# Disparities in Long-Term Outcomes Between Benign and Malignant Diseases After Hartmann's Procedure: A Retrospective Observational Study

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# Abstract

**Background:** The long-term course following Hartmann's procedure may vary by primary disease, but remains unclear. Herein, we aimed to compare the incidence of reversal after Hartmann's procedure (HR) between benign and malignant diseases and explore post-HR long-term outcomes.

**Methods:** Patients who underwent Hartmann's procedure between June 2005 and December 2021 at a single center were retrospectively evaluated. The primary endpoint was the difference in HR incidence between benign and malignant diseases. The secondary endpoints were identification of the predictive factors for HR incidence and stoma-free survival and anorectal functions after reversal between patients with benign and malignant diseases.

**Results:** Among 261 patients, the benign and malignant disease groups comprised 102 and 159, respectively. Cumulative HR incidence was significantly lower in the in the malignant disease than in the benign disease groups ($P$ <0.001). However, malignant disease was not an independent factor for HR in the multivariate analysis. Low Charlson's comorbidity index ($P$ <0.001), urgent Hartmann's procedure (performed as a lifesaving procedure; $P$ <0.001), and home discharge ($P$ <0.001) were significantly associated with HR incidence. Among 43 patients who underwent HR, the rate of stoma-free survival in the malignant disease group reduced significantly as the duration from reversal increased compared with the benign disease group ($P$=0.020). No significant between-group differences were observed in anorectal function (n=23).

**Conclusion:** The incidence of HR and the stoma-free survival rate after HR may be lower in patients with malignant disease than in those with benign disease, although anorectal function after HR did not differ significantly.


# Introduction

Hartmann's procedure (HP) is a surgery for reducing the risk of postoperative complications in patients requiring emergency surgery for left-sided colonic benign disease, patients with colorectal cancer who have oncologic emergencies, and patients with poor general condition (frail or older adults) [1–3]. Although HP remains an important surgical option, the incidence of HP reversal (HR) was significantly lower than that of stoma closure after primary anastomosis [4]. A permanent stoma significantly impairs a patient's quality of life and increases medical costs. Furthermore, previous studies have demonstrated that the incidence of HR is significantly different between benign and malignant diseases [5, 6].

HR is considered a challenging surgery with a high risk of anastomotic complications and mortality [7, 8]. However, even in successful HR cases in which the patient is stoma-free, several complications, such as cancer recurrence or death, can occur during follow-up, particularly if they had malignant diseases. Only a few studies have examined the long-term outcomes of HR [9, 10]. To the best of our knowledge, no study has investigated long-term outcomes after HR in benign and malignant diseases.

Therefore, in this study, we aimed to compare the incidence of HR between benign and malignant disease groups and examine the long-term outcomes of HR in a cohort from a single institution.

## Patients and methods

# Study design and patient population

This retrospective observational study was approved by the Human Research Ethics Committee of Hakodate Municipal Hospital (Hokkaido, Japan; Reference numbers 2020–85 and 2022 – 228) and was conducted in accordance with the tenets of the 1964 Declaration of Helsinki and its later amendments. The requirement for informed consent was waived owing to the retrospective nature of the study. The study and manuscript adhere to the STROBE guidelines for observational studies.

Patients who underwent HP for any disease between January 2005 and December 2021 were included. HP was defined as the removal of a damaged colonic segment with the abandonment of the sutured distal colon stump and creation of an end colostomy in the upstream colonic segment [3]. We excluded patients who (1) underwent HP for gynecological or recurrent malignant diseases (because there were no cases of colostomy reversal), and (2) died during hospitalization after HP. The patients were classified into benign and malignant disease groups according to the disease for which HP was indicated. In our department, indications for colostomy reversal were good general condition and no major pelvic complications after HP (such as dehiscence of the rectal stump). The following situations were also considered in cases of malignant disease: (1) no disease recurrence for at least 6 months from HP after adjuvant chemotherapy in patients who underwent curative HP, and (2) no disease for which systemic treatment was being received in patients with distant metastasis. After HP, patients with malignant disease were regularly followed up for treatment or examination. Conversely, patients with benign disease were followed up by irregular visits alone for various reasons (visit for any other disease, visit by emergency, etc).

