Use of ValtracTM-Secured Intracolonic Bypass in Laparoscopic Rectal Cancer Resection

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Abstract: The occurrence of anastomotic leakage (AL) remains a major concern in the early postoperative stage. Because of the relatively high morbidity and mortality of AL in patients with laparoscopic low rectal cancer who receive an anterior resection, a fecal diverting method is usually introduced. The ValtracTM-secured intracolonic bypass (VIB) was used in open rectal resection, and played a role of protecting the anastomotic site. This study was designed to assess the efficacy and safety of the VIB in protecting laparoscopic low rectal anastomosis and to compare the efficacy and complications of VIB with those of loop ileostomy (LI).

Medical records of the 43 patients with rectal cancer who underwent elective laparoscopic low anterior resection and received VIB procedure or LI between May 2011 and May 2013 were retrospectively analyzed, including the patients’ demographics, clinical features, and operative data.

Twenty-four patients received a VIB and 19 patients a LI procedure. Most of the demographics and clinical features of the groups, including Dukes stages, were similar. However, the median distance of the tumor edge from the anus verge in the VIB group was significantly longer (7.5 cm; inter-quartile range [IQR] 7.0–9.5 cm) than that of the LI group (6.0 cm; IQR 6.0–7.0 cm). None of the patients developed clinical AL.

The comparisons between the LI and the VIB groups were adjusted for the significant differences in the tumor level of the groups. After adjustment, the LI group experienced longer overall postoperative hospital stay (14.0 days, IQR 12.0, 16.0 days; P < 0.001) and incurred higher costs ($6300 (IQR: $5900, $6600)) than the VIB group (7.0 days, IQR: $4800; P < 0.05). Stoma-related complications in the ileostomy group included dermatitis (n = 2), stoma bleeding (n = 1), and wound infection after closure (n = 2). No BAR-related complications occurred. The mean time to ValtracTM-ring loosening was 14.1 ± 3.2 days.

The VIB procedure, as a good partner with the laparoscopic rectal cancer resection, appears to be a safe and effective, but time-limited, diverting technique to protect an elective low colorectal anastomosis.

INTRODUCTION

At present time, laparoscopic resection of rectal cancer has been performed by skilled laparoscopic surgeons and resulted in acceptable oncologic and functional outcomes.1–4 The occurrence of anastomotic leakage (AL) still is a major concern in the early postoperative stage. Among patients undergoing laparoscopic rectal resection, the rate of postoperative AL has been reported to be approximately 6% to 17%,5–9 which is similar to open surgery.10,11 However, performing laparoscopic rectal cancer excision and an intracorporeal anastomosis has some technical drawbacks, such as the lack of direct tactile sense, inadequate traction, and an ineffective cutting angle of the end-linear surgical stapler.14 Therefore, laparoscopy is considered an additional risk factor for leakage in rectal surgery.7,15 AL often results in prolonged hospital stays, reoperation, and increased morbidity and mortality.16,17 Several operative techniques and methods, such as a diverting ileostomy,18,19 tube coecostomy,20 omentoplasty,21 and intracolonic bypass,22–24 have been used in attempts to reduce the incidence of AL and/or morbidity. Among them, the proximal diverting stomy had reduced leak in patients with anastomotic complications.18,19 However, its use results in stoma-related complications and the secondary operation to close the stoma leads to increased patient suffering and cost.25 Besides, ileostomy is usually created at the right lower quadrant because of its vicinity to the ileoceleal valve. During the laparoscopic rectal procedure, another wound is required for the stoma procedure, resulting in a scar after take-down.26

We have evaluated the ValtracTM-secured intracolonic bypass (VIB) in open rectal resection; and the effective and safe results were found in protecting the anastomotic site by our and others’ studies.24,27 A VIB consists of a ValtracTM ring, that is, biofragmentable anastomosis ring (BAR; United States Surgical, Princeton, NJ) and a condom connected to the BAR. The VIB is positioned in the colon 5 to 7 cm proximal to the anastomotic site. Because its use in laparoscopic rectal resection is not clear, we have introduced a VIB into laparoscopic rectal cancer resection to protect the distal anastomotic site. This study was designed to assess the efficacy and safety of the VIB-laparoscopy procedures in protecting the low rectal anastomosis and to compare the efficacy and complications of the VIB with those of a loop ileostomy (LI).

