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# Hartmann's Procedure Versus Intersphincteric Abdominoperineal Excision in Patients with Rectal Cancer

# Report from the Swedish Colorectal Cancer Registry (SCRCR)

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**Objective:** The primary outcome was to compare overall postoperative surgical complications within 30 days after Hartmann's procedure (HP) compared with intersphincteric abdominoperineal excision (iAPE). The secondary outcome was major surgical complications (Clavien-Dindo ≥ III).

**Background:** There is uncertainty regarding the optimal surgical method in patients with rectal cancer when an anastomosis is unsuitable.

**Methods:** Rectal cancer patients with a tumor height >5 cm, registered in the Swedish Colorectal Cancer Registry who received HP or iAPE electively in 2017–2020 were included, (HP, n = 696; iAPE, n = 314). Logistic regression analysis adjusting for body mass index, American Society of Anesthesiologists classification, sex, age, preoperative radiotherapy, tumor height, cancer stage, operating hospital, and type of operation was performed.

**Results:** Patients in the HP group were older and had higher American Society of Anesthesiologists scores. The mean operating time was less for HP (290 vs 377 min). Intraoperative bowel perforations were less frequent in the HP group, 3.6% versus 10.2%. Overall surgical complication rates were 20.3% after HP and 15.9% after iAPE (P = 0.118). Major surgical complications were 7.5% after HP and 5.7% and after iAPE (P = 0.351). Multiple regression analysis indicated a higher risk of overall surgical complications after HP (odds ratio: 1.63; 95% confidence interval = 1.09–2.45).

**Conclusions:** HP was associated with a higher risk of surgical complications compared with iAPE. In patients unfit for anastomosis, iAPE may be preferable. However, the lack of statistical power regarding major surgical complications, prolonged operating time, increased risk of bowel perforation, and lack of long-term outcomes, raises uncertainty regarding recommending intersphincteric abdominoperineal excision as the preferred surgical approach.

Keywords: Hartmann's procedure, intersphincteric abdominoperineal resection, rectal cancer

# INTRODUCTION

Rectal cancer is among the most common cancers, and 0.7 million new cases were reported globally in 2020. In Sweden, rectal cancer often occurs in elderly patients; their median age at the time of diagnosis is 70 years, and the incidence peaks in the 80–84-year age group.<sup>2</sup>

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Informed consent was waived because of the retrospective nature of the study and the use of anonymous clinical data.

The data supporting the findings in this study are available upon request from the authors

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The number of rectal resections for cancer performed in elderly patients in Sweden has increased because of increased average life expectancy.<sup>3</sup> Elderly patients are more likely to have comorbidities, a low level of functioning, and a weak pelvic floor. These conditions make them unsuitable for anterior resection with anastomosis because of the risk of postoperative physical dysfunction such as fecal incontinence or major low anterior resection syndrome and increased risk of potentially lethal anastomotic leakage.<sup>4</sup>

Over 100 years ago, Hartmann described a procedure for resection of cancer in the distal colon without removal of the rectum. Because it is considered a simple, rapid, and safe choice for elderly patients, the use of Hartmann's procedure (HP) for rectal cancer has increased over the years in Sweden. However, intersphincteric abdominoperineal excision (iAPE) has been suggested as an alternative method. This operation is similar to HP, but the anorectal stump is removed using the perineal approach with dissection in the intersphincteric plane.

In the early 2000s, a few retrospective studies conducted on a small series of patients reported significant morbidity after HP, including a high risk of pelvic abscess, particularly after low transection of the rectum. <sup>7-9</sup> This has prompted a debate regarding the possible superiority of iAPE over HP, in which some argue that removal of the anorectal stump with dissection in the intersphincteric plane lowers pelvic morbidity without causing the significant perineal morbidity of a classic APE. <sup>10</sup>

Later retrospective studies, some of which were conducted on large cohorts, evaluating low Hartmann's procedure for rectal cancer have indicated acceptable outcomes, with comparatively low rates of surgical complications. 11,12