# Study endpoints

The primary endpoint was the difference in HR incidence between benign and malignant diseases. The secondary endpoints were predictive factors for the incidence of HR and stoma-free survival (SFS) and anorectal function after HR in patients with benign and malignant diseases.

# Data collection and assessments

Patient characteristic data collected from the medical records included age, sex, body mass index (BMI), American Society of Anesthesiologists physical status (ASA-PS), Charlson comorbidity index (CCI), indication for HP, type of surgery for HP, surgical approach for HP, adjacent organ resection during HP, length of residual stump, postoperative complications (intra-abdominal abscess and dehiscence of residual stump), and discharge location. Surgical outcomes of HR included the surgical approach, anastomotic method, and diverting stoma. Data on postoperative complications and mortality rates were also collected. The calculation of CCI has been previously reported [11]. CCI was classified into low and

high scores according to the following cut-off value. Residual stumps were classified as located above the sacral promontory, between the sacral promontory and peritoneal reflection, and below the peritoneal reflection. Postoperative complications were assessed using the Clavien–Dindo classification [12]. The observational period was calculated from HP or HR to the last follow-up date. SFS was defined as the rate of stoma-free survival at the time from HR.

Anorectal function was evaluated before HP (pre-HP) and after HR (post-HR) using the low anterior resection syndrome (LARS) score. The survey targeted patients who were alive in September 2022. Pre-HP function was retraced and assessed at the time of the survey. The patients' LARS scores were graded into three categories: no LARS (LARS score ≤ 20), minor LARS (LARS score between 21 and 29), and major LARS (LARS score > 20).

# Statistical analysis

Categorical variables are summarized as frequencies and percentages. Continuous variables are summarized as mean ± standard deviation. Between-group comparisons were performed using Welch's *t*-test for continuous variables and Fisher's exact test for categorical variables. Comparisons of two correlated measurements between pre-HP and post-HR functions were performed using a paired *t*-test. Comparisons between the three groups were performed using one-way analysis of variance. The CCI cutoff values for predicting HR incidence were determined based on the receiver operating characteristic curves in the benign disease and malignant disease groups separately. The cumulative incidence of HR was estimated and compared between the groups using the Gray test. Predictive factors for HR incidence were analyzed using univariate and multivariate analyses with a logistic regression model. Variables with $P < 0.1$ in the univariate analysis were entered into the multivariate analysis as covariates. SFS was calculated and compared between the groups using a multi-state Markov model. Statistical significance was set at $P < 0.05$. All statistical analyses were performed using EZR (version 1.61; Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (version 4.2.2; The R Foundation for Statistical Computing, Vienna, Austria) and a modified version of R Commander (version 2.8-0) designed to add statistical functions frequently used in biostatistics [13].

## Results

# Patient flow and characteristics between the benign and malignant disease groups

A total of 324 patients who underwent HP for any disease between January 2005 and December 2021 were eligible for the study. However, 23 patients who underwent HP for gynecological or recurrent malignant diseases and 40 patients who died during hospitalization were excluded. Eventually, 261 patients were included in this study. Among these, 102 and 159 patients were included in the benign disease and malignant disease groups, respectively. HR was performed for 43 patients. The patient flow chart is shown in Fig. 1.

The characteristics of the 261 patients are presented in Table 1. There were significant differences in sex ($P = 0.043$), ASA-PS ($P < 0.001$), type of surgery for HP ($P < 0.001$), surgical approach for HP ($P = 0.024$), adjacent organs resection during HP ($P < 0.001$), length of the residual stump ($P < 0.001$), and discharge location ($P < 0.001$) between the benign and malignant disease groups. The indications for HP, reversal rate, and time-to-reversal are shown in Table 2. The most common indications for HP were diverticular disease and colorectal cancer with obstruction in patients with benign and malignant diseases, respectively. The mean time-to-reversal for benign and malignant diseases were 11.0 and 12.2 months, respectively ($P = 0.622$). Among 159 patients with colorectal cancer, HR was not performed for any patients with stage I cancer, and it was performed for very few patients with stage IV cancer (4.5%). Among three patients with stage IV cancer, two underwent curative surgery for simultaneous peritoneal metastases and one experienced chemotherapy-related disappearance of liver metastases.

