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Ghost Ileostomy: Safe and Cost-effective Alternative to Ileostomy After Rectal Resection for Deep Infiltrating Endometriosis

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Abstract. *Background/Aim: Endometriosis infiltrating the rectum often requires resection with a protecting stoma. A ghost ileostomy (GI) is an alternative to prevent the psychological burden for the young women affected. The present study evaluated the safety and cost-effectiveness of the ghost ileostomy (GI) procedure in a group of patients after rectal resection for deep infiltrating endometriosis. Patients and Methods: The prospective controlled interventional trial was conducted in 54 consecutive patients with deep infiltrating endometriosis of the rectum. GI was considered after ultra-low resection with primary anastomosis, previous colorectal anastomosis, or pelvic redo surgery. Loop ileostomy (LI) was performed after simultaneous colpotomy with suture, only. Operating time, morbidity according to the Clavien-Dindo classification (CDC), duration of hospital stay, and patient satisfaction were obtained. Individual costs were estimated for the endometriosis procedure with or without a GI or LI, including stoma supply and closure expenses. Results: Of the 54 patients, 27 received GI (50%), whereas 4 underwent LI (7%). The remaining 23 patients received no outlet (NO). The complication rate did not differ among the GI, LI, and NO groups. Two cases were re-operated and required a diverting stoma, one in the GI and the NO group each. The additional healthcare expenses for each patient receiving a LI averaged 6,000 €. The patients were very satisfied with the option of a GI. Conclusion: GI is a cost-effective and safe alternative to LI after rectal resection for deep infiltrating endometriosis in cases where it is required. The individual costs per patient were reduced substantially, with a cumulative savings of 160,000 € in healthcare expenditure. Additionally, the method clearly lowers the psychological burden on the young women concerned.*

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Endometriosis is a benign gynecological disease that affects approximately 7-10% of women, with clinically relevant conditions affecting approximately 3% of female patients at a fertile age (1). Pain is the most common symptom of endometriosis and presents as dysmenorrhea, dyspareunia, dyschezia, dysuria, and chronic pelvic pain (2). The incidence of rectum involvement varies between 5% and 12%. Pain and defecation problems often require bowel resection, including the rectum (3, 4). To reduce the risk of anastomotic leakage (AL) in cases of low or ultralow rectal resection, a protective loop ileostomy (LI) is often required. This results in a substantial psychological burden in patients with endometriosis (5, 6). Furthermore, the LI procedure is disputed, since the stoma itself imparts significant risk for

complications (between 21% and 70%), such as wound infection, renal failure, parastomal hernias, and bowel obstruction (7, 8). Additionally, hospital readmissions are required for the stoma closure. An alternative option for the patients at risk is required.

Ghost ileostomy (GI) was established as an alternative to LI for patients undergoing rectal resection for rectal cancer (9, 10). In GI, a silicon loop marks a suitable preterminal ileum loop. In cases of severe intra-abdominal complications, such as AL, the marked small bowel loop is easily converted to a diverting stoma (11-13).

The present study offered the GI procedure to a group of patients who underwent rectal resection surgery for deep infiltrating endometriosis. The performance of GI was defined by clinical parameters and individually evaluated by the surgeon in charge during the operative procedure. LI was obligatorily performed in cases of a colpotomy during endometriosis resection, because of the high risk of developing a rectovaginal fistula. The clinical outcome parameters and cost-effectiveness of patients receiving GI, LI, and no outlet (NO) were compared.

Patients and Methods

Participants. The present prospective controlled interventional trial was conducted in 54 consecutive women with deep infiltrating endometriosis of the rectum presenting in the endometriosis center level III of the gynecological department in our hospital between October 2019 and March 2021. Preoperative interdisciplinary diagnostic workup, multidisciplinary indication at our endometriosis board, and preparation were performed for each patient. Surgical therapy was performed for pronounced, deep infiltrating endometriosis if the symptoms persisted despite hormonal therapy or in cases where hormonal therapy was not possible. Informed consent included a detailed explanation of the surgical procedure, general and individual risks, and potential complications. Furthermore, the GI procedure was included as an option in case of planned rectal resections. Written informed consent was obtained from all individual participants included in the study. The operative procedure was performed by the interdisciplinary team with specially trained gynecologists and surgeons.