METHODS

Patients

Institutional Review Board approval was obtained from First Affiliated Hospital, Zhejiang University. All patients were informed about the laparoscopy and LI procedures, and written
consent was obtained from the patient 1 day prior to surgery. Inclusion criteria for the laparoscopy surgery included a localized tumor >5 cm but ≤12 cm from the anal verge, compliance with laparoscopy procedures, and sufficient heart and lung function to withstand laparoscopic surgery. Exclusion criteria for minimally invasive approach were cancers infiltrating contiguous organs (T4) and counter-indications to the pneumoperitoneum. If the long axis of tumor size not larger than 6 cm, it will also be excluded. Preoperative study was based on locoregional staging by transanal ultrasonography or MRI and by contrast enhanced CT scan of the thorax, abdomen and pelvis. Patients with locally advanced rectal carcinomas (T3N0) and all N+ patients were preoperatively treated by neoadjuvant chemoradiation: 25 fractions of 45 Gy in 5 weeks with oral capecitabine 825 mg/m² twice daily. All patients treated with preoperative chemoradiation were operated within 6 to 8 weeks after completing their neoadjuvant treatment. Appropriate demographic information pertaining to sex, age, BMI, comorbidities, level of tumor, and neoadjuvant therapies was obtained. Outcomes, measured by operating time, length of hospital stay, cost, return of bowel function and complication rates were assessed. Wounds were monitored during daily rounds and follow-up visits for signs of infection.

We retrospectively reviewed the medical records of 43 consecutive rectal cancer patients who had undergone elective laparoscopic low anterior resection with VIB or LI procedure to protect the lower anastomosis in the Department of Colorectal Surgery, the First Affiliated Hospital, Zhejiang University from May 2011 to May 2013.

Surgery

Surgical Technique for Laparoscopic Low Anterior Resection

The patient was placed in a modified lithotomy, right side down, Trendelenburg position. An initial 10-mm port placement was carried out using the open technique, and pneumoperitoneum was accomplished using carbon dioxide. The gas line was connected and the telescope introduced. Then two 5-mm ports were inserted in the upper right and left abdominal quadrants and two more 12-mm ports were placed in the lower right and left abdominal quadrants under laparoscopic guidance.

The procedure permitted the performance of the laparoscopic no-touch isolation technique, the so-called “medial-to-lateral” approach and total mesorectal excision (TME) principles. After mobilization of the left colon, if necessary, mobilization of the splenic flexure was performed; interrupted monofilament absorbable thread (3-0 Vicryl™; Johnson & Johnson) was tightened around the colonic wall at the site of serosal splits in the colonic lumen necessitating replacement of serosal splits (Figure 1C). Purse string sutures were placed at the proximal stumps using a monofilament absorbable thread with straight needles (3-0 Maxon™, United States Surgical). A pocket was made near the proximal end of the sigmoid colon and the anvil of an end-to-end anastomotic staple (Ethicon Endo-Surgery; Johnson & Johnson) was inserted and fixed (Figure 1D). The stapler was inserted through the anus into the pelvic cavity. After stapling, both the anastomotic site and stapler were carefully evaluated and any anastomotic tears were treated by suturing. Figure 1E showed the passing of the whole near end of the sigmoid colon through the auxiliary incision port (left lower abdomen) into the abdominal cavity where the colorectal anastomosis was performed using laparoscopy. As shown in Figure 1F, the distal end of the condom was pulled down through the rectal anastomosis and guided outside the anus. The problems associated with the BAR were the induction of serosal splits in the colonic lumen necessitating replacement with a smaller diameter BAR.

LI Technique

The technical aspects of LI are well known. The stomas are placed on the lower right side of the abdomen, and closed 3 to 6 months later. The problems associated with the stoma usually were caused by drawing the ileum from the stoma and resulted in extensive serosal splits.

