LAPAROSCOPIC COLORECTAL ANASTOMOSIS USING THE NOVEL CHEX® CIRCULAR STAPLER: A CASE-CONTROL STUDY.

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ABSTRACT

Aim. The widespread availability of circular stapling devices to perform colorectal anastomosis has changed surgery especially in laparoscopy. The aim of this study was to assess safety and effectiveness of a new circular stapler, the Chex® CS (APVL Medic's, Niort, France - Frankenmann, Shuzhou, China) in terms of operative results.

Methods. From May 2007 to April 2009, a case-control study was conducted including 54 patients who underwent left colonic resection with stapled anastomosis according to the "double stapling" technique, with the Chex® stapler. These patients were matched from a review board-approved database to 64 similar patients with anastomosis realized with another device used in our department: the CDH® stapler (Ethicon Endo-Surgery, Inc; Cincinnati, OH, USA) or the EEA® stapler (Autosuture, Covidien, MA, USA). Matching criteria were sex, age, BMI, ASA grade, diagnosis, realization of a temporary stoma, and surgical approach. Primary end-points were post-operative mortality and morbidity. Surgeons were asked to fill a questionnaire concerning device ergonomia, using an analogic visual scale.

Results. Mortality was nil. The overall morbidity rate was similar between the two groups. There was no difference concerning the rate of anastomotic leakages (9% *versus* 8%, p=1). Mean overall appreciation was scored 8.1/10 (3-9.5), including best score for stapler removing (9.5). No major device failure was observed during the study.

Conclusion. This study suggests that colorectal anastomosis using the Chex® circular stapler is safe without increasing the overall morbidity, especially in terms of anastomotic leakage.

INTRODUCTION

The technique of transanally introducing a circular stapled device to perform colorectal anastomoses has been widely used[1-9]. Moreover, recently, the laparoscopic approach in colorectal surgery has improved the widespread popularity of stapling devices.

Many studies have demonstrated the effectiveness and the safety of such stapling procedure. A recent French prospective multicentric study concluded that elective colorectal surgery was associated with a 1 to 2% of mortality rate and a 20 to 40% morbidity rate[10]. Postoperative anastomotic leakage represented the main postoperative complication with significant clinical implications. A Cochrane review comparing both procedures (i.e. stapled versus handsewn procedures) for colorectal surgery was insufficient to demonstrate any superiority of the stapling method over handsewing, regardless of the level of anatomosis[11].

However, besides good results, the major drawback of this stapling procedure remains related to the cost-benefit ratio[1]. Moreover, the higher costs of laparoscopic equipment require more financial resources[12]. Despite the potential financial benefit in terms of improvements in clinical recovery and shorter hospital stay after laparoscopic procedures, the use of intra-operative cost-effective device could be justified.

The aim of this study was to assess safety and effectiveness of a new circular stapler, the Chex® CS (APVL Medic's, Niort, France - Frankenmann, Shuzhou, China) in terms of operative results.

PATIENTS AND METHODS

From May 2007 to April 2009, we prospectively included 54 patients who underwent left colonic resection for colorectal cancer and/or benign disease, using the Chex® CS28 circular stapler (APVL Medic's, Niort, France - Frankenmann, Shuzhou, China), according to the "double stapling" technique introduced by Knight and Griffen[9].

All patients undergoing colorectal resection in our department are currently included prospectively into a review board-approved database[10]. Data collection included patients features (gender, age, body mass index (BMI), American Society of Anesthesiology score (ASA score), diabetes mellitus, recent steroid treatment, prior laparoscopy or laparotomy, cardiopulmonary, neurologic and gastrointestinal comorbidities), disease features (diagnosis, TNM score for colorectal cancer), the surgical procedure (urgent or elective procedure, type of colorectal resection, anastomosis height, protective stoma, abdominal drainage, associated procedures, intraoperative peritoneal contamination, technical operative complications, and operative time), and the post operative outcome (mortality and morbidity).

Surgical procedure

For laparoscopic patients, the surgical procedure was performed through a total laparoscopic approach with only a 5-cm incision in the right iliac fossa for both specimen extraction and, if required, temporary diverting ileostomy.