Data collection. Data regarding patient hospital records, surgical ward follow-up charts, laboratory and imaging reports, operation reports, discharge letters, and individual health care expenses were extracted from the electronic database of our hospital. The records were checked by two reviewers (A.V.H and C.R.).

Age, body mass index (BMI), American Association of Anesthesiologist (ASA) (14), operating time, postoperative morbidity, and mortality according to the Clavien-Dindo classification (CDC) (15), duration of hospital stay, and number and reason of readmissions, if applicable, were obtained.

Patients who underwent GI were asked upon discharge about their comfort with the silicon loop and their personal satisfaction with their decision. The level of satisfaction was assessed using a numeric scale with four values (1-4), with 1 corresponding to very satisfied, 2 to satisfied, 3 to not satisfied, and 4 to very dissatisfied.

The refunds to each patient were collected according to the German Diagnosis-related Groups System (gDRG). In cases with a LI, the stoma supplies and the readmission costs for the stoma closure were included.

Surgical procedure. At the end of the rectal resection, the need for a stoma was evaluated. The clinical criteria indicating a patient at risk included redo anastomosis, ultralow rectal resection, previous pelvic surgery, and colpotomy for endometriosis resection, as outlined in the flow chart (Figure 1). GI was performed only in cases, where the patient would have otherwise received a protective LI. LI was mandatory in case of a colpotomy because of the risk of developing a recto-vaginal fistula. A suitable small bowel loop 20-30 cm before the ileocecal valve was identified to perform a GI. The small bowel meso was tunneled and marked with a silicone loop (Roeser Loops super maxi, Ref No 10.11522; Roeser Medical GmbH, Bochum, Germany; CE 0481). The silicone loop was externalized and fixed at the 5-mm trocar site in the right upper quadrant with two nonabsorbent sutures (Figure 2a and b). Finally, a drainage bag was placed. The GI procedural time varied between 5 and 7 min, whereas LI required between 20 and 35 min.

Further diagnostic workup was initiated in cases of the pelvic fluid collection, bowel dysfunction, such as ileus, signs of AL, or signs of a severe inflammatory response syndrome (SIRS) defined by fever, tachycardia, tachypnoea, and elevated lab signs. If necessary, the GI was converted into a diverting stoma. In other cases, the silicon strap was removed after bowel function recovery or at discharge.

Statistical analysis. Data were analyzed with the SPSS statistical package, version 27.0.0.1. (IBM Corp., Armonk, NY, USA). Quantitative variables were described as means (+/– SD) and were compared using the Kruskal-Wallis *H* test and Mann-Whitney *U*-test. Qualitative variables were summarized by count, percentage, median, and interquartile range and were compared with Fisher's exact test. A two-sided *p*-value less than 0.05 was considered statistically significant. As no adjustments for multiple testing were performed, the analyses were exploratory.

Ethical approval and consent to participate. This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of the Aerztekammer North Rhine (Düsseldorf, Germany; Registration number: 2019013). The study was registered with clinicaltrials.gov (NCT04573075). Written and oral informed consent were obtained from all participants.

