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# PREDICtors for health-related quality of life after elective sigmoidectomy for DIVerticular disease: the PREDIC-DIV study protocol of a prospective multicentric transnational observational study

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## ABSTRACT

**Introduction** Diverticulitis is among the most common abdominal disorders. The best treatment strategy for this complicated disease as well as for recurrent stages is still under debate. Moreover, little knowledge exists regarding the effect of different therapeutic strategies on the health-related quality of life (HrQoL). Therefore, the PREDIC-DIV (PREDICtors for health-related quality of life after elective sigmoidectomyfor DIVerticular disease) study aims to assess predictors of a change in HrQoL in patients after elective sigmoidectomy for diverticular disease.

**Methods and analysis** A prospective multicentre transnational observational study was started in November 2017. Patients undergoing elective sigmoid resection for diverticular disease were included. Primary outcome includes HrQoL 6 months postoperatively, staged by the Gastrointestinal Quality of Life Index (GIQLI). Secondary outcomes include HrQoL 6 months after sigmoidectomy, assessed using the Short Form 36 Questionnaire and a custom-made Visual Analogue Scale-based inventory; HrQoL after 12 and 24 months; postoperative morbidity; mortality; influence of surgical technique (conventional laparoscopic multiport operation vs robotic approach); histological grading of inflammation and morphological characteristics of the bowel wall in the resected specimen; postoperative functional changes (faecal incontinence, faecal urge, completeness of emptying, urinary incontinence, sexual function); disease-specific healthcare costs; and changes in economic productivity, measured by the iMTA Productivity Cost Questionnaire. The total follow-up will be 2 years.

**Ethics and dissemination** The protocol was approved by the medical ethical committee of the Bavarian Medical Council (report identification number: 2017-177). The study was conducted in accordance with the Declaration of Helsinki. The findings of this study will be submitted to a peer-reviewed journal (*BMJ Open*, *Annals of Surgery*, *British Journal of Surgery*, *Diseases of the Colon and the Rectum*). Abstracts will be submitted to relevant national and international conferences.

## Strengths and limitations of this study

- This is the first multicentric study intending to identify predictors of a postoperative change in quality of life with a prospective approach.
- In addition to postoperative disorders of faecal emptying, the study assesses data on urinary and sexual function.
- For the first time in this field, prospective data on the influence of a standard laparoscopic multiport approach versus robotic surgery are gathered.
- The study is designed as a prospective observational study, using no randomisation.
- Since patients scheduled for sigmoidectomy can present asymptomatic and/or persisting abdominal complaints, the cohort may be inhomogeneous in regard to the quality-of-life assessment at the baseline, and a selection bias cannot be definitely ruled out because a decision regarding surgery is partly made on an individual basis.

**Trial registration number** The study is registered with the ClinicalTrials.gov register as NCT03527706; Pre-results.

## INTRODUCTION

Acute diverticulitis of the left colon is among the most frequent abdominal disorders in the western world—in fact, the disease frequency is actually increasing. US population-based data show an incidence rate of 115/100 000 in the period from 1980 to 1989 and of 188/100 000 between 2000 and 2007.[1]

To date, the decision regarding surgery can be made increasingly restrictive following current guideline recommendations.