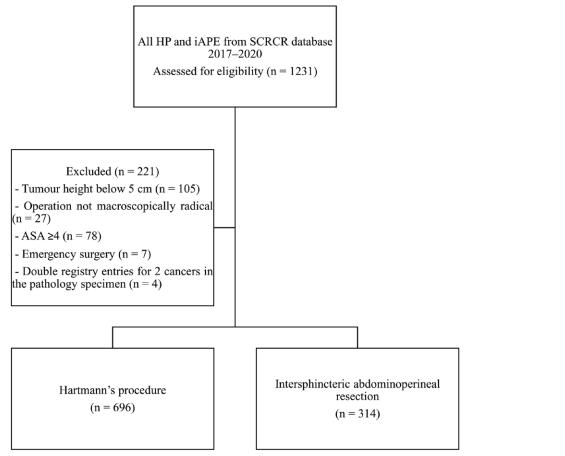


FIGURE 1. Study flowchart. Rectal cancer patients treated with HP or iAPE in Sweden 2017–2020. HP indicates Hartmann's procedure; iAPE, intersphincteric abdominoperineal excision.

A couple of retrospective studies comparing HP to iAPE, have been conducted on very small and unbalanced cohorts, and draw mixed conclusions. Some indicate no significant difference in surgical complications, <sup>13,14</sup> while others report a higher risk of major surgical complications and reoperation after iAPE. <sup>15</sup>

More recently, a prospective nonrandomized trial comparing HP versus iAPE for rectal cancer indicated no significant differences in surgical complications. <sup>16</sup> Two meta-analyses have been published on the subject. The former favored iAPE regarding surgical complications, <sup>17</sup> while the latter (which included the prospective trial), indicated no significant differences between the groups. <sup>18</sup>

Management of mid- and high-rectal cancers in frail patients who are unfit for anastomosis remains a clinical challenge, as there is insufficient scientific support regarding the optimal choice of surgical procedure. This emphasizes the necessity for additional research, particularly focusing on surgical complications, to provide comprehensive insights for guiding clinical decision-making within this patient population.

The aim of this national registry-based study was to compare 30-day surgical complications after HP versus iAPE for rectal cancer.

# **METHODS**

The Swedish Colorectal Cancer Registry (SCRCR) has been in use for rectal cancer since 1996. All patients diagnosed with rectal cancer in Sweden are registered, and data are collected prospectively. The SCRCR has a completeness close to 100% and high validity. <sup>19</sup> The SCRCR includes a large number of variables for pre-, per-, and postoperative data, including age, sex,

American Society of Anesthesiologists (ASA) classification and tumor, node, metastasis-stage, preoperative treatment, type of surgery, and postoperative complications. Since 2017, the registry records whether an APE has been performed with intersphincteric dissection, which allows the differentiation of iAPE from APE.

In this retrospective population-based cohort study, all patients treated in Sweden for rectal cancer (defined as adeno-carcinoma within 15 cm from the anal verge, measured with rigid sigmoidoscopy) with HP or iAPE between January 1, 2017 and December 31, 2020 were identified via the SCRCR. The study cohort comprised electively operated patients with ASA classification  $\leq 3$  and a tumor height  $\geq 5$  cm from the anal verge who received a local radical resection. The exclusions were made so that the cohort could potentially undergo either procedure (Fig. 1).

All outcome variables analyzed were derived from the 30-day registry form, and the postoperative complications were defined according to the Clavien-Dindo classification.<sup>20</sup> Primary outcome was overall surgical complications within 30 days. The secondary outcome was major surgical complications, defined as Clavien-Dindo ≥ III within 30 days. Overall complications were defined as medical, infectious, or surgical complications within 30 days. Primary and secondary outcome variables were compared between the HP and iAPE groups.

# **Statistical Analysis**

Categorical variables are presented as numbers and percentages. Continuous data are reported as means. Missing data were excluded, and complete case analyses were performed.

TABLE 1.

Baseline Patient Characteristics for Rectal Cancer Patients Treated With HP or iAPE in Sweden 2017–2020.

	All Patients (n =1010)		HP (n = 696)		iAPE (n = 314)		
	N	%	N	%	N	%	
Male sex	630	62.4	421	60.5	209	66.6	
Female sex	380	37.6	275	38.5	105	33.4	
Age (mean)*		73.4		74.5		70.9	
BMI (mean)*		26.1		26.3		25.7	
ASA 1	80	7.9	50	7.2	30	9.6	
ASA 2	474	46.9	304	43.7	170	54.1	
ASA 3	456	45.2	342	49.1	114	36.3	
TNM-stage I	282	27.9	186	26.7	96	30.4	
TNM-stage II	292	28.9	209	30	83	26.4	
TNM-stage III	340	33.7	240	34.5	100	31.8	
TNM-stage IV	95	9.4	61	8.8	34	10.8	
Tumor height from anal verge (cm)*		9.25		9.85		7.93	
Neoadjuvant RT	584	57.8	390	56	194	61.8	
Neoadjuvant CHT	199	19.7	137	19.7	62	19.7	

<sup>\*</sup>Continuous variables are presented as means.