Results

Participants' characteristics. The baseline characteristics exhibited no significant differences among the three subgroups (Table I). Of the 54 women, 32 received an anterior rectal resection (ARS), and 22 received a low or ultra-low anterior rectal resection (LARS). A GI was performed in altogether 27 cases; in 14 of the 32 cases after ARS, and in 13 of the 22 cases GI after a LARS. A LI was performed in all 4 cases after an extended endometriosis resection with colpotomy. Laparoscopy was performed in all

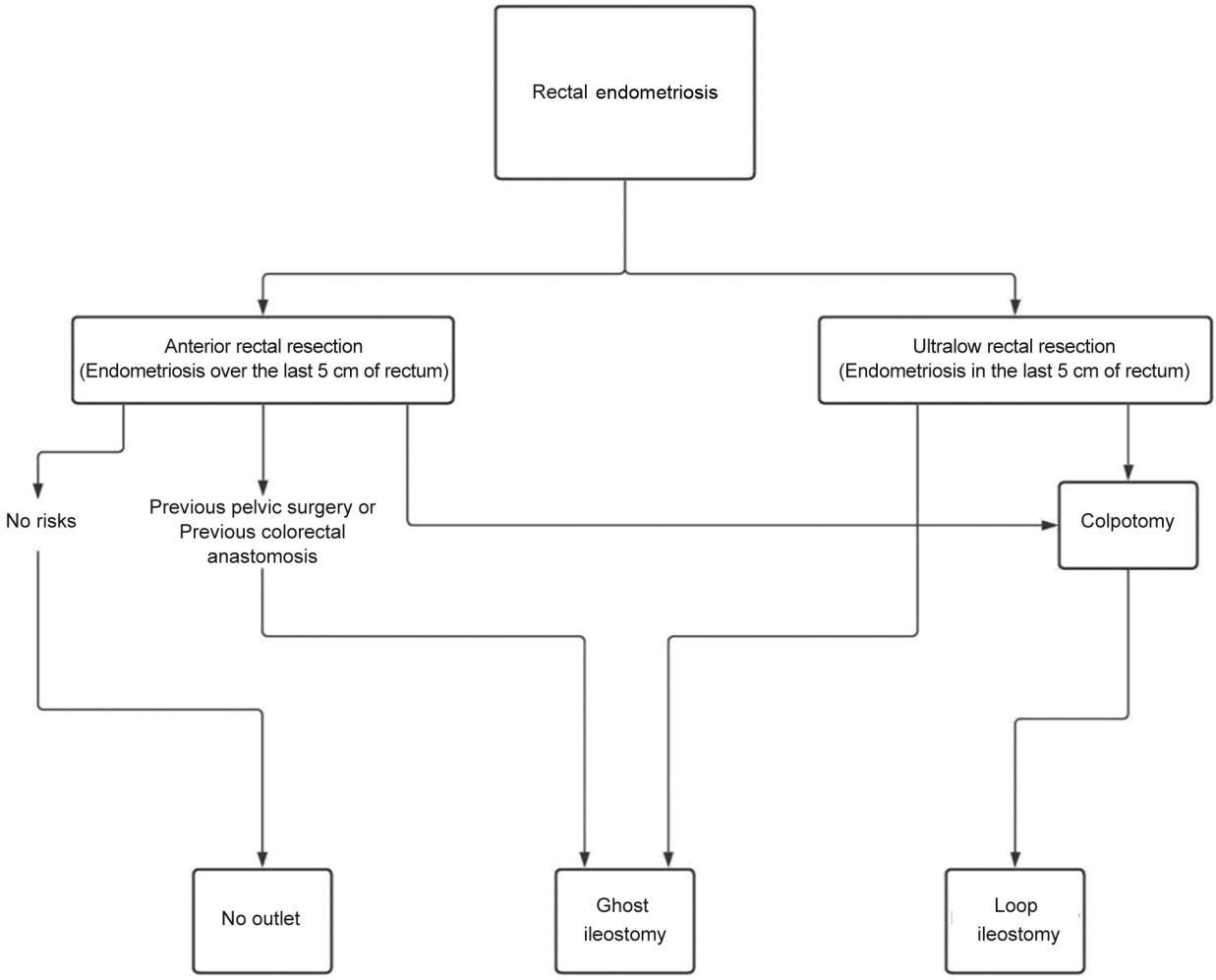

Figure 1. *Flow chart illustrating the standard operating procedure (SOP) on the decision of performing a ghost ileostomy (GI) after rectal resection for deep infiltrating endometriosis of the rectum.*

cases; no conversions were necessary. Operating time was higher in the LI group [295 min (160-385)] than the GI group [140 min (106-189)] and the NO group [120 min (100-170); p=0.044]. The duration of hospital stay was 11 days (8-14 days) in the LI group and was significantly higher than the GI group [8 days (7-8 days)] and the NO group [6 days (5-8 days)].

