Rectal Cancer Surgery in Patients Older Than 80 Years: Is Hartmann's Procedure Safe?

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Abstract. Background/Aim: The current study aimed to identify the safety and efficacy of Hartmann's procedure (HP) among elderly patients (age≥80 years) with rectal cancer. Patients and Methods: Data on surgical outcome, survival rate, and incidence of stoma reversal were retrospectively compared between patients aged over 80 years who underwent anterior resection (AR) and HP. Results: In total, 79 elderly patients underwent rectal cancer surgery. Of these patients, 54 (68.4%) underwent AR and 25 (31.6%) HP. The two groups did not differ significantly in terms of age, nutrient status, and tumor characteristics. Eight (14.8%) patients who underwent AR and six (24.0%) who underwent HP presented with intra-abdominal complications (p=0.35). The overall survival and recurrentfree survival rates between the two groups did not differ. Conclusion: HP for elderly patients with rectal cancer has similar complication rates to AR, and achieved similar oncological outcomes.

The growing number of rectal cancer cases is a major health problem worldwide (1). Recently, with aging, the number of elderly patients with rectal cancer has increased (2, 3). Anterior resection (AR) is a surgical procedure for rectal cancer that involves primary resection with anastomosis. Anastomotic leakage is a major complication of AR for rectal cancer, and most surgeons pay attention to this complication

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(4). Previous studies have revealed that the incidence rate of anastomotic leakage after rectal cancer surgery is approximately 5-17%, and the mortality rate due to anastomotic leakage is 4-12% (5-8). In particular, elderly and frail patients are considered at grater risk of perioperative complications. Hence surgeons should be cautious when choosing surgical procedures for elderly patients with rectal cancer. Hartmann's procedure (HP) is generally performed for rectal cancer in patients who are at risk of serious comorbidities or impaired sphincter function (9, 10). Pahlman et al. showed that the proportion of patients with rectal cancer who underwent HP increased from 10% to 15% in recent years (11). Furthermore, Jung et al. revealed that the proportion of elderly patients who underwent HP was higher than that of younger patients (16.9% vs. 4.9%) (12). There is no risk of anastomotic leakage in patients who undergo HP because it does not involve the creation of colorectal anastomosis. In contrast, a previous report revealed that there is postoperative pelvic abscess is more frequent in HP (13). Thus, it is paradoxical whether HP is safe as a surgical procedure for elderly people. The only other option for those with high-risk rectal cancer would be not to operate. However, it is expected that the number of elderly patients with rectal cancer who undergo primary resection will increase due to the aging of the population. HP is often selected for high-risk patients but its safety in elderly patients with rectal cancer have not been clarified. Therefore, it is a surgeon's task to clarify the optimal surgical procedure for rectal cancer surgery in the elderly. Several studies have examined surgical outcomes for patients with rectal cancer. However, most of the studies included cases with abdominoperineal excision, and none of these studies have reported the outcomes of surgery with and without anastomosis among elderly patients with rectal cancer who are eligible for anastomosis and whose anus can be preserved (14-16). In addition, the definition of the age for 'elderly' is inconsistent with a threshold ranging from 60 to 85 years.

Thus, the current study aimed to validate the safety and efficacy of HP compared with AR among elderly patients (>80 years) with rectal cancer.

Patients and Methods

Selection of patients. Between January 2004 and December 2016, 863 consecutive patients underwent surgery for rectal cancer at the Department of Surgery, Saiseikai Yokohamashi Nanbu Hospital. Patients aged over 80 years who underwent curative resection were included in this study. The definition of rectum and distal colon differs between previous studies. That is, these structures were defined based on the distance from the anal verge, and rectal cancer was defined as cancer arising up to 12-15 cm from the anal verge (17, 18). Therefore, in the current study, rectal cancer was defined based on the following criteria: (i) presence of rectal adenocarcinoma and (ii) inferior margin of the tumor located in the rectum and up to 15 cm from the anal verge. Patients with synchronous or metachronal cancer, those who received preoperative radiation therapy or neoadjuvant chemotherapy, those with anal canal cancer, and those who underwent intersphincteric resection or abdominoperineal excision were excluded from this study. The patients were divided into two groups: Those who underwent surgery with anastomosis (the AR group) and those who underwent surgery without anastomosis (the HP group). We retrospectively compared data on characteristics of the patients, surgical outcomes, and long-term outcomes between the two groups.