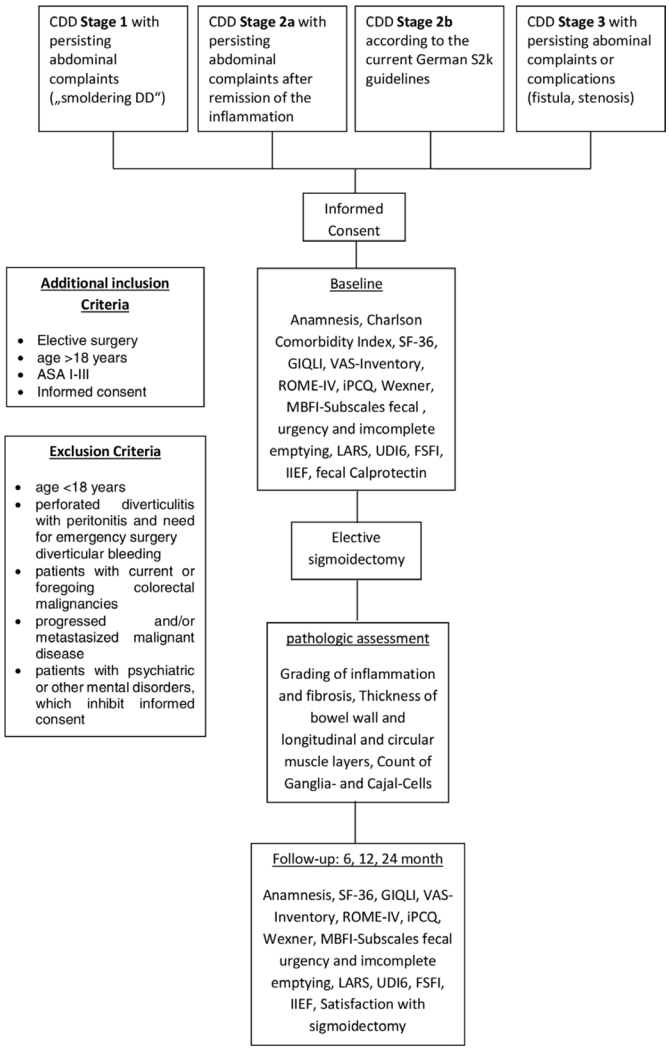


**Figure 1** Study flow and inclusion and exclusion criteria.

Nevertheless, the yearly number of surgeries is constantly high.[2] Suggestions for conservative therapy in uncomplicated stages and emergency surgery in perforated disease with generalised peritonitis are consensual. However, the treatment of complicated stages with or without a pericolic abscess as well as the management of a recurrent disease is controversial. While the majority of international guidelines recommend conservative management of the acute stages of a disease, potentially complemented by interventional percutaneous drainage, suggestions regarding how to proceed after a remission of the inflammation diverge. According to German and North American guidelines, an elective sigmoidectomy should be performed in cases of 'macroabscesses'.[3–5] Other relevant European guidelines avoid determining a general 'stage-based' need for surgery in cases of diverticulitis complicated by an abscess, proposing a case-by-case allocation of patients to elective surgery or watchful waiting/conservative treatment.[6 7] Currently, the health-related quality of life (HrQoL), as a quantifiable parameter, receives little attention within the assessment for possible surgery. Moreover, evidence on disease-specific characteristics influencing postoperative quality of life is lacking.

## METHODS AND ANALYSIS

### Objectives

The PREDIC-DIV study intends to assess predictors of a change in HrQoL in patients after elective sigmoidectomy for diverticular diseases.

### Design

The PREDIC-DIV (PREDICtors for health-related quality of life after elective sigmoidectomyfor DIVerticular disease) study is a prospective, multicentre, and transnational observational study. The study was started in November 2017. Recruitment will be completed in October 2021. Overall, the inclusion of 165 patients is planned. Participating study centres include the (1) Department of General, Abdominal, Endocrine and Minimally Invasive Surgery, Munich Clinic Bogenhausen, Germany (2) Department of Surgery, Paracelsus Medical University, Salzburg, Austria and (3) Department of General, Abdominal, Vascular and Thoracic Surgery, Klinikum Dritter Orden, Munich, Germany.