# Cumulative incidence of Hartmann's procedure reversal and associated predictive factors

Figure 2 shows that the cumulative incidence of HR in the malignant disease group was significantly lower than that in the benign disease group (26.4% vs. 7.3% at 1 year after HP and 33.6% vs. 15.7% at 3 years after HP, $P < 0.001$). The results of univariate and multivariate analyses of the predictive factors for reversal are summarized in Table 3. Malignant disease was not an independent significant factor for HR incidence in the multivariate analysis, but CCI ($P < 0.001$), type of surgery for HP ($P < 0.001$), and discharge location ($P < 0.001$) were significant factors.

# Surgical outcomes of reversal and stoma-free survival after reversal

The surgical outcomes of the 43 patients who underwent reversal are shown in Table 4. The laparoscopic approach was the most common surgical approach in the benign disease group, and open surgery was the most common approach in the malignant disease group. The length of the residual stump, anastomotic method, diverting stoma, postoperative complication grade, mortality rate, and duration of postoperative follow-up were not significantly different between the benign and malignant disease groups. Owing to anastomotic complications on day 1 after reversal, one of the 25 patients with benign disease underwent stoma recreation (second Hartmann's operation). However, the patient's stoma was not reversed. Among the 18 patients with malignant disease, one underwent stoma recreation (ileostomy) because of anastomotic complications on day 7 after HR, and the stoma was reversed approximately 3 years after the recreation. Three patients underwent stoma recreation owing to cancer recurrence in the pelvis (transverse colostomy for peritoneal recurrence in one patient with stage III cancer with a 7.9-month interval to reversal, a second Hartmann's operation for local recurrence in a patient with stage II cancer with an 11.3-month interval, and Mile's operation for local recurrence in a patient with stage IV cancer with an interval of 10 months). Figure 3 shows the Kaplan–Meier curves for SFS after HR in the benign and malignant disease groups. SFS significantly decreased in the malignant disease group with the passage of time from HR, compared with the benign disease group (benign disease vs. malignant

disease, 1-year SFS: 96.0% vs. 83.3%, $P = 0.294$; 3-year SFS: 82.4% vs. 50.5%, $P = 0.081$; 5-year SFS: 82.4% vs. 50.5%, $P = 0.081$, 10-year SFS: 82.4% vs. 36.3%, $P = 0.020$).

# Assessments of anorectal function

Twenty-three (76.7%) of the 30 survivors underwent functional assessments. The post-HR LARS scores of the 23 patients were significantly worse than the pre-HP scores ($P = 0.013$). Post-HR minor LARS occurred in three patients (13.0%), and post-HR major LARS occurred in four patients (17.4%). The post-HR LARS scores and the occurrence of post-HR LARS were not significantly different between the benign and malignant disease groups. Subsequent analysis based on the length of the residual stump revealed that post-HR LARS scores were significantly lower when the residual stump was short ($P < 0.001$). Residual stumps below the peritoneal reflection were associated with major LARS. The results of the functional assessments are summarized in Table 5.

# Discussion

The cumulative incidence of HR was lower for malignant disease than for benign disease, although malignant disease was not an independent significant predictive factor for the incidence of reversal in the multivariate analysis. After reversal, SFS reduced significantly in the malignant disease group than in the benign disease group as the time from HR increased. HR was comparable in terms of functional outcomes in both groups.

HP remains an important surgical option due to the increasing incidence of colorectal cancer and diverticulosis of the left colon worldwide and in Asian countries, respectively [14]. The rate of stoma closure was reported to be lower after HP than after primary anastomosis [4]. In particular, the stoma closure rate after HP was different between benign and malignant diseases [5, 6]. Our findings showed that the cumulative incidence of HR was significantly different in the univariate analysis, but not in the multivariate analysis, between benign and malignant diseases.

Furthermore, our findings demonstrated that low CCI, urgent surgery, and home discharge were independently associated with a higher incidence of colostomy reversal. The CCI score captures the age and comorbidities of the individual and represents their background [11]. Royo-Aznar et al. [5] reported that patients with a low CCI had a higher rate of HR. In this study, the incidence of colostomy reversal was not significantly associated with ASA-PS at the time of HP, but was significantly associated with CCI. If patients with severe systemic disease at the time of HP (high ASA-PS) recovered, had a low CCI, and were discharged home, they had a good chance of HR. Urgent surgery meant that HP had to be performed and it was a lifesaving procedure. In such cases, the patient has a good chance of HR if they recover. Our data could help surgeons provide accurate information to patients and their families about the prospect of colostomy closure and a permanent stoma prior to obtaining informed consent.