Surgical procedure. The colorectal specialists discussed the surgical strategy with all the patients prior to surgery. The individual surgical approach was determined based on the background characteristics of the patients, such as presence of comorbidities, nutritional status, sphincter function, and American Society of Anesthesiologists performance status (ASA-PS). All surgical procedures were performed according to the concept of central vessel ligation and total mesorectal excision. In the AR group, anastomosis was performed with the double-stapling technique using a circular stapler. A diverting stoma was constructed in patients with low anastomosis or those at high risk of anastomotic leakage. In all patients in the HP group, a colostomy was created via the abdominal wall.

Evaluation of surgical and long-term outcomes. Tumor histology was determined using the World Health Organization classification system (19). The Union for International Cancer Control TNM classification (seventh edition) was used to identify pathological stage (20). Surgical outcomes, such as type of surgical procedure, operative time, volume of blood loss, extent of lymphadenectomy, length of hospital stay, presence of complications, reoperation, and mortality, were evaluated. The Clavien-Dindo (CD) classification system was used to determine complication grade (21). Grade II or higher complications based on the CD classification system were considered major complications in this study. In addition, the incidence rate of intra-abdominal complications was compared between the HR and AR groups. Anastomotic leakage, pelvic abscess, ileus, and enteritis were considered as intra-abdominal complications. The postoperative long-term outcomes included postoperative recurrence rate of rectal cancer, disease-free survival (DFS), and overall survival (OS). DFS was defined as the time between the primary surgery and disease progression or death from any cause, and OS was defined as the time between the

primary surgery and death from any cause. In addition, the incidence rate of postoperative stoma closure during the study period was evaluated.

Ethics. This study was approved by the Institutional Review Board of Saiseikai Yokohamashi Nanbu Hospital (NANBU D-23), and written informed consent for the use of medical records was obtained from the patients. The study was conducted based on the ethical guidelines of the Declaration of Helsinki.

Statistical analysis. Student's t-test and Mann-Whitney U-test were used to compare continuous variables with a parametric and non-parametric distributions, respectively. The chi-squared test or Fisher's exact test was utilized to compare proportions. Survival was assessed using the Kaplan-Meier method, and group data were compared using the log-rank test. All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). All statistical analyses were two-tailed, and p-values of less than 0.05 were considered statistically significant.

Results

Demographic and clinicopathological characteristics of the patients. In total, 79 consecutive elderly patients aged over 80 years who were diagnosed with rectal cancer were included in this study. Of them, 54 (68.4%) underwent AR and 25 (31.6%) HP. The clinicopathological characteristics between the two groups are summarized in Table I. The two groups were similar in terms of age, sex, body mass index, prognostic nutritional index, ASA-PS score, and incidence of cardiopulmonary comorbidities. The tumor diameter of the HP group was larger than that of the AR group (45 vs. 50 mm, p<0.035), and the proportion of patients who presented with tumors in the lower rectum was also higher. Tumor characteristics, including tumor depth and nodal status, were similar between the two groups.

Comparison of short-term surgical outcomes in patients who underwent AR and HP. The surgical outcomes are listed in Table II. The proportion of patients who underwent laparoscopic surgery was higher in the AR than in the HP group (37.0% vs. 8.0%, p<0.001). Operative time, volume of blood loss, and extent of lymphadenectomy were similar between the two groups. In the AR group, 10 (18.5%) patients underwent diverting ileostomy during the initial surgery. All these patients presented with a tumor in the lower rectum (≤7 cm). No statistically significant difference was observed in terms of the intra-abdominal complication rate between the two groups (14.8% vs. 24.0%; p=0.35). Anastomotic leakage was observed in three (5.6%) patients who underwent AR. Of them, two who had a diverting stoma created during the initial surgery were successfully treated with conservative management. By contrast, one patient who

Table I. Patients' characteristics in the anterior resection and Hartmann's procedure groups.