Odds ratios (ORs) were calculated using logistic regression analyses and presented together with 95% confidence intervals (CI). Comparison between groups was made using the chi-square test or the Fischer exact test when appropriate. P values  $\leq 0.05$  for 2-sided tests were considered to be statistically significant.

Adjustments were made for variables body mass index (BMI), ASA classification, sex, age, preoperative radiotherapy, tumor height, cancer stage, and type of operation. These were chosen according to the disjunctive cause criterion, <sup>21</sup> to reduce potential confounding bias. They were consequently considered to either be a cause of the surgical method chosen or a cause of the outcome, or both, but did not constitute instrumental variables or mediator variables.

The operating hospital was included in the model as a random effect. Model fit was evaluated by examining observed and expected residual distributions, coupled with the Kolmogorov–Smirnov test using the DHARMa package of R.<sup>22</sup> Q–Q plots of random effect estimates were also used to ensure their normal distribution.

Unadjusted ORs were calculated using IBM SPSS v 28.0.1.0 and adjusted ORs using  $R.^{23}$ 

Ethical approval was obtained from the Swedish Ethical Review Authority (registration number 2021-02474).

# **RESULTS**

## **Study Population**

A total of 2859 patients were identified from the SCRCR and assessed for inclusion. Patients who underwent APE

(n = 1628) were excluded. Of the remaining 1231 patients, 796 had undergone HP and 435 iAPE. Two hundred and twenty-one patients were excluded for the following reasons: tumor height <5 cm from the anal verge (n = 105), nonradical surgery (n = 27), ASA classification >3 (n = 78), nonelective surgery (n = 7), and patients registered twice because of 2 cancers in the resected bowel specimen (n = 4). In the latter cases, we excluded the registry entry for the more proximal tumor (Fig. 1). The study cohort included 1010 patients, 696 of whom had undergone HP and 314 iAPE. The operations were performed at over 50 different hospitals across Sweden.

# **Patients' Baseline Characteristics**

The HP group was older than the iAPE group (mean age 74.5 vs 70.9 years), had more comorbidities (ASA = 3 for 49.1% vs 36.3% of patients), and had longer mean tumor height from the anal verge (9.85 vs 7.93 cm). TNM-stage was similar between groups (Table 1).

## Operative data

HP was less frequently performed using minimally invasive surgery, 53.6% versus 63.1%, OR = 0.68; 95% CI = 0.52–0.89; P=0.005). Intraoperative bowel perforations were less frequent in the HP group, 3.6% versus 10.2%, OR = 0.37; 95% CI = 0.21–0.65; P<0.001), and the mean operating time was shorter ( $290 \ vs \ 377 \ min$ ) (Table 2).

TABLE 2.

Operative Data for Rectal Cancer Patients Treated with HP or iAPE in Sweden 2017–2020

	All Patients (n = 1010)		HP (n = 696)		iAPE (n = 314)	
	N	%	n	%	n	%
Open surgery	439	43.5	323	46.4	116	36.9
MIS	571	56.5	373	53.6	198	63.1
Laparoscopy	218	21.5	154	22.1	64	20.4
Robot assistance	353	35	219	31.5	134	42.7
Intraoperative bowel perforation Mean operation time (minutes)*	57	5.6 317	25	3.6 290	32	10.2 377

<sup>\*</sup>Continuous variables are presented as means

CHT indicates chemotherapy; RT, radiotherapy.

TNM stage, American Joint Committee on Cancer TNM (tumor, node, metastasis) system.

MIS indicates minimally invasive surgery.

TABLE 3.