HR is a difficult surgery with a high risk of anastomotic complications and mortality [7, 8]. However, with the introduction of minimally invasive techniques [15–18], the incidence of complications after HR has

lowered [19–22]. Therefore, the indications of HR can now be expanded. Although there are many reports on short-term outcomes after HR [22, 25], only a few studies have examined its long-term outcomes [9, 10]. We speculate that the long-term follow-up of patients after HR may result in the identification of problems such as cancer recurrence in patients with malignant disease and anorectal disorders. These issues require further investigation.

Because patients with malignant disease undergoing HP often have colorectal obstruction or perforation, subsequent disease recurrence may occur even if the reversal is successful [24, 25]. In this study, stoma recreation was required in three cases of cancer recurrence in the pelvis. Furthermore, SFS reduced significantly in the malignant disease group compared to the benign disease group as the time from HR increased. For malignant diseases, an appropriate indication for HR, such as setting the adequate interval between surgeries, may avoid unnecessary HR. As mentioned earlier, in our center, HR is indicated when 1) there is no disease recurrence for at least 6 months post-HP and after adjuvant chemotherapy in patients who underwent curative HP, and 2) there is no disease progression in patients with distant metastasis controlled by systemic therapy. Although there was no significant difference, the interval from HP to HR in the three patients who underwent stoma recreation owing to cancer recurrence was shorter than that in the remaining 15 patients in the malignant disease group (9.7 months vs. 12.4 months, $P$ = 0.250). A previous study reported HR intervals of 282 days (9.3 months) for malignant disease [6]. Determining the appropriate interval for HR could be the object of future research. Additionally, it is important to obtain informed consent before HR in patients with malignant disease owing to the risk of recurrence.

Few studies have examined anorectal function after HR. In their study of 64 patients with colostomy reversal, Sander et al. [10] reported that 15.6% and 17.2% of patients had minor LARS and major LARS, respectively. Caille et al. [9] stated that among 21 patients who underwent reversal after HP due to failure of the previous anastomosis, 33.3% reported minor LARS and 23.8% reported major LARS. In our study, 13.0% of 23 patients reported minor LARS and 17.4% reported major LARS. This result is comparable to those of previous studies. Furthermore, the present study revealed no significant differences in anorectal function between those with benign and malignant diseases. However, a short residual rectal stump could be associated with poor function. Although there were only two patients with residual stumps below the peritoneal reflection, they experienced major LARS. Interestingly, a previous study demonstrated that the length of the rectal stump did not differ significantly among patients with no, minor, and major LARS [10]. Further studies will be required to investigate the association between anorectal function and the length of residual stump. Based on our finding of a high incidence of HR, we suggest that interventions such as pelvic floor muscle exercises should be considered before HR for patients with a high likelihood of HR and a short residual stump.

This study had some limitations. First, we retrospectively collected data from the surgical database and medical records of a single center. Second, the sample size might not be sufficient to examine each variable related to the outcomes. Multicenter studies with large samples and minimal bias are required for more reliable statistical analyses. Third, the effect of time from HR on post-HR anorectal function

varied from case to case, which may have influenced the functional assessment results. Fourth, because pre-HP anorectal function was retraced and assessed at the time of the survey, the actual function may not have been accurately represented. Further prospective studies are required to overcome these limitations.

Our findings indicated that the incidence of HR and SFS after HR could be worse in patients with malignant disease than in those with benign disease, although anorectal function after reversal was not significantly different. The postoperative long-term course of HR may vary between patients according to the indication for HP.

# Declarations


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### Conflicts of Interest:

Authors declare that they have no conflict of interest.

### Ethics approval statement:

The study was approved by the Human Research Ethics Committee of Hakodate Municipal Hospital (Hokkaido, Japan; Reference numbers 2020–85 and 2022-228) and was conducted in accordance with the tenets of the 1964 Declaration of Helsinki and its later amendments.