		AR (n=54)	HP (n=25)	<i>p</i> -Value
Age, years	Median (range)	83 (80-92)	83 (80-90)	0.59
Gender, n (%)	Male	13 (52.0)	35 (64.8)	0.33
	Female	19 (35.2)	12 (48.0)	
ASA-PS category, n (%)	0-1	0 (0)	0 (0)	0.25
	2	50 (92.6)	21 (84.0)	
	3	4 (7.4)	4 (16.0)	
	4	0 (0)	0 (0)	
BMI, kg/m^2	Median (range)	21.7 (14.3-26.8)	19.7 (14.2-36.2)	0.42
Comorbidities, n (%)	Cardiac	17 (31.5)	7 (28.0)	0.63
	Pulmonary	5 (9.3)	2 (8.0)	
	Diabetes	12 (22.2)	2 (8.0)	
Serum albumin, g/dl	Median (range)	4.0 (2.6-4.4)	3.7 (2.6-4.3)	0.014
PNI	Median (range)	46.4 (32.1-62.1)	44.4 (32.6-59.5)	0.15
Tumor location, n (%)	High (>7 cm)	31 (57.4)	8 (32.0)	0.036
	Low (≤7 cm)	23 (42.6)	17 (68.0)	
Serum CEA (ng/ml)	Median (range)	3.1 (1.2-750)	6.3 (2.3-131.6)	0.75
Tumor diameter (mm)	Median (range)	45 (16-100)	50 (22-90)	0.035
Histological type, n (%)	Differentiated	51 (94.4)	24 (96.0)	>0.99
	Undifferentiated	3 (5.6)	1 (4.0)	
pT Stage, n (%)	T1	7 (13.0)	1 (4.0)	0.36
	T2	12 (22.2)	3 (12.0)	
	T3	28 (51.9)	18 (72.0)	
	T4	7 (13.0)	3 (12.0)	
pN Stage, n (%)	N0	32 (59.3)	13 (52.0)	0.56
	N1	19 (35.2)	9 (36.0)	
	N2	3 (5.6)	3 (12.0)	
	N3	0 (0)	0 (0)	
pStage, n (%)	0	4 (7.4)	0 (0)	0.30
	I	13 (24.1)	3 (12.0)	
	II	15 (27.8)	10 (40.0)	
	III	22 (40.7)	12 (48.0)	

ASA-PS: American Society of Anesthesiologists performance status; BMI: body mass index; CEA: carcinoembryonic antigen; PNI: prognostic nutritional index. Statistically significant *p*-values are shown in bold.

did not have a diverting stoma established during the initial surgery required one during the second surgery because of peritonitis induced by anastomotic leakage. The lengths of postoperative hospital stay were 12 days in the AR group and 22 days in the HP group (p<0.001). None of the patients underwent reoperation in the HP group, and there were no surgery-related deaths in either group. In the AR group, three (30.0%) patients with a diverting stoma during the study period were eligible for stoma reversal. However, seven patients did not undergo stomal closure. In the HP group, none of the patients underwent HP reversal because they did not wish to undertake the surgical risk.

Long-term outcomes. Data on adjuvant therapy, recurrence pattern, and prognosis are summarized in Table III. Three (5.6%) patients in the AR group and two (8.0%) in the HP group received adjuvant chemotherapy. Patients who received this treatment took oral 5-fluorouracil prodrug (capecitabine) for 6 months after the surgery. In total, nine

(16.7%) patients in the AR group and 11 (44.0%) in the HP group experienced recurrence. Only three patients in the AR group and two in the HP group received post-recurrence therapy. The survival rates are depicted in Figure 1. There were no significant differences between the AR and HP groups in terms of OS (3-year survival rate: $80.1\% \ vs.$ 79.7%; p=0.55) and DFS (3-year survival rate: $72.2\% \ vs.$ 56.2%; p=0.068).

Discussion

The current study assessed the surgical outcomes of surgery for rectal cancer among elderly patients aged over 80 years. The following are the major findings of this study: Firstly, the incidence rate of perioperative complications was not significantly different between the AR and HP groups. Secondly, the oncological outcomes did not differ between the groups. Thirdly, in the AR group, approximately 30% of patients underwent diverting stoma reversal. Although HP

Table II. Surgical outcomes of the patients in groups treated with anterior resection (AR) versus Hartmann's procedure (HP).