### Allocation for surgery

All consecutive patients allocated for surgery and matching the inclusion criteria were eligible to be included in the study. The allocation to conservative or surgical therapy was performed prior to inclusion in the study and independent of potential enrolment. Possible indications for surgery are listed below (see also figure 1):

- Persisting abdominal complaints (smouldering diverticular disease) after uncomplicated diverticulitis (Classification of Diverticular Disease (CDD) Stage 1, modified Hinchey 0+Ia).
- Persisting abdominal complaints after covered perforation and/or pericolic 'microabscesses' (<1 cm) and after remission of inflammation (CDD Stage 2a, modified Hinchey Ib (abscess size <1 cm)).
- Expired inflammation with pericolic 'macroabscesses' (>1 cm) (CDD Stage 2b, modified Hinchey Ib+II) according to the current German S2k guidelines.
- Chronic or recurrent diverticulitis with persisting abdominal complaints or complications (fistula, stenosis) (CDD **Stage 3**).

### Outcomes

#### Primary outcome

- Postoperative HrQoL 6 months postoperatively; quality of life will be measured by the Gastrointestinal Quality of Life Index (GIQLI.[8]

#### Secondary outcomes

The secondary outcome parameters are depicted in table 1.

#### Inclusion criteria

- Elective surgery.
- Age >18 years.
- ASA (American Society of Anesthesiologists Classification) I–III.
- Informed consent.

Table 1 Secondary outcome parameters

| Outcome parameter | Description/score |
|---|---|
| HrQoL, 6 months postoperatively | SF-36[19] |
| HrQoL, 6 months postoperatively | A customised VAS-based inventory will be used, composed of six VASs overall, addressing the quality of life and gastrointestinal symptoms (abdominal pain, overall quality of life, bloating, diarrhoea, constipation, influence on quality of life by these symptoms) |
| HrQoL, 12 and 24 months postoperatively | SF-36, GIQLI, VAS |
| Postoperative morbidity | Clavien-Dindo classification[20] |
| Mortality | 30-day mortality and mortality associated with the development of complications related to the recurrence of diverticulitis |
| Postoperative functional changes and associated influence on quality of life | ► Faecal incontinence: Wexner score[21]<br>► Faecal incomplete emptying and faecal urge (subscales of the Memorial Bowel Function Index,[22] LARS score)[23]<br>► Urinary incontinence: UDI6[24 25]<br>► Male sexual function: IIEF[26]<br>► Female sexual function: FSFI[27] |
| Histopathological and morphological changes of the bowel wall in the resected specimen | ► Within the 'diverticulitis' region: grading of inflammation (G1–G4)[9]<br>► At the colorectal junction: diameter of the bowel wall, total muscular layer, longitudinal versus circular muscular layer, grade of fibrosis, content of Cajal and ganglia cells |
| Disease-specific healthcare costs and days off work | Insurance request |
| Preoperative and postoperative economic productivity | iMTA Productivity Cost Questionnaire[28] |
| Pre-MBP to post-MBP ratio of faecal calprotectin | Faecal calprotectin before MBP and intraoperatively |
| Influence of surgical approach | Comparison of results after conventional laparoscopic multiport operation, robotic approach and conversion to open surgery. |

FSFI, Female Sexual Function Index; GIQLI, Gastrointestinal Quality of Life Index; HrQoL, health-related quality of life; IIEF, International Index of Erectile Function; LARS, low anterior resection syndrome; MBP, mechanical bowel preparation; SF-36, Short Form 36; UDI6, Urinary Distress Inventory; VAS, Visual Analogue Scale.

### Exclusion criteria

- Age <18 years.
- Perforated diverticulitis with peritonitis and the need for emergency surgery.
- Diverticular bleeding.
- Patients with current or foregoing colorectal malignancies
- Progressed and/or metastasized malignant disease.
- Patients with psychiatric or other mental disorders, which inhibit informed consent (figure 1).