Assessment of Anastomosis, Anastomotic Leakage and Dehiscence

Symptoms of AL were evaluated by digital examination and radiographic evidence of dilated bowel but no obvious obstruction. Bowel obstruction was defined as the similar symptoms and radiographic evidence of dilated bowel with clear obstruction.

Assessment of Bowel Function

Return of bowel function was defined as the first passage of flatus or bowel movement with tolerance of an oral diet. Ileus was defined as delayed return of bowel function; its symptoms included abdominal distention, intolerance of an oral diet, nausea, or radiographic evidence of dilated bowel but no obvious obstruction. Bowel obstruction was defined as the similar symptoms and radiographic evidence of dilated bowel with clear obstruction.

VIB Technique

The VIB technique utilized 6 basic steps, depicted in Figure 1. The BAR consisted of polyglycolic acid (87.5%) and barium sulfate (12.5%) and was biodegradable and radiologically detectable (Sigma–Aldrich, St. Louis, MO, USA). The size of the BAR was selected to accommodate the intestinal diameter and wall thickness: the 25/2.0 and 28/2.0 sizes were commonly applied in the VIB procedure. A condom Durex (Qingdao London Durex Co., Ltd, Qingdao, Shandong Province, China) was ligated to the BAR (Figure 1A). As shown in Figure 1B, the BAR with attached condom was inserted into the proximal colonic stump more than 5 cm from the colonic verge. The BAR-condom component was sutured in place with a monofilament absorbable thread (3-0 Vicryl™; Johnson & Johnson) that was tightened around the colonic wall at the site of the BAR gap (Figure 1C). After colonic appendices and 1 or 2 straight arteries were cut in the site, the BAR was closed until a click was heard. Supporting stitches were placed in the presence of serosal splits (Figure 1C). Purse string sutures were applied at the proximal stumps using a monofilament absorbable thread with straight needles (3-0 Maxon™, United States Surgical). A pocket was made near the proximal end of the sigmoid colon and the anvil of an end-to-end anastomotic staple (Ethicon Endo-Surgery; Johnson & Johnson) was inserted and fixed (Figure 1D). The stapler was inserted through the anus into the pelvic cavity. After stapling, both the anastomotic site and stapler were carefully evaluated and any anastomotic tears were treated by suturing. Figure 1E showed the passing of the whole near end of the sigmoid colon through the auxiliary incision port (left lower abdomen) into the abdominal cavity where the colorectal anastomosis was performed using laparoscopy. As shown in Figure 1F, the distal end of the condom was pulled down through the rectal anastomosis and guided outside the anus. The problems associated with the BAR were the induction of serosal splits in the colonic lumen necessitating replacement with a smaller diameter BAR.
pelvic abscess, abdominal drain discharge of feces, pus, or gas, discharge of pus from the rectum, or rectovaginal fistula.

Statistical Analyses

Due to the small sample size of both treatment groups, the continuous data and ordinal data were presented by median with inter-quartile range (range between the 25th and 75th percentiles). Comparisons between groups with non-parametric data used the Mann–Whitney U test. The categorical data were presented as number and percentage of group, and the Fisher’s exact test was performed for their comparisons between groups. The ANCOVA (analysis of covariance) models were performed to compare VIB with LI group with adjustment for tumor level.

FIGURE 1. A depiction of the VIB procedure. (A) The joining of the Valtrac\textsuperscript{TM} ring—biofragmentable anastomosis ring (BAR)—and the condom. (B) Insertion of the Valtrac\textsuperscript{TM} ring into the sigmoid colon portion. (C) The Valtrac\textsuperscript{TM} ring was fixed at approximately 5 cm apart of transaction end and fixed with a monofilament absorbable thread (3-0 Vicryl\textsuperscript{TM}; Johnson & Johnson) tightened around the colonic wall at the site of the BAR gap. After colonic appendices and 1 or 2 straight arteries were cut in the site, the BAR was closed until a click was heard. Supporting stitches were placed in the presence of serosal splits. (D) A pocket was made near the proximal end of sigmoid colon and a mushroom head-like stapler was inserted. (E) The whole near end of sigmoid colon was passed through the auxiliary incision port in the left lower abdomen into the abdominal cavity. The colorectal anastomosis was performed at this site. (F) The distal end of the condom was pulled through the rectal anastomosis and guided outside the anus.
A 2 tailed $P < 0.05$ was considered statistically significant. All statistic analyses were accessed by the SPSS statistical software package (Version 15.0, SPSS, Inc., Chicago, IL).