### Patient consent statement:

The requirement for informed consent was waived owing to the retrospective nature of the study. The study and its report adhere to STROBE guidelines for observational studies.

### Authorship contributions:

KIm, HK, AS, KS, KIt, TF, KIc, MO, DY, YT, MU, MK, and NT conceptualized and designed the study. KIm wrote the manuscript and performed the statistical analyses. KIm, HK, AS, KS, KIt, TF, KIc, MO, DY, YT, MU, MK, and NT performed the operations and collected clinicopathological data. NT supervised the study.

KIm, HK, AS, KS, KIt, TF, KIc, MO, DY, YT, MU, MK, and NT interpreted the results and wrote the report. All the authors have read and approved the final manuscript.

**Data availability statement:**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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# Tables

Tables 1 to 5 are available in the Supplementary Files section.

# Figures

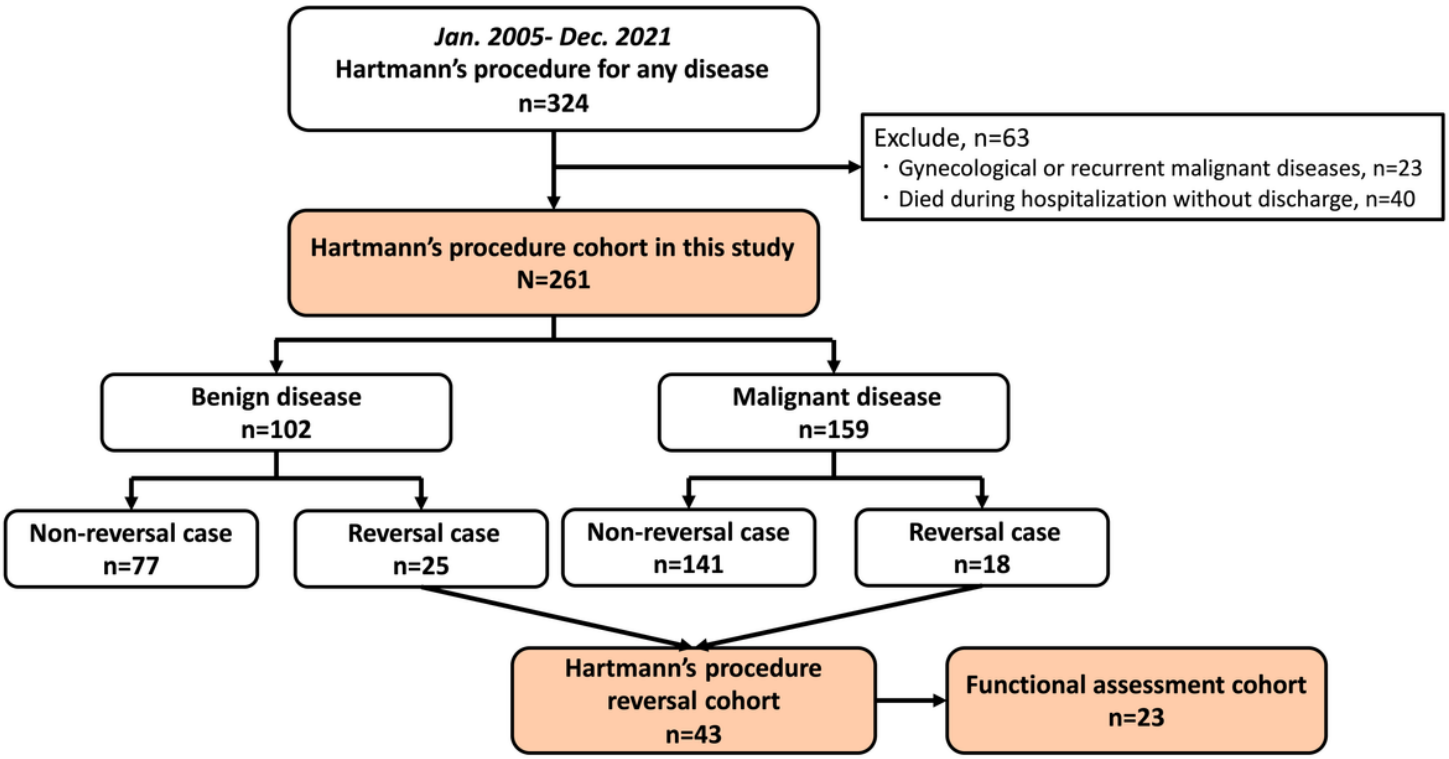
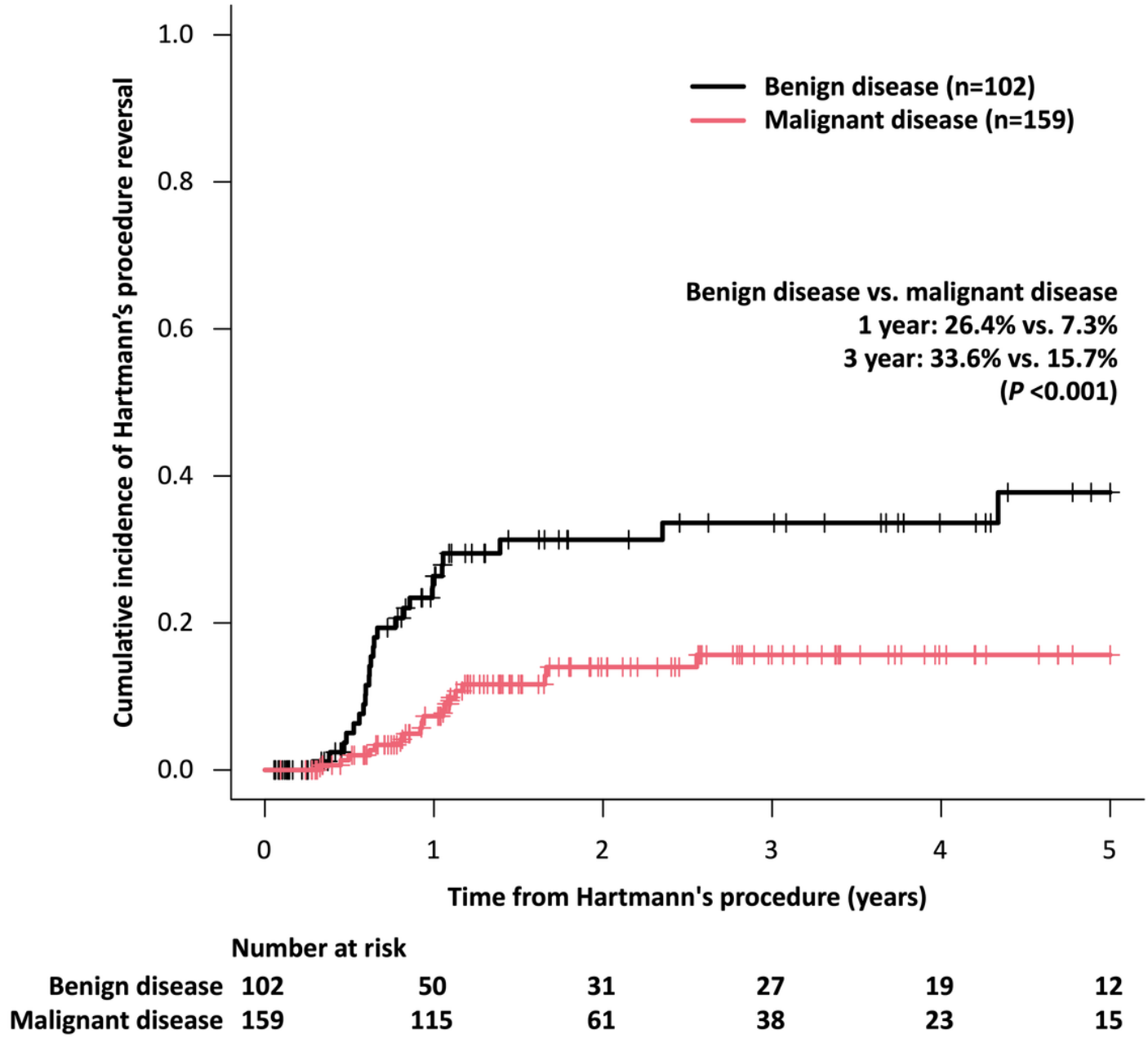



**Figure 1**

Study population and patient flow chart




## Figure 2

Cumulative incidence of Hartmann's procedure reversal between benign (black line) and malignant (red line) disease cases