Complications, Adverse Events, Length of Stay, and Mortality at 30-day Follow-up, for Rectal Cancer Patients Treated with HP or iAPE in Sweden 2017–2020

	All Patients (n = 1010)		HP (n = 696)		iAPE (n = 314)		P
	N	%	n	%	N	%	
Overall complications	387	38.3	266	38.2	121	38.5	0.944
Overall surgical complications	191	18.9	141	20.3	50	15.9	0.118
Overall surgical complications (C-D ≥ III)	70	6.9	52	7.5	18	5.7	0.351
Wound infection	55	5.4	37	5.3	19	6.1	0.657
Wound infection (C-D ≥ III)	14	1.4	10	1.4	4	1.3	1.000
Intra-abdominal infection	69	6.8	55	7.9	14	4.5	0.045
Intra-abdominal infection (C-D ≥ III)	27	2.7	22	3.2	5	1.6	0.153
Wound dehiscence	13	1.3	10	1.4	3	1.0	0.764
Wound dehiscence (C-D ≥ III)	10	1.0	8	1.1	2	0.6	0.733
Bleeding/hematoma	14	1.4	11	1.6	3	1.0	0.568
Bleeding/hematoma (C-D ≥ III)	5	0.5	4	0.6	1	0.3	1.000
Stoma complication	22	2.2	15	2.2	7	2.2	0.940
Stoma complication (C-D ≥ III)	18	1.8	11	1.6	7	2.2	0.471
Intensive care (C-D IV)	42	4.2	35	5.0	7	2.2	0.039
Reoperation (C-D IIIb)	80	7.9	63	9.1	17	5.4	0.048
Readmission	107	10.6	76	10.9	31	9.9	0.617
Mean length of stay (days)*		8.8		9.4		7.5	0.022
Death (C-D V)	11	1.1	9	1.3	2	0.6	0.518

<sup>\*</sup>Continuous variables are presented as means.

# **Complications Within 30 Days**

The rate of overall surgical complications was 20.3% after HP and 15.9% after iAPE (P = 0.118). Major surgical complications occurred in 7.5% after HP and 5.7% after iAPE (P=0.351)

The overall postoperative complication rates were similar in the HP and iAPE groups (38.2% vs 38.5%; [P=0.944]). The percentages of patients needing treatment in an intensive care unit (Clavien-Dindo IV) were 5.0% after HP and 2.2% after iAPE (P=0.039). Reoperation (Clavien-Dindo IIIb) was more frequent after HP (9.1%) than after iAPE (5.4%) (P=0.048). Intra-abdominal infections were more frequent after HP (7.9% vs 4.5%; P=0.045).

The 30-day postoperative death rate did not differ significantly between the HP and iAPE groups (1.3% vs 0.6%; P = 0.518) (Table 3).

After adjustment for BMI, ASA classification, sex, age, preoperative radiotherapy, tumor height, TNM stage, and operating hospital, in a multiple logistic regression analysis, the OR for overall surgical complications after HP vs iAPE was calculated as 1.63 (95% CI 1.09–2.45) (Table 4).

The multiple regression analysis indicated that male sex may be associated with an increase in surgical complications: OR 1.93 (95% CI 1.34-2.78).

Goodness-of-fit was assessed as not poor using the Kolmogorov–Smirnov test (P = 0.925).

After adjustment for BMI, ASA classification, sex, age, preoperative radiotherapy, tumor height, TNM stage, and operating hospital, in a multiple logistic regression analysis, the OR for major surgical complications after HP versus iAPE was calculated as 1.27 (95% CI = 0.69–2.31).

# TABLE 4.

Univariate and Multiple Regression Analyses with Overall Surgical Complication as the Dependent Variable and the Operating Hospital as the Random Effect, for Rectal Cancer Patients Treated with HP or iAPE in Sweden 2017–2020.

		Univariate (n = 1010)				Multiple		
					(n = 1001)			
		OR	95% CI for OR		OR	95% CI	for OR	
			Lower	Upper		Lower	Upper	
BMI	<18.5 or >25 18.5–25	1.12 1	0.81	1.54	1,00 1	0.71	1.40	
ASA	3 1–2	1.22 1	0.83	1.68	1.23 1	0.87	1.73	
Sex	Male Female	1.84 1	1.30	2.62	1.93 1	1.34	2.78	
Age		0.99	0.97	1.00	0.99	0.97	1.00	
Preoperative RT	Yes No	1.13 1	0.82	1.57	1.07 1	0.75	1.51	
Tumor height from anal verge (cm)		1.01	0.95	1.07	0.98	0.91	1.04	
TNM-stage	IV I—III	1.16 1	0.69	1.95	1.11 1	0.64	1.94	
Type of surgery	HP iAPE	1.34 1	0.94	1.91	1.63 1	1.09	2.45	

RT indicates radiotherapy; TNM, Cancer stage, American Joint Committee on Cancer TNM (tumor, node, metastasis) system.