The technique routinely involved for cancer (in both laparoscopic and open technique) included high ligation of the inferior mesenteric vessels, complete mobilization of the splenic flexure and colonic resection according to the tumor localization (i.e. 5 cm below the lower edge of the tumor). For benign disease, dissection was made close to the colon and rectum with sigmoid vessels ligation to avoid nerve injury. Then, the rectum was transected using an

endoscopic linear stapler and a transanal stapled colorectal anastomosis was performed, according to the “double stapling” technique[9]. The doughnuts were always inspected for completeness after anastomosis and anastomotic integrity was tested systematically during operation by transanal instillation of fluid.

Comparative study

Each patient of the Chex® group was identified from the database and manually matched with all identical patients from the database in whom anastomosis was realized with another device used in our department, either the CDH® stapler (Ethicon Endo-Surgery, Inc; Cincinnati, OH, USA) or the EEA® stapler (Autosuture, Covidien, MA, USA), according to the individual matching procedure published by Miettinen et al.[13]. Matching criteria were gender, age (± 10%), BMI (±10%), ASA grade, diagnosis, temporary stoma, and surgical approach (laparotomy or laparoscopy). Investigators were blinded to the primary and secondary end points in both groups during manual matching to reduce bias.

End-points definition

The primary end-points were intra-operative and postoperative complications. Mortality was defined as death occurring during the hospital stay or within 30 days. Anastomotic leakage was defined as clinical and asymptomatic leakage. Clinical suspicion of anastomotic leakage was systematically confirmed by a CT-scan with contrast enema. Asymptomatic anastomotic leakage was assessed on a CT-scan with contrast enema, systematically performed before stoma reversal for all patients with diverting stoma.

Secondary end-point was surgeons’ satisfaction. Both surgeons (YP, FB) were asked to fill a specific questionnaire about the use of the stapler (concerning general ergonomia, anvil opening, anvil removing, shaft insertion, rectal stump perforation, anvil and shaft mating,

stapler closing, stapling, stapler removing, “donuts” quality and general appreciation), using an analogic visual scale. Notations were from 0 to 10, increasing with the level of satisfaction.

Cost-analysis

A cost-analysis was performed from a surgical perspective. Thus, only direct surgical costs were assessed, including surgical staplers, surgical procedures (including emergency reoperation), invasive radiological procedures (i.e. percutaneous drainage), and hospital stay. Costs were evaluated using the French health care system price-list (“classification commune des actes médicaux”, CCAM).

Statistical analysis

Continuous data are presented as median ± standard deviation (range) and were compared with the Mann-Whitney U test. Proportions are presented as number of patients (percentage of patients) and were compared with either the Pearson χ^2 test or the Fisher exact test, as appropriate. The level of statistical significance was set at $p < 0.05$ and tests were always 2-sided. Analysis was performed using Statistical Package for the Social Sciences (SPSS, version 16.0, Chicago, IL, USA)

RESULTS

Chex® group

There were 54 patients (21 males, 39%) with a mean age of 58 ± 2 (range 20 to 88) years. ASA score was 1 for 13 patients (24%), 2 for 36 patients (67%), and 3 for 5 patients (9%). Mean BMI was 25 ± 0.7 (range 18 to 41) kg/m^2. Main indications for surgery were sigmoid diverticulitis in 27 patients (50%) and colon cancer in 19 patients (35%), as detailed in **Table 1**.

Laparoscopic approach was used in 51 patients (94%). Two patients required conversion in laparotomy, because of major obesity (n=1) and for intra-operative intestinal injury (n=1). A temporary ileostomy was performed in 15 patients (28%) because of local conditions.

Control group

As detailed in **Table 1**, the control group included 64 patients with no statistical difference from the Chex group on the matching criteria: Gender (P=0.227), Age (P=0.442), ASA grade, BMI (P=0.135), surgical approach (P=0.659), and diverting stoma (P=0.594). Indication for surgery was colon cancer in 24 patients (38%, P=0.795 comparing to Chex group), colon adenoma in 4 patients (6%, P=0.730), sigmoid diverticulosis in 34 patients (53%, p=0.735), sigmoid volvulus in 1 patients (2%, P=1) and inflammatory bowel disease (IBD) in 1 patients (2%, P=0.592).

Postoperative mortality and morbidity

Postoperative outcome for both groups are detailed in **Table 2**.

There was no postoperative death in both groups.

The overall morbidity rate showed no significant difference between both groups (n=9, 17% in the Chex group versus n=16, 25% in the control group, P=0.270).

Five patients (9%) experienced clinical and/or asymptomatic anastomotic leakage in the Chex® group, without significant difference comparing to the control group (n=5, 8%, P=1).