		AR (n=54)	HP (n=25)	<i>p</i> -Value
Surgical approach, n (%)	Open	34 (63.0)	23 (92.0)	<0.001
	Laparoscopic	20 (37.0)	2 (8.0)	
Operative time, min	Median (range)	222 (78-383)	194 (130-465)	0.66
Bleeding, ml	Median (range)	94 (3-2217)	262 (15-749)	0.29
Lymphadenectomy, n (%)	D1	7 (13.0)	7 (28.0)	0.24
	D2	22 (40.7)	7 (28.0)	
	D3	25 (46.3)	11 (44.0)	
Lymph nodes harvested, n	Median (range)	18 (3-38)	12 (1-34)	0.042
Distal margin, mm	Median (range)	30 (5-95)	20 (5-48)	0.042
Diverting stoma, n (%)	Total	10 (18.5)	-	
	Reversal: Yes	3(30.0)	0 (0)	-
Postoperative stay (day)	Median (range)	12 (7-58)	22 (11-93)	< 0.001
Complications, n (%)	Total	17 (31.5)	11 (44.0)	0.32
	Intra-abdominal complications	8 (14.8)	6 (24.0)	0.35
	Anastomotic leakage	3 (5.6)	-	
	Pelvic abscess	2 (3.7)	2 (8.0)	
	Ileus	3 (5.6)	4 (16.0)	
	Enteritis	0 (0)	0 (0)	
	Re-operation, n (%)	1 (1.9)	0 (0)	-

There were no surgery-related deaths. Statistically significant p-values are shown in bold.

Table III. Recurrence pattern, post-recurrence therapy and prognosis compared between AR and HP groups.

		AR (n=54)	HP (n=25)	<i>p</i> -Value
Follow-up period, months	Median (range)	43 (3-120)	39 (5-142)	
Adjuvant chemotherapy,	Yes	3 (5.6)	2 (8.0)	0.65
n (%)	No	51 (94.4)	23 (92.0)	
Recurrence, n (%)	Total	9 (16.7)	11 (44.0)	0.01
Site	Liver	2 (3.7)	4 (16.0)	
	Lung	4 (7.4)	2 (8.0)	
	Lymph node	2 (3.7)	5 (20.0)	
	Local	1 (1.9)	0 (0)	
Treatment for recurrence,	Yes	3 (5.6)	2 (8.0)	
n (%)	No	6 (11.1)	9 (36.0)	0.62
Status, n (%)	Alive	43(79.6)	18(72.0)	
	Dead	11(20.4)	7(28.0)	0.57
Cause of death	Rectal cancer	5 (9.2)	6 (24.0)	0.15
	Other disease	6 (11.1)	1 (4.0)	

Statistically significant *p*-values are shown in bold.

was performed for safety and led to similar oncological outcomes compared with AR, it should be noted that the risk of complications in the elderly was found to be equivalent to that of AR.

Special attention must be paid to surgery for rectal cancer among elderly patients due to its invasiveness and risk of complications. In patients who underwent rectal cancer surgery, the risk of morbidity after surgery increases with age. That is, the morbidity rates were 41% in patients aged below 80 years and 58.2% in those aged over 85 years (16). A previous study by Tottrup *et al.* showed that the rate of

postoperative pelvic complications was higher by up to 33% in patients who underwent HP than in those who underwent AR (13). However, another study showed that only 3% of patients who underwent HP presented with pelvic abscess (10). These results were paradoxical. This can be attributed to the fact that the age of patients included in previous studies varied widely from 60 to 80 years. Moreover, there are only few studies, including the current one, on elderly patients. In this research, there was no significant difference in the incidence rate of perioperative complications between patients who underwent HP and AR. It should be noted that

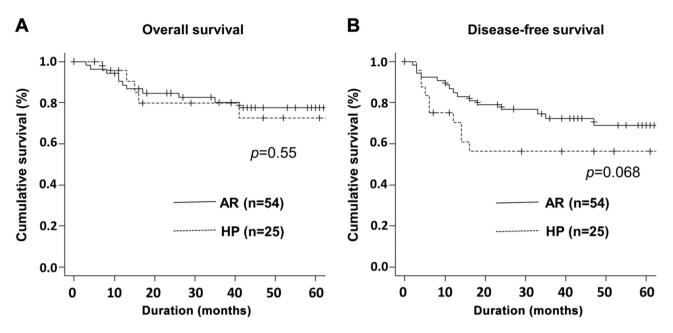


Figure 1. Overall (A) and disease-free (B) survival for patients who underwent anterior resection versus Hartmann's procedure.

