Technology

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ABSTRACT

Background: Modern surgical staplers should provide to reduce the risk of anastomotic leak. This study was undertaken to evaluate the performance characteristics of the new IntoCare™ Stapler in colorectal surgery. Ideally, a stapler would accommodate variations in tissue thickness by reducing the possibility of moving the tissue, perform proper compression of the tissue, not injure the tissue after the anastomosis is performed and be easy to use by the surgeon.

Methods: We included 20 patients in our study who underwent colorectal surgery from October 2023 to January 2024.

Results: One patient needed reintervention for anastomotic leak 1/20 (5%). In particular, this patient presented several comorbidities as respiratory disease, diabetes, cardiovascular disease. He suffered from an occlusive disease of the left colon and underwent an anterior resection of the rectum with anastomosis in a single operation.

Probably in this case the anastomotic leak does not depend by the use of the IntoCare stapler system.

Conclusion: The use of The IntoCare™ Stapler was safe, effective and easy to use. These advantages were recognized by surgeons who evaluated the use of the device preclinically. A larger study with a larger number of patients is needed to demonstrate any reduction in anastomotic leakage.

Keywords

Stapler, Colorectal surgery, Anastomotic leak.

Introduction

Colorectal surgery represented in the last ten years several challenges to improve the efficacy and the safety of procedures especially in the reduction of the anastomotic leak rates. The risk of anastomotic leak is still an important problem in colorectal surgery because it remains one of the most significant complications with

relevant morbidity and mortality.

The use of “Intelligent” staplers as IntoCare™ system is emerging to facilitate the creation of anastomoses in colorectal surgery.

There are few studies yet regarding the use of these innovative devices in the field of colorectal surgery, in our observational study we illustrate the use of the IntoCare stapler technology and we evaluated the incidence of possible anastomotic dehiscence.

Materials and Methods

Study design

We conducted a single-center retrospective review of all patients who underwent a colorectal surgery with IntoCare™ stapler from October 2023 to January 2024. All operations were performed by a single surgeon to reduce technique errors related to surgeon's experience. All patients who had a left colectomy, sigmoid colectomy, subtotal colectomy, total colectomy or low anterior resection for malignancy, diverticular disease, or inflammatory bowel disease, was included for analysis. In total, 20 patients met our inclusion criteria. Data on preoperative patient demographics, intraoperative variables, and postoperative outcomes were collected.

The IntoCare™ stappler was used during all operations. We used two types of IntoCare™ staplers: linear IntoCare™ powered linear stapler and Intocare Disposable powered circular stapler. The linear stapler system improves the control of the closing with the possibility to stop the firing at any position, closing in parallel and closing in constant speed.

Automatic firing is possible with the pressing by one button furthermore there is an indicator of real time of firing progress and a led indicator that signals when the tissue is adequately dehydrated to push the button of firing. The intocare Disposable powered circular stapler has a system to have less distal movement to avoid tissue trauma in the extraction of the stapler after making the anastomosis to improve stapler linear integrity. Another point is the possibility to decide in real time an adjustable compressed tissue thickness with a led indicator. In both staplers the refills feature are in Titanium; this allows for correct point formation, preventing it from breaking or cutting if it is in the path of the blade (cross stapling).

Results

From our research, the total number of patients who underwent colorectal resection with robotic stapler was 20. 11 Patients underwent laparoscopic surgery (55 %), 9 patients underwent open surgery (45 %). We performed 10/22 (45.4 %) end to end anastomoses, 9/22 (41%) end to side anastomoses, 3/22 (3.6%) side to side anastomoses. Multivisceral resection with creation of two anastomoses was performed in two patients.

Baseline Characteristics

General baseline characteristics age, sex, BMI, and general status (ASA score) were detected. The of patients were male (53.8 % vs 58.3 % respectively). The age range was 65±15.