Compared to the control group, reoperation was required in the Chex group in 4 patients (7%) for peritonitis induced by anastomotic leakage (n=3) and peristomial hernia (n=1) versus 2 patients (3%) because of peritonitis induced by anastomotic leakage (n=1) and stoma related small bowel obstruction, without significant difference (P=0.410)

Hospital stay showed no significant difference between both groups: 9 ± 5 (range 5 to 25) days in the Chex group versus 11 ± 10 (range 5 to 75) in the control group (P=0.594).
No post-operative anastomotic stricture was observed in both groups with a mean follow-up of 12 ± 8 (range 1 to 25) months in the Chex group and 28 ± 7 (range 13 to 44) in the Control group**.**

Satisfaction score

All 11 studied items obtained a mean score ranged from 8 to 9.5 out of 10, as detailed in **Table 3**. General appreciation was scored 8.1 ± 1.8 (range 3 to 9.5). The less appreciated item was the anvil removing from the device with a mean score of 8.0 ± 1.6 (range 2 to 9.5). The most appreciated item was the stapler removing, after performing the anastomosis, which scored 9.5. ± 1.9 (range 8 to 10).

No major device failure was observed during the study.

Cost-analysis

Mean evaluated total cost was 10,563 ± 721 (6,071-29,198) € in the Chex group v*ersus* 12,451 ± 1,411 (6,142-79.058) € in the control group, without significant difference (p=0.151).

DISCUSSION

The present study showed that stapled anastomosis using the Chex® circular device is safe and convenient without increasing morbidity and mortality compared to other known usual devices. The rate of postoperative anastomotic leakage was similar between the two groups.

In the last years, advances in intestinal stapling devices have led to an increased frequency of stapled bowel anastomoses. Many studies have evaluated the stapled versus handsewn methods for colorectal anastomosis. The majority concluded to the insufficiency of evidence to demonstrate any superiority of a method over the other[2, 3, 11]. Therefore, stapled technique presents a variety of benefits: better blood supply, reduced tissue manipulation, less edema, uniformity of sutures, and rapidity. These factors are believed to facilitate the anastomosis healing without increasing the incidence of postoperative complications such as anastomotic leak, prolonged ileus or stricture. In spite of this, anastomotic dehiscence remains a significant complication of colorectal surgery. In a meta-analysis, the authors showed no clinically relevant difference in mortality and anastomotic leakage rate between the two methods[3]. The only differences concerned patients with stapled anastomosis, which were more likely to experience intra-operative technical mishaps and postoperative anastomotic strictures. In the present study, the very short follow-up (12 ± 8 (range 1 to 25)) did not allow to evaluate this latter risk. A systematic review of randomized controlled trials[14], noted that stricture occurred to a significant extent in patients undergoing colorectal stapled anastomosis, especially in infra-peritoneal location. It has been hypothesized that there may be an overactive inflammatory response, leading to stricture formation[15]. However, the majority was easily managed with endoscopic dilatation or asymptomatic.

Moreover, technical problems occurred significantly more often following stapled anastomoses. A technical mishap is generally defined as a misfiring, or a malfunction, rather than any difficulty in completing the anastomosis. The main expected risk could be, as Mac Rae et al. reported, significant morbidity in the stapled group after technical mishap[3]. In the current study, no major device failure requiring was observed and the morbidity rate was similar between the two groups.

The use of staplers for anastomosis in colorectal surgery has been questioned by the French Society of Digestive Surgery (SFCD) in 2000[1]. The authors recommended, as much as possible, the routine use of handsewn method for cost reasons. Moreover, a systematic review has shown that both techniques (stapler vs. handsewn) were effective, and the choice should be based on personal preference[3]. This point highlights the financial aspect of stapling methods. The question of cost is related to the length of the operative procedure, length of hospitalization, price of sutures and value of devices used, among other factors. The Cochrane analysis showed that when only the cost of the material used in the anastomosis was taken into consideration, the stapler was more expensive[11]. In France, the Chex® CS stapler is sold 239 euros (exclusive of taxes), whereas the only 2 other circular staplers available in France, the CDH® stapler (Ethicon Endo-Surgery, Inc; Cincinnati, OH, USA) and the EEA® stapler (Autosuture, Covidien, MA, USA) are sold 310.07 euros (exclusive of taxes) and 314.66 euros (exclusive of taxes), respectively.