RESULTS

Between May 2011 and May 2013, we performed the VIB technique in 24 cases of laparoscopic low anterior resection and LI technique in 19 cases. The demographic data and preoperative symptoms of the patients were similar between the 2 groups for most variables, including gender, median age, median body mass index (BMI), and various co-morbidities (Table 1). The median ASA scores between the groups were not significantly different (Table 1). Similar numbers of patients in the 2 groups had been treated with neoadjuvant radiochemotherapy (Table 1). However, patients of VIB group had significantly longer median distance to the lower edge of the tumor above the anal verge than those of LI group (median tumor level: 7.5 cm vs 6.0 cm, $P = 0.029$) (Table 1).

The operative data of the patients are shown in Table 2. The groups showed no significant differences in level of anastomosis, number of linear stapler firings, operation time, and distribution of Dukes stages (Table 2, $P > 0.05$). The following intraoperative and postoperative adverse events were also not significantly different between the 2 groups: Staple-line bleeding, wound infection, and stapled anastomotic stenosis. Anastomotic dehiscence occurred in 2 cases in VIB group and no case in LI group, but there was no clinical manifestation of leakage. Because of readmission for stoma closure for 1 patient in the LI group, the overall post-operative hospital stay of the LI group was significantly greater than that of the VIB group (medians of 14.0 vs 7.0 days for post-operative stay, respectively, $P < 0.001$); Likewise, the median cost of the LI group was significantly greater than that of the VIB group (median $6300 vs $4800, $P < 0.001$). Complications associated with the stoma in the LI group included dermatitis (n = 2), stoma bleeding (n = 1), and wound infection after closure (n = 2). No BAR-related complications occurred. The mean time to BAR loosening was 14.5 ± 3.5 days (data not shown). The mean follow-up time was 1 year. Thirty-five patients (VIB, n = 20 and LI, n = 15) received a colonoscopic examination.

Since the median distance between the anus and tumor level was significantly longer in the VIB group, the ANCOVA models adjusted for the tumor level during the comparison of outcomes of the VIB with LI groups (Table 3). Patients of the VIB group had significantly shorter length of post-operative stay and lower cost than those of LI group, with the estimated difference of 7.34 days of post-operative stay ($P < 0.001$) and $1330 cost ($P < 0.001$). However, patients of VIB group took significantly longer time to first flatus ($12.67 h, P < 0.001$), which may reflect that the VIB group had a significantly longer median time before first oral intake (7.31 h, $P < 0.001$) than the LI group. Furthermore, the sustenance of the LI patients did not need to proceed through the colorectal portion before the first flatus is recorded.
DISCUSSION

AL after rectal cancer resection remains one of the most serious early postoperative complications both in open and laparoscopic surgery.5–12 AL has a negative prognostic impact on local recurrence and an association between AL and reduced long-term survival has been reported.16,17 Previous studies of laparoscopic and open surgery for rectal cancer have reported no statistical differences in terms of the AL rate.10–13 The most important risk factor for AL is the distance of the anastomosis from the anal verge. The high-risk level for AL is reported to be 5 to 7 cm from the anal verge.5,7 Other factors that increase the risk for AL are preoperative abdominal and pelvic radiotherapy, corticosteroid treatment, smoking, obesity, hypertension, male gender, age, and medical conditions, including diabetes, cardiovascular disease, weight loss, hypoproteinemia, anemia, and metabolic disorders.5–9 Laparoscopy is considered an additional risk factor for leakage in rectal surgery, because laparoscopic rectal transection utilizes at least 2 linear staplers (in this series, mean number of linear stapler firings was 2.5/C6 1.5), with a cutter, and can lead to an excessively long stapling line with an inadequate cutting angle, which may result in AL.14,15

The relatively high incidence of leakage in the high-risk group indicates the importance of protecting the anastomosis; thus, surgeons are constantly designing diverting methods.