Morbidity and mortality. Postoperative complications were observed in 10 cases, 5 occurred in the GI group, 3 in the NO group, and 2 in the LI group (p=0.214). No deaths occurred. The CDC classification was divided into minor (CDC 1-3a) and major (CDC 3b-5) complications, with no significant differences between the groups (p=0.109). AL occurred in 2 cases, one in the GI group and one in the NO group, which consequently required a diverting stoma. No other GI had to be switched to stoma. The details and the individual complications are listed below (Table II).

Patient satisfaction. The satisfaction score averaged at 1.38. The majority of patients chose "1," the highest level of satisfaction (n=19; 70%). Only one patient was not satisfied at all. Even though she did not feel pain, she insisted on the premature removal of the silicon strap. Follow-up with this patient was uneventful.

Cost analysis. According to the gDRG system, the average refund per case for the primary endometriosis surgery, including rectal resection, was 10,350 €. The refund covers the surgical procedure, including the complete hospital stay. The refund did not vary between the procedures with NO, GI, or LI. Individual costs for the GI included the silicon loop (0.8 €) and additional sutures (1.22 €). The monthly

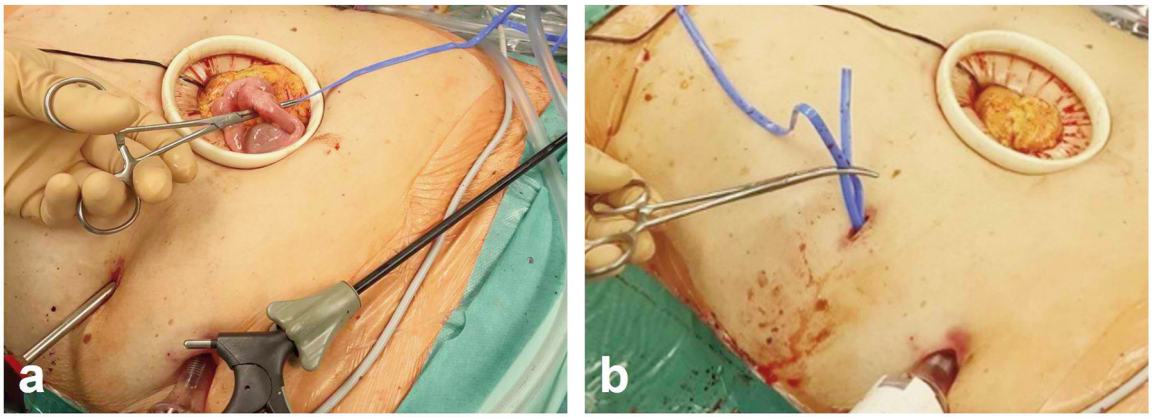

Figure 2. *Procedural steps for performing the ghost ileostomy (GI). (a) The suitable small bowel loop 20-30 cm prior to the ileo-cecal valve is extracted though the mini laparotomy at the belly, the mesentery is tunneled, and marked with a silicone loop. (b) The loop is externalized through a trocar site at the right upper quadrant and fixed with non-absorbable sutures. The authors affirm that human research participants provided informed consent for publication of the images in Figure 2a/b.*

Table I. *Characteristics and surgical outcomes of participants undergoing rectal resection for deep infiltrating bowel endometriosis shown for all patients and the three subgroups [ghost ileostomy (GI), loop ileostomy (LI), and no outlet (NO)].*