C-D indicates Clavien-Dindo.

#### **Short-term Oncologic Outcome**

Mean circumferential resection margin (CRM) was  $12.9 \,\mathrm{mm}$  after HP and  $10.7 \,\mathrm{mm}$  after iAPE (P = 0.376). CRM  $\leq 1.0 \,\mathrm{mm}$  was in  $5.6 \,\%$  after HP and  $8.0 \,\%$  after iAPE (P = 0.097).

#### DISCUSSION

The aim of this nationwide population-based cohort study was to compare 30-day complications associated with 2 surgical procedures, HP and iAPE, for mid- and upper-rectal cancer. The results indicate a higher risk of overall surgical complications following HP compared with iAPE. Major surgical complications did not differ significantly. Overall complication rates were similar.

One proposed advantage of iAPE over HP is fewer intraabdominal infections caused by blow-out or leakage from the anorectal stump that remains in situ after HP. In this study, abdominal infections were more frequent in the HP group, a finding that supports this idea.

The main disadvantages of iAPE are the longer operating time and greater surgical trauma. However, these factors do not appear to cause significant increase in neither surgical nor overall complications within the 30-day postoperative period.

Following standard APE, intraoperative bowel perforation is reported in approximately 3% of patients and is associated with an increased risk of local recurrences.<sup>24</sup> In our material, the risk of bowel perforation during iAPE was notably elevated at 10.2%, and similar rates have been reported in previous literature.<sup>16</sup> Although this is not a well-studied subject, we consider this to be a cause for concern.

To minimize the potential consequences of intraoperative bowel perforation, intersphincteric dissection could be performed after transection of the rectum distal to the tumor and removal of the specimen. Additionally, we also recognize the possibility of bias due to surgeries initially planned as HP being converted to iAPE intraoperatively due to inadvertent perforation of the rectum.

The circumferential resection margin is correlated with an increased risk of local recurrence.<sup>25</sup> In the present study, we found no significant difference in positive CRM between the groups. CRM  $\leq$ 1.0 mm was 5.6 % after HP and 8.0 % after iAPE (P = 0.097).

We found a higher risk of postoperative complications in men, and this has also been reported by others.<sup>7</sup> Although not part of our original research question, we may attribute this to anatomic differences such as the narrower male pelvis, which may make rectal surgery generally more difficult.

The results of the present study agree with those in the literature, which indicate a tendency toward favoring iAPE over HP. Two meta-analyses have been published on HP versus iAPE; one found no difference in postoperative complications.<sup>18</sup> and the other favored iAPE regarding the risk of complications.<sup>17</sup> The possible superiority of iAPE over HP was evaluated recently in a nonrandomized prospective study, which indicated similar complication rates for the 2 procedures.<sup>16</sup>

One strength of this study is that it reflects the real-world results in detail by using data from the SCRCR for a large cohort of patients who could have undergone either procedure at many different hospitals across Sweden. Swedish colorectal units usually have local policies advocating either HP or iAPE and primarily use that method. Despite this, we found differences between the 2 groups in terms of age, ASA classification, and tumor height, which we attribute to surgeons tending to use HP more often for frail patients with high cancers. However, having included these patient characteristics in the multiple regression analysis, the adjusted OR should not have been affected by such differences.

The HAPIrect trial (ClinicalTrials.gov identifier NCT01995396) is the first randomized trial to compare the standard low HP with iAPE in patients with rectal cancer. The aim is to provide the basis for decision-making when the

clinician and patient opt for a surgical method. Surgical complications in frail and/or elderly patients often lead to lengthy hospital stays and the need for reoperation, which increase patient suffering and the allocation of hospital resources. Therefore, it is important to identify which method is safer, even if they do not differ considerably. Oncological outcomes and quality of life will also be evaluated.

In conclusion, in this nationwide population-based cohort study HP was associated with a higher risk of surgical complications. In rectal cancer patients unfit for an anastomosis, iAPE may be preferable. However, the lack of statistical power and precision regarding major surgical complications, prolonged operating time, increased risk of bowel perforation, and lack of data concerning long-term outcomes, raises uncertainty regarding recommending intersphincteric abdominoperineal excision as the preferred surgical approach.

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