TABLE 2. Operative Data of the Patients

|                      | Total (n = 43) | VIB (n = 24) | LI (n = 19) | P-Value |
|----------------------|---------------|--------------|-------------|---------|
| Level of anastomosis (cm)<sup>b</sup> | 4.0 (4.0, 5.0) | 4.0 (4.0, 5.0) | 4.0 (3.0, 5.0) | 0.214   |
| Operative time (min)<sup>b</sup>           | 150.0 (125.0, 180.0) | 147.5 (125.0, 172.5) | 150.0 (120.0, 180.0) | 0.825   |
| Number of linear stapler firings<sup>b</sup> | 2.0 (2.0, 3.0) | 2.0 (2.0, 3.0) | 2.0 (2.0, 2.0) | 0.170   |
| Intraoperative adverse events                          |               |              |             |         |
| Staple-line bleeding<sup>c</sup>  | 3 (7.0%)     | 2 (8.3%)     | 1 (5.3%)    | >0.99   |
| Postoperative adverse event<sup>e</sup>   |               |              |             |         |
| Anastomotic dehiscence<sup>c</sup> | 2 (4.7%)     | 2 (8.3%)     | 0 (0.0%)    | 0.495   |
| Wound infection<sup>c</sup>                 | 2 (4.7%)     | 1 (4.2%)     | 1 (5.3%)    | >0.99   |
| Stapled anastomotic stenosis<sup>c</sup>  | 3 (7.0%)     | 1 (4.2%)     | 2 (10.5%)   | 0.575   |
| Length of post-operative stay (days)<sup>a,b,d</sup> | 9.0 (7.0, 14.0) | 7.0 (6.0, 8.0) | 14.0 (12.0, 16.0) | <0.001 |
| Cost ($1000 U.S. dollars)<sup>a,b,d</sup>   | 5.8 (4.7, 6.4) | 4.8 (4.5, 5.6) | 6.3 (5.9, 6.6) | <0.001 |

Dukes stages<sup>c</sup>

|     | A       | B       | C       |
|-----|---------|---------|---------|
| 7   | 16.3%   | 4 (16.7%) | 3 (15.8%) | 0.908   |
| 25  | 58.1%   | 13 (54.2%) | 12 (63.2%) |         |
| 11  | 25.6%   | 7 (29.2%) | 4 (21.1%) |         |
| 15.0 | 13.0, 17.0) | 15.0 (13.5, 16.5) | 16.0 (13.0, 18.0) | 0.491   |
| 73.0 | 66.0, 80.0) | 79.0 (74.0, 88.0) | 66.0 (59.0, 69.0) | <0.001 |
| 81.0 | 78.0, 90.0) | 85.5 (80.5, 94.5) | 79.0 (76.0, 83.0) | 0.002   |

BAR = biofragmentable anastomosis ring, VIB = Valtrac™-secured intracolonic bypass, LI = loop ileostomy.

<sup>a</sup>P < 0.05 indicates a significant difference between the 2 groups.

<sup>b</sup>Data are presented as median (inter-quartile range) and tested by Mann–Whitney U test.

<sup>c</sup>Data are presented as number of patients (percentage) and tested by Fisher’s exact test.

ASA = American Society of Anesthesiologists, BMI = body mass index, VIB = Valtrac™-secured intracolonic bypass, LI = loop ileostomy.

<sup>d</sup>Data are presented as number of patients (percentage) and tested by Fisher’s exact test.