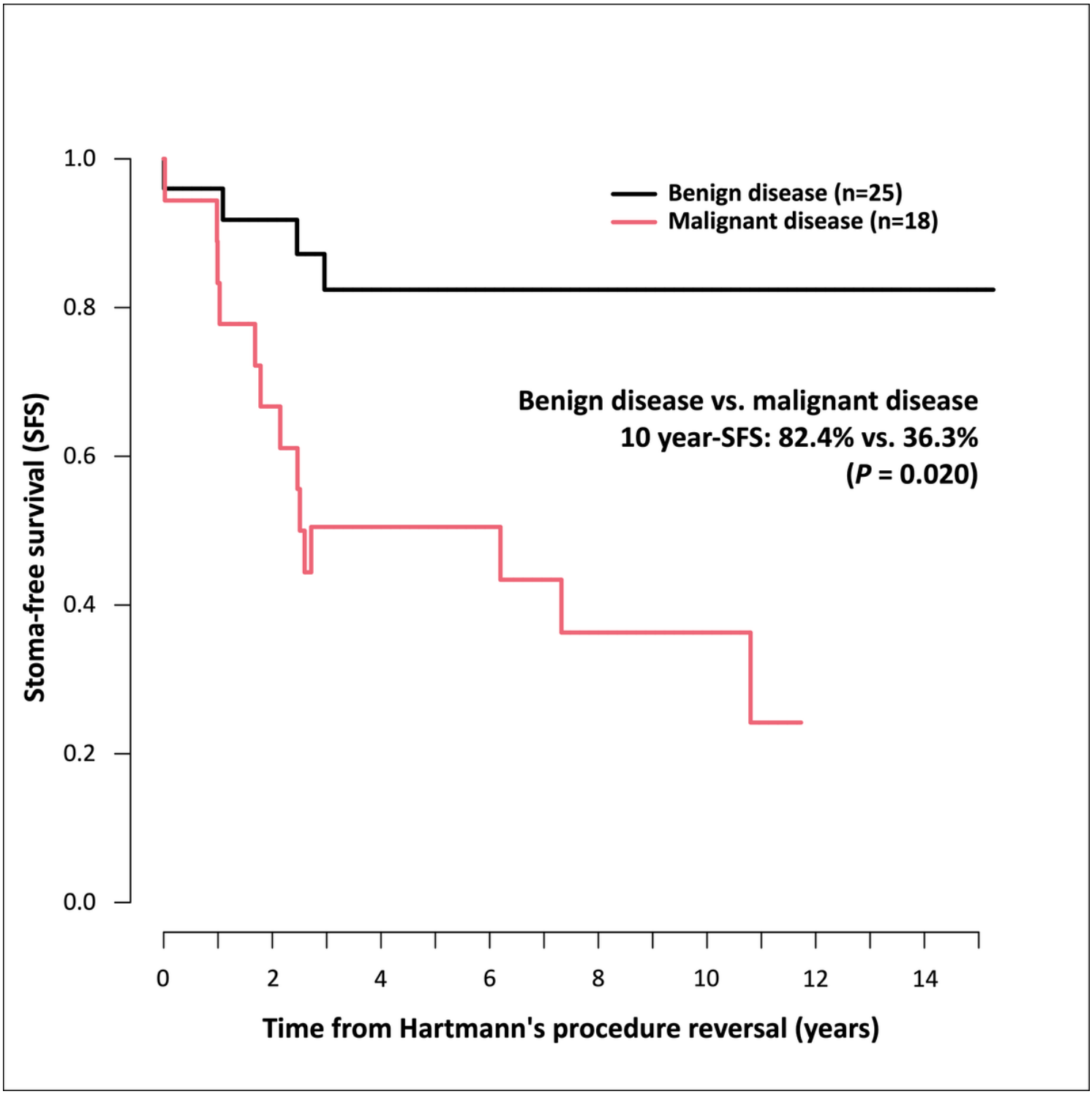



**Figure 3**

Stoma-free survival (SFS) after Hartmann's procedure reversal between benign (black line) and malignant (red line) disease cases

## Supplementary Files

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- Table1.xlsx
- Table2.xlsx
- Table3.xlsx
- Table4.xlsx
- Table5.xlsx