HP does not invoIve the creation of anastomoses and therefore is not at risk of anastomotic leakage but the risk of complications is not different from that for AR. Surgical invasiveness occasionally leads to life-threatening complications, particularly among elderly individuals. Surgeons should keep these aspects in mind. Stornes *et al.* assessed the incidence of surgical complications after rectal cancer surgery (16). Their results revealed that the 100-day mortality rate was 12.1% among patients aged below 80 years. However, it increased to 22.2% in patients aged over 85 years. Therefore, not only the oncological aspect but also safety must be considered in the surgical treatment of elderly patients with rectal cancer.

Another important finding of the current study was that most patients did not undergo stomal reversal. Whether a colostomy or an ileostomy should be created during rectal cancer surgery is controversial. Generally, an end colostomy is created during HP. By contrast, ileostomy is often selected as a diverting stoma for AR because the small intestine is longer than the large intestine and it has good mobility. Thus, it is easier to create a stoma. However, in some ileostomy cases, water management is challenging. In 2019, Gavriilidis et al. conducted a systematic review and meta-analysis of stoma-related complications (22). They found high-output stoma occurred in 4% of patients with ileostomy but not in those with colostomy. In relation to this, AR with diverting colostomy may be a better treatment strategy. However, there is a risk of complications correlated with stomal reversal in patients with colostomy. Rullier et al. reported that the incidence rate of complications was higher in patients who underwent reversal of colostomy than in those who underwent reversal of ileostomy (34% vs. 12%, p = 0.004) (23). In addition, in Germany, a multicenter observational study was performed on 200 patients. The results showed that anastomotic leakage was observed in 3% of patients in the colostomy reversal group, but none in the ileostomy reversal group (24). Thus, particularly among elderly patients with rectal cancer, the risk of complications correlated with stoma and stomal reversal, whether colostomy or ileostomy, cannot be ignored. Furthermore, based on the stomal reversal rates in the current research, several elderly patients did not undergo this procedure even if it had already been scheduled. Notably, some patients presented with reduced anorectal function due to the surgery. In terms of anorectal function, rectal surgery might cause postoperative fecal incontinence, which leads to a lower quality of life. These disadvantages were more notable in elderly than in young individuals.

The current study had several limitations. Firstly, the sample size was only small. Moreover, the study had a retrospective design and was conducted at a single center. Hence, these factors might limit the generalizability of the results. Secondly, although the target area of lymphadenectomy did not significantly differ, the HP group was more likely at high risk of recurrence. Furthermore, there was no difference in the postoperative complication rate. One reason for this may be that HP tends to be performed in high-risk cases such as in those with larger tumors and lower rectal cancer. Surgeons are aware of the

risk of complications after surgery for such cases. Thus, invasive surgery is avoided. Considering the low post-recurrence treatment rate, a balance between safety and oncological treatment is important among elderly patients. Therefore, further studies must be conducted to identify an optimal surgical procedure for elderly patients with rectal cancer with consideration of these factors.

In conclusion, the current retrospective study revealed that HP for the elderly has the same risk of complications as AR. In addition, HP achieved similar oncological outcomes for elderly patients with rectal cancer compared with AR. Therefore, HP can be a treatment option for elderly patients with rectal cancer, and it should be selected based on the presence of comorbidities and the performance status of elderly patients, particularly when there is a high risk of anastomosis.

Conflicts of Interest

The Authors declare that they have no conflicts of interest.

Authors' Contributions

All Authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Kenta Iguchi, Hiroyuki Mushiake, Seiji Hasegawa, Daisuke Inagaki and Tadao Fukushima. The first draft of the article was written by Kenta Iguchi and all Authors commented on previous versions of the article. All Authors read and approved the final article.

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