	All patients n=54	GI n=27	LI n=4	None n=23	*p*-Value
Age, y, median (IQR)	32 (29-37)	31 (28-34)	31 (29-36)	35 (30-40)	0.207
ASA, n (%)					0.438
1	29 (53.7%)	16 (59.3%)	1 (25%)	12 (52.2%)	
2	25 (46.3%)	11 (40.7%)	3 (75%)	11 (47.8%)	
BMI, median (IQR)	24 (22-26)	24 (22-27)	21(19-32)	25 (22-25)	0.608
Operation time in min, median/IQR	140 (104-180)	135 (105-185)	295 (160-385)	120 (100-150)	0.044
Duration in hospital, day, median (IQR)	7 (6-8)	8 (7-8)	11 (8-14)	7 (5-8)	0.038
Resection, n (%)					0.413
Anterior rectum	32 (59.3%)	14 (51.9%)	2 (50%)	16 (69.9%)	
Low anterior rectum	22 (40.7%)	13 (48.1%)	2 (50%)	7 (30.4%)	

Data are presented as the median and interquartile range (IQR) for continuous variables and as total number and percentages (%) for binary variables. The *p*-value indicates the level of statistical significance.

stoma supplies averaged 400 €. The stoma remained in place for a minimum of 6 weeks. Stoma closure required hospital readmission of 3-7 days with a cost refund of 5,400 €. The stoma raised the healthcare expenses by 6,000 €.

Receiving a stoma prolonged the hospital stay compared with the GI and NO group for observing the proper functioning of the stoma, teaching stoma care, and organizing stoma surveillance after discharge.

Performing a GI slightly increased the hospital stay by 1-2 days compared to the NO group, because the patients were kept under observation after removing the silicone loop to ensure proper bowel function. The difference was not significant.

Discussion

We performed GI in 27 patients with rectal resection after extended endometriosis resection. Only one AL occurred in the GI group requiring a diverting stoma. For 26 of the 27 patients with GI, a protective stoma could be prevented. Another AL occurred in the NO group, also requiring a stoma. These events underline the risk for AL even in the group of healthy young women with low comorbidity and they contribute to the debate around the protective stoma.

A protective LI is not cost-effective according to the healthcare refund. The average rebate per case for primary endometriosis surgery, including a rectal resection, was

Table II. *Morbidity presented as overall morbidity and classified according to the Clavien Dindo Classification (CDC) of the patients undergoing rectal resection for deep infiltrating bowel endometriosis.*

	All patients n=54	GI n=27	LI n=4	None n=23	*p*-Value
Overall morbidity, n (%)	10 (18.5%)	5 (18.5%)	2 (50%)	3 (13.0%)	0.214
Minor (CDC 1-3a), n (%)	6 (11.1%)	2 (7.4%)	2 (50%)	2 (8.7%)	
Major (CDC 3b-5), n (%)	4 (7.4%)	3 (11.1%)	0	1 (4.3%)	
Mortality, n (%)	0	0	0	0	
Clavien-Dindo Classification, n (%)					0.068
CDC 0 (none)	44 (81.5%)	22 (81.5%)	2 (50%)	20 (87%)	
CDC 1	4 (7.4%)	1 (3.7%)	2 (50%)	1 (4.3%)	
CDC 2	1 (1.9%)	0	0	1 (4.3%)	
CDC 3a	1 (1.9%)	1 (3.7%)	0	0	
CDC 3b	4 (7.4%)	3 (11.1%)	0	1 (4.3%)	
Complications, n (%)	10 (18.5%)	5 (18.5%)	2 (50%)	3 (13%)	
Pulmonary events	2 (3.7%)	1 (3.7%)	0	1 (4.3%)	
Access complication	2 (3.7%)	2 (7.4%)	0	0	
Anastomosis insufficiency	2 (3.7%)	1 (3.7%)	0	1 (4.3%)	
Gastrointestinal events	1 (1.9%)	0	0	1 (4.3%)	
Urologic events	2 (3.7%)	0	2 (50%)	0	
Sepsis	1 (1.9%)	1 (3.7%)	0	0	