<sup>e</sup>Data are presented as number of patients (percentage) and tested by Fisher’s exact test.
ever, its effectiveness in reducing AL has been questioned.25,26

Vide added safety benefits and cost savings, although a random-
using a conglomerate BAR-condom component that may pro-
success had been lacking. Here, we illustrated a method for
colon with larger thickness. Furthermore, although condom
size and used in correct manner. The BAR with larger size may
emphasized that the BAR should be selected with appropriate

| TABLE 3. Summary of the Comparisons Between VIB and LI With Adjustment for Tumor Level (cm) |
|---------------------------------------------------------------|
|                                | β (95% CI) | P-Value |
| Length of post-operative stay (days) |            |         |
| Intercept                      | 14.26 (11.48, 17.04) | <0.001  |
| Level of tumor (cm)            | 0.06 (−0.31, 0.43)  | 0.738   |
| Surgerya                       | −7.34 (−8.85, −5.83) | <0.001  |
| VIB                            | −1.33 (−1.89, −0.77) | <0.001  |
| LI Reference group             |            |         |
| Cost ($1000 U.S. dollars)      |            |         |
| Intercept                      | 6.47 (5.44, 7.50)   | <0.001  |
| Level of tumor (cm)            | −0.01 (−0.15, 0.13) | 0.880   |
| Surgerya                       | 1.26 (7.24, 18.10)  | <0.001  |
| VIB                            | −1.33 (−1.89, −0.77) | <0.001  |
| LI Reference group             |            |         |
| Time to first flatus (h)       |            |         |
| Intercept                      | 57.19 (47.18, 67.19) | <0.001  |
| Level of tumor (cm)            | 1.21 (−0.13, 2.55)  | 0.075   |
| Surgerya                       | 12.67 (7.24, 18.10) | <0.001  |
| VIB                            | −1.33 (−1.89, −0.77) | <0.001  |
| LI Reference group             |            |         |
| Time to oral intake (h)        |            |         |
| Intercept                      | 74.05 (64.87, 83.22) | <0.001  |
| Level of tumor (cm)            | 0.65 (−0.58, 1.88)  | 0.291   |
| Surgerya                       | 7.31 (2.33, 12.29)  | 0.005   |
| VIB                            | −1.33 (−1.89, −0.77) | <0.001  |
| LI Reference group             |            |         |

VIB = Valtracª-secured intracolonic bypass, LI = loop ileostomy, CI = confidence interval.

*P < 0.05 indicates a significant influence on the corresponding dependent variable revealed by ANCOVA.

Routine use of defunctioning stoma for low anterior resection has been recommended to decrease the leakage rate.18,19 However, its effectiveness in reducing AL has been questioned.25,26 Using an intracolonic bypass to protect a low rectal anastomosis avoids problems associated with a defunctioning stoma.22–24,27 The VIB procedure was performed in open rectal resection, and it was an effective and safe method for protecting the anastomotic site by our and others’ studies.23,24 Routine use of defunctioning stoma for low anterior resection seems easy and effective as shown by the low complication rate and comparable outcomes to those reported in the traditional open surgery.25,26 In addition, the laparoscopic use of VIB does not require additional or longer abdominal incisions. In fact, the VIB was introduced into the proximal colon using the same incision required for specimen extraction. Furthermore, the laparoscopy has become a definitive milestone in the history of minimally invasive surgery. Non-stoma is reflected in the concepts of minimally invasive surgical strategy. Therefore, VIB is more suitable for laparoscopic rectal resection and more acceptable for the patients both physically and psychologically, neither no stoma nor additional incision is needed. In our experience, the use of the VIB guarantees protecting an elective low colorectal anastomosis, especially during laparoscopic conditions. The proposed VIB technique permits its use without giving up the benefits of laparoscopic access.

Limitations of our study were several-fold: our study was a small retrospective comparative series in a single institution with a short follow-up. It was a nonrandomized retrospective trial so bias in patient selection may have been present. The study lacked adequate power to determine the superiority of the VIB over other diverting techniques. Thus, the findings of this study need to be confirmed by subsequent controlled prospective, randomized studies. In conclusion, the VIB procedure was as a good partner with the laparoscopic rectal cancer resection, is a safe, effective, but time-limited, diverting technique to protect an elective low colorectal anastomosis.

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