## Sample size

The sample size was determined to detect a minimum important difference in changes in the GIQLI (postoperative score–preoperative score) between patient subgroups defined by potential prognostic factors. A mean difference in changes in the GIQLI total score between two groups of 10 points is considered clinically relevant.[9 10] Based on the analysis by Forgione *et al*,[11] a within-group SD of 20 points was assumed, translating to an effect size (Cohen's d) of d=0.5. Under the given assumptions, the study will be adequately able (≥80%) to detect a relevant difference between two groups if the smaller of the two groups consists of at least 50 patients (significance level $\alpha$=5%). In this regard, the inclusion of 150 complete data sets of patients is intended to result in adequately sized groups. To compensate for a potential loss in the follow-up period, 165 patients will be included.

## Follow-up

Follow-up data were collected 6, 12 and 24 months postoperatively. Patients were called by phone to ensure compliance. Thereafter, questionnaires were sent by mail. Therein, evidence of delayed complications, the need for interval nonsurgical and surgical therapy, functional changes, the quality of life and functional parameters were assessed.

## Classification

The disease is staged using the German CDD.[3 5] Additionally, Hinchey, modified Hinchey and Ambrosetti classifications are applied[12 13] (table 2).

## Subgroups

### Conventional laparoscopic versus robotic sigmoidectomy

Sigmoidectomy is intended to be routinely performed laparoscopically, since its advantages were unequivocally proven within the 'Sigma Trial'.[14] In study centres 1 and

Table 2 Classification systems for DD and diverticulitis

| Classification of Diverticular Disease (CDD) | | | | Hinchey-Classification | | Modified Hinchey-Classification | | |
|---|---|---|---|---|---|---|---|---|
| Stage | | | Description | Stage | Description | Stage | | Description |
| 1 | | | Uncomplicated diverticulitis | | | | | |
| | a | | Diverticulitis without (inflammatory) reaction in the surrounding tissue | | | 0 | | Mild clinical diverticulitis |
| | b | | Diverticulitis with phlegmon | I | Pericolic abscess or phlegmon | I | a | Confined pericolic inflammation or phlegmon |
| 2 | | | Complicated diverticulitis (CD) | | | I | b | Confined pericolic abscess |
| | a | | CD with micro-abscess (≤ 1 cm) | II | Pelvic, intra-abdominal or retroperito-neal abscess | II | | Pelvic, intra-abdominal or retroperitoneal abscess |
| | b | | CD with macro-abscess (> 1 cm) | | | | | |
| | c | 1 | CD with free perforation and purulent peritonitis | III | Generalized purulent peritonitis | III | | Generalized purulent peritonitis |
| | | 2 | CD with free perforation and feculent peritonitis | IV | Generalized feculent peritonitis | IV | | Generalized feculent peritonitis |
| 3 | | | Chronic DD | | | | | |
| | a | | Symptomatic DD | | | | | |
| | b | | Recurrent diverticulitis without complications | | | | | |
| | c | | Recurrent diverticulitis with complications | | | | | |
| 4 | | | DD with diverticular bleeding | | | | | |
| Ambrosetti Classification | | | | | | | | |
| Stage | | | | | | Description | | |
| Moderate diverticulitis | | | | | | Localized sigmoid wall thickening (> 5 mm) Pericolic fat stranding | | |
| Severe diverticulitis | | | | | | Abscess Extraluminal air Extraluminal contrast | | |

CD, complicated diverticulitis; DD, diverticular disease.

3, the standard treatment is conventional multiport laparoscopic sigmoidectomy (for the technical aspects, see below). In study centre 2, a sigmoidectomy is generally performed via a robotic approach (see below). Therefore, patients are not allocated to different surgical techniques within one study centre, but subgroup data are compared between study centres 1+3 and 2. When comorbidities forbid capnoperitoneum, such as severe cardiac or pulmonary diseases, or suspected adhesions due to prior open major abdominal surgery, open surgery is preferred at all centres. Even those patients will be included in the analysis. Additionally, patients who undergo conversion from initial laparoscopic to an open approach will be included. Under the given assumptions and expecting that approximately two-thirds of the included patients undergo conventional laparoscopic surgery, approximately 150 patients (100 with laparoscopic surgery, 50 with robotic surgery) need to be included in the study to detect a relevant difference between the groups with a power of 80% (significance level $\alpha$=5%).