Pre-operative Comorbidity

General comorbidity as cardiovascular disease, kidney failure, pulmonary disease, diabetes, and smoke were detected. Cardiovascular disease and diabetes were the major comorbidities,

Post-operative Outcomes, Follow-up and Surveillance

All of the patients were checked for operative time, blood transfusion, post-operative complications based on the Clavien–

Dindo classification, length of hospital stay and mortality within 90 days.

The conversion rate to open surgery were performed in two cases 2/20 (10 %). In the cases the conversion was necessary for failure in visualization of anatomic structures. The average duration of the surgery was 156 min.

In Overall postoperative morbidity after colorectal resection with severe complications (Clavien-Dindo grade > III) rate was 5 % (1/20).

One patient needed reintervention for anastomotic leak 1/20 (5%). In particular, this patient presented several comorbidities as respiratory disease, diabetes, cardiovascular disease. He suffered by an occlusive disease of the left colon and underwent an anterior resection of the rectum with anastomosis in a single operation. The readmission to hospital at 90 days to surgery was 0 but in a subgroup of patients with more than one comorbidity they were discharged later. The average length of stay was 7.15 days.

Discussion

Anastomotic leakage represents one of the most severe complications of colorectal surgery. In the literature, the morbidity and mortality rate is between 3.2 and 36%. The conditions for a safe anastomosis are an appropriate blood supply, healthy bowel ends, and a tension-free anastomosis. High BMI, high ASA scores and the duration of operation may affect the onset of anastomotic leak. Other factors may be a local inflammatory state such as inflamed bowel conditions as diverticulitis or inflammatory bowel disease, or an inflammation due to previously irradiated bowel because of radio-chemotherapy may prevent the execution of a safe anastomosis. Another factor regarding anastomotic leaks is the distance of the anastomosis from the anal margin, for this reason the most at-risk anastomoses are the low or rectal ones. Leak rates are higher following low anterior resection.

The narrow confines of the pelvis, especially in males, forces the stapler not to have a good cutting angle, for this reason the surgeon is forced to use more than one stapler cartridge for rectal division.

There are also risk factors related to the type of stapler such as the influence of multiple stapler firings on anastomotic leak rate and the execution of an anastomosis after adequate tissue compression [1,2].

Features such as the ability to access narrow points such as the pelvis, ability to rotate the end part to fit the narrow parts, ability to compress the tissue well, lack of overlapping of the metal staples with lower risk of fewer malformed staples, and greater end effector stability, are all factors related to the quality of the stapler. These advantages were recognized by surgeons who evaluated the use of the device preclinically [3].

The aim of the study is to present our experience with IntoCare™

stapler that has a system to reduce the problem related to the use of staplers during colorectal surgery.

For each patient, a form was filled out in which the surgeon assessed whether or not additional stitches were needed, the ease of use of the instrument, and whether he or she was satisfied with the final anastomosis result. No additional stitch was added to reinforce the anastomosis in any patient, and intraoperatively there were no problems in using the IntoCare stapler.

In our study only one patient had an anastomotic leak that required reoperation, this patient had multiple comorbidities and it was most likely not safe to perform end-to-end colo-rectal anastomosis, without a protective stoma.

This dehiscence therefore may not be associated with the use of the IntoCare stapler.

Limitations of the study

To evaluate whether the use of the Intocare stapler reduces anastomotic dehiscence or not, it is necessary to perform a study with a larger number of patients. But from our experience, the use of this stapler is simple, fast and safe.

Conclusions

Anastomotic leak is due to various factors, both related to the characteristics of the patient (BMI , comorbidities, ASA score) and due to local factors such as especially rectal surgery, the presence or absence of local inflammation. Is also important the technique used by the surgeon . The type of stapler used could influence the risk of anastomotic leak .The stapler used must be an ergonomic stapler, which prevents multiple firings and which determines a correct compression of the tissues without however traumatizing them especially in low colorectal anastomoses after the synthesis of the anastomosis.

References

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