Minor and major complications are differentiated, and the type of complication is specified. Data is shown for all patients and the three subgroups [ghost ileostomy (GI), loop ileostomy (LI), and no outlet (NO)], respectively. Data are presented as total number and percentages (%) for binary variables.

approximately 10,000 €, regardless of the procedure performed. Patients with a protective LI require longer operating times, longer duration of hospital stay, and thus more health professional resources. These exceeding resource requirements are not refunded in the DRG system. The additional expenses for stoma supply and the readmission for a stoma closure summed up to 6,000 € per patient. Our analysis did not include expenses for stoma-related complications, because the analysis of a group of 4 patients with LI cannot be generalized. The findings, however, are concurrent with those of Floodeen *et al*. and Zenger *et al*., who demonstrated, that a diverting stoma was a risk factor for increased resource use and healthcare expenses for patients with rectal cancer (12, 16).

In the present study, the GI prevented a diverting stoma for the individual patient and reduced healthcare costs and resources significantly. The sum of more than 150,000 € was spared for the German healthcare system.

Endometriosis is a psychological burden in the clinical course, especially for younger women (17). Undergoing surgery with the possibility of diverting stoma raises stress levels in the patient and affects the quality of life. Although no actual data exist on the psychological burden of a stoma for patients undergoing bowel surgery, the influence of preoperative pain and anxiety on the postoperative functional outcome has been demonstrated for orthopedic patients scheduled for surgery (18). Consequently, a procedure that avoids a stoma is required. The present study observed relief in patients during the initial consenting talk about the option of a GI, even though a protective stoma could not be excluded in all the cases. The postoperative level of satisfaction of the patients undergoing GI was high, emphasizing the psychological advantage GI offers.

The present study has certain limitations. The small sample size limited the statistical analysis and reduced the universality of the results. Furthermore, the study, although conducted prospectively, did not randomize the participants. The surgeon decided individually whether to implant a GI or not. Although our standard operating procedure as outlined in the flow chart standardized the process of decision the procedure still inherits the risk of bias. This reduces the statistical inference of the conclusion. Nevertheless, our clinical results concerning the safety and efficacy of the procedure confirmed the experience from other groups (19-22). Additionally, our analysis proved the cost-effectiveness of the GI procedure. The present study encouraged us to establish the GI procedure as a routine alternative to LI for patients undergoing rectal resection in our hospital.

To finally prove the advantage of GI, a prospective randomized trial is required. A prospective randomized trial for GI after LARS for rectal cancer has been initiated in 2020 (23). After endometriosis resection, however, the ethical feasibility requiring random assignment to GI or LI for patients will be controversial and not feasible in clinical

practice, as the benefits of the GI are clear. A trial design rather comparing the results of the GI procedure to no diverting stoma would be an alternative. Furthermore, risk factors for AL and surgical techniques preventing it, need to be systematically investigated (5, 20, 24). Meanwhile, the GI procedure might be established as a routine technique to avoid a stoma.

Conclusion

Our data confirmed the medical and psychological arguments to establish GI in routine rectal endometriosis procedures. The current arguments are strengthened by the cost-effectiveness of the procedure. We recommend GI as a cost-effective and patient-safe treatment alternative for deep infiltrating endometriosis patients who would otherwise require a diverting stoma. Further randomized trials are required to definitely prove the advantage.

Conflicts of Interest

The Authors declare no conflicts of interest. The authors declare that no funds, grants, or other support were received during the preparation of this manuscript. The authors have no relevant financial or non-financial interests to disclose. This manuscript has neither been presented at any conference nor submitted to any other journal for consideration for publication.

Authors' Contributions

A Vega Hernández: Project development, Data collection and management, Manuscript writing; J Otten: Data management, Data analysis; H Christ: Data analysis; C Ulrici: Project development; E Piriyev: Manuscript writing and editing; S Ludwig: Manuscript writing and editing; C Rudroff: Protocol/project development, Data collection and management, Manuscript writing and editing

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