### Uncomplicated versus complicated diverticulitis

Assuming that approximately one-third of patients suffer from an uncomplicated disease and two-thirds from complicated stages, with a sample size of 150 planned patients (uncomplicated: n=50; complicated: n=100), the study will also be adequately able to detect a relevant difference between complicated and uncomplicated stages with a power of 80% (significance level $\alpha$=5%).

## Preoperative preparation

All patients preoperatively receive mechanical bowel preparation (Macrogol 2 L) supplemented with oral antibiotics (2 g paromomycin and 1 g metronidazole) at 19:00 and 23:00 on the day before surgery. Additionally, a perioperative intravenous antibiotic single-shot dose is administered within 30 min before operation. The selected preoperative intravenous antibiotic depends on the recommendations of the local department of hygiene.

## Surgical technique

The surgical approach (lateral-to-medial or medial-to-lateral) is the surgeon's choice and will not influence

study inclusion. However, the lateral-to-medial approach is the standard treatment at all three study centres.

### Conventional laparoscopic multiport sigmoidectomy

Conventional laparoscopic resection of the sigmoid colon is performed using four ports. The camera port is placed 3 cm supraumbilically (12 mm), and the two ports on the right side, in the mid (12 mm) and lower (5 mm) abdomen, in line with the spina iliaca anterior superior. The fourth port is positioned in the left lower abdomen (5 mm). The left colon is mobilised from the lateral side along Gerota's fascia. The splenic flexure is mobilised only laterally but not ventromedially. The mesentery of the sigmoid colon is then medially fenestrated at the promontory level. The superior rectal artery as well as the inferior mesenteric artery and vein are identified and routinely preserved. A tubular dissection of the mesentery of the sigmoid colon is then performed. The sigmoid arteries are cut using tissue-sealing devices. A linear stapler device is applied for division of the large intestine. The sigmoid is retracted through a Pfannenstiel incision or enlargement of the left lower abdominal incision. Colorectal anastomosis is performed using a double stapling technique following open resection of the affected colon. The oral resection level is situated in a region where no diverticula exist or a relevant decline in diverticular concentration is identified. Aboral resection is performed at the level of the colorectal junction identified by the taenia coli, broadening onto the upper rectum.

### Robotic sigmoidectomy

The patient is placed into the lithotomy position. Shoulder braces are used to enable a deep Trendelenburg position. For the robotic approach, the operation is performed with a Da Vinci X system using the four-arm technique, using four 8 mm da Vinci ports. One port is placed umbilically, one in the left upper abdomen, one in the right middle abdomen and the last one through an Octo-Port inserted by using a McBurney's incision. A 7 mm air-seal cannula is placed under the right costal arch for air insufflation and smoke evacuation. The preparation starts medially and continues laterally. The left colonic flexure is usually mobilised from the lateral side. The mesentery is then dissected using a Da Vinci vessel sealer. Within this step, preservation of the superior rectal artery is generally intended. The aboral dissection level is identified analogous to the conventional laparoscopic approach. The mobilised colon is then pulled out of the abdominal cavity through the Octo-Port. The subsequent steps are identical to those of the conventional technique.

## Data management

Completed informed consent forms remain at the participating hospital. Participating patients receive a copy of the signed form. Data will be anonymised and recorded in a Microsoft Excel database. Follow-up was coordinated by each participating hospital. Data are added to the database.

Data anonymisation is performed using a code consisting of the first letter of the respective name of the participating hospital and the ongoing number of participating patients at the respective hospitals. All Excel data are password-protected.