In the present study, cost analysis did not demonstrate a significant cost reduction associated with the use of the Chex stapler. The relatively small number of included patients, as well as the fact that the post-operative course showed no significant difference between the 2 groups might explain this result. However the Chex® stapler is sold in France approximately 75 € cheaper than the other devices, making an average 7.500 € cost reduction per year in our department. The cost of an operative procedure, however, must be analyzed

within a wider context involving not only the monetary value of the materials but also the value resulting from the ease of execution, total time consumed, cost of complications related to the method employed, among other factors. Fingerhut *et al* showed that the time taken to perform the anastomosis was significantly shorter in stapled colorectal anastomoses[2]. This factor had a relative value when analyzed in isolation, i.e. when not associated with the total length of the operative procedures or hospitalization of the patient. An Italian study has evaluated the cost/benefit ratio of stapled anastomoses in colorectal surgery on the basis of an 8 year experience taking into account the overall costs in surgery as well as short term and long term benefits. Mechanical suturing was found to be superior based on the average postoperative hospital stay which decreased from 20 to 14 days [16].

CONCLUSION

In conclusion, this control-case study has suggested that colorectal stapled anastomosis using the Chex® circular device was safe with similar operative results compared to other known devices. This procedure was also convenient with high surgeons' satisfactory without major failure. Further data with longer follow-up is required to assess long term post-operative course.

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Table 1. Pre-operative findings of 118 patients undergoing left colonic resection

	Chex® n = 54	Control group n = 64	*P*-value
Male Gender	21 (39)[b]	32[b]	0.227
Age	58 ± 2.1 (20-88)[a]	58 ± 1.7 (33-87)[a]	0.442
Body Mass Index	25 ± 0.7 (18-41)[a]	26 ± 0.6 (18-44)[a]	0.135
ASA grade			
1	13 (24)[b]	16 (25)[b]	0.907
2	36 (67)[b]	42 (66)[b]	0.905
3	5 (9)[b]	6 (9)[b]	0.983
Diagnosis			
Adenocarcinoma	19 (35)[b]	24 (38)[b]	0.795
Adenoma	5 (9)[b]	4 (6)[b]	0.730
Diverticulosis	27 (50)[b]	34 (53)[b]	0.735
Volvulus	1 (2)[b]	1 (2)[b]	1
IBD	2 (4)[b]	1 (2)[b]	0.592
Laparoscopic Approach	51 (94)[b]	62 (97)[b]	0.659
Diverting Stoma	15 (28)[b]	16 (25)[b]	0.733

a: mean ± SD (range)
b: number of patients (percentage of patients)

Table 2. Surgical outcome of 118 patients undergoing left colonic resection

	Chex® n = 54	Control group n = 64	*P*-value
Mortality	0	0	1
Morbidity			
Reoperation	4 (7)[b]	2 (3)[b]	0.410
Anastomotic leakage	5 (9)[b]	5 (8)[b]	1
Isolated pelvic abcess	0	2 (3)[b]	0.499
Rectal haemorrhage	1 (2)[b]	1 (2)[b]	1
Anastomotic stricture	0	0	1
Wound abcess	0	3 (5)[b]	0.249
Stoma related complication	1 (2)[b]	1 (2)[b]	
Medical morbidity	7 (13)[b]	6 (9)[b]	0.568
Patients with one or more complications	9 (17)[b]	16 (25)[b]	0.270
Hospital Stay	9 ± 5 (5-25)[a]	11 ± 10 (5-75)[a]	0.594

a: mean ± SD (range)
b: number of patients (percentage of patients)

Table 3. Satisfaction score of Chex® CS circular stapler

	Score
General ergonomia	8.8 ± 0.9 (5-10)[a]
Anvil opening	8.6 ± 1.3 (5.5-10)[a]
Anvil removing	8.0 ± 1.6 (2-9.5)[a]
Device insertion	8.7 ± 1.2 (5-10)[a]
Rectal stump perforation	8.8 ± 1 (4.5-10)[a]
Anvil and shaft mating	8.4 ± 1.7 (2-10)[a]
Stapler closing	8.6 ± 1.3 (4-10)[a]
Stapling	9.0 ± 0.6 (7-10)[a]
Stapler removing	9.5. ± 1.9 (8-10)[a]
Doughnuts assessment	8.7 ± 1.3 (3-10)[a]
General appreciation	8.1 ± 1.8 (3-9.5)[a]

a: mean ± SD (range)