## Statistical analysis

Description of the HrQoL is performed using the mean and SD of all available data at the respective follow-up points (preoperatively and 6, 12 and 24 months postoperatively). The 95% CI is estimated for relevant differences of the mean. A respective description is added separately for relevant subgroups (conventional laparoscopic vs robotic surgery, guideline-specific vs individualised therapy). A paired t-test is applied to compare the means of different scores at two different time points. Unpaired t-tests were used for comparison of the changes in the mean (preoperative to postoperative) between relevant subgroups. If relevant differences are identified within the baseline characteristics of the different subgroups, they will be adjusted using linear regression models. Boxplots are generated for the depiction of quantitative variables. For categorical variables, the absolute and relative prevalence are calculated for the complete cohort as well as for relevant subgroups. Changes in categorical variables are evaluated using the McNemar test. The comparison of independent groups is performed by application of the $\chi^2$ and Fisher's exact test. 95% CIs are presented for the relevant sizes. The perturbance variables are adjusted using a logistic regression model. The correlation coefficients are estimated, and data are presented in a scatter plot to evaluate the context of quantitative variables. All $p$ values are two sided. The significance level is set at $p<0.05$.

## Patient and public involvement

A verbal survey prior to the study design showed that an improvement in the quality of life is reasonably intended by the majority of patients undergoing sigmoidectomy for diverticulitis and potentially matching the inclusion criteria. Therefore, quality of life was chosen as the primary outcome of this study. Patients were not directly involved in the design and recruitment of the study. All participants received written information including the ClinicalTrials.gov URL and the corresponding author's ResearchGate account, where the study results will be published.

# DISCUSSION

Patients scheduled for elective sigmoidectomy according to a 'stage-based' algorithm suffer from a wide range of symptom severities. A direct correlation between the symptom severity and the initial stage of the disease could not generally be shown. The authors presuppose that elective resection intends to improve patients' quality of life.

This assumption is based on the benign character of the disease, as well as the evidence-based knowledge of a

low risk for severe complications in recurrences, independent of the severity of the initial inflammation episode.

Presumably, patients with a disease-specific quality-of-life impairment will benefit more so than those without symptoms. To facilitate preoperative patient selection, predictors influencing postoperative quality of life should be identified to allow a forecast of changes in postoperative quality of life.

Importantly, elective surgical treatment is associated with the relevant intrinsic morbidity (9.6% major complications within the Sigma Trial), the potential need for unplanned stoma formation of 1%–14% and a significant risk of persisting postoperative complaints.[2 14–16] Up to 25% of patients who have undergone a scheduled sigmoid colectomy suffer from ongoing abdominal symptoms.[17] Levack *et al* found the risk of faecal incontinence to be 24.8% after a sigmoidectomy. Moreover, faecal urgency occurred in 19.6% of patients, and incompleteness of emptying occurred in 20.8%.[18]

Therefore, decisions regarding surgery should be made after much consideration. Since the risk of complications and unplanned emergency surgery, such as stoma formation, is not influenced by a higher number of inflammation episodes, this should not be chosen as the reason for surgical therapy.

Due to the high incidence of the disease, its socioeconomic influence is highly relevant. The authors hypothesise that the HrQoL significantly influences economic productivity and disease-specific healthcare costs. Therefore, an improved predictability of the quality of life after a surgical approach may lead to decreasing healthcare costs in affected patients.

## Availability of data and materials

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

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**Contributors** MS designed the study, is the main investigator, performed data acquisition and wrote the article together with JP. AA reviewed the study design and the article. Il reviewed the study design and planned the statistical analysis. SB performed the literature research and constructed the database. ST was involved in the study design and is a local investigator at study centre. FDC was involved in the study design, performed literature research and is a local investigator at study centre. AN, NL and EK planned the pathological analysis of the specimens and drafted the respective section of the study protocol. AH planned and reviewed the article and was responsible for native English translation. KE performed literature research and reviewed the design and the article. JP is a local investigator at study centre 2, wrote the manuscript together with MS and was involved in the study design. PS and DK are local subinvestigators at study centre 2; both reviewed the manuscript and were involved in the construction of the study protocol. All authors have read and approved the manuscript and ensured that this is the case.

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