SYSTEMATIC REVIEWS AND META-ANALYSES

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Patient-reported Outcomes After Conservative or Surgical Management of Recurrent and Chronic Complaints of Diverticulitis: Systematic Review and Meta-analysis

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BACKGROUND & AIMS: **Patients with diverticulitis develop recurrences and chronic abdominal symptoms. Recurrent diverticulitis is seldom complicated, which has led to a conservative treatment approach. However, some studies suggest that surgical intervention reduces recurrence and chronic abdominal problems. We conducted a systematic review and meta-analysis of quality of life (QOL) and other patient-reported outcomes (PROs) after conservative vs surgical treatment of uncomplicated diverticulitis.**

METHODS: **We searched the CENTRAL, MEDLINE, EMBASE, and PsycInfo databases for randomized trials and cohort studies reporting on QOL or other PROs after conservative or operative treatment for uncomplicated diverticulitis from January 1990 through May 2014. Eight PROs were defined and graded according to their clinical relevance. Risk of bias was assessed by using the Cochrane Collaboration tool. Subgroup and sensitivity analyses were performed to test the robustness of the results. The review protocol was registered through PROSPERO (CRD42013005854).**

RESULTS: **We analyzed data from 21 studies that comprised 1858 patients; all studies had a high risk of bias. There were no head-to-head comparisons of gastrointestinal symptoms or general QOL between elective surgical vs conservative treatment of recurrent diverticulitis. On the basis of Short-Form 36 scores, patients had higher QOL scores after elective laparoscopic resection (73.4; 95% confidence interval [CI], 65.7–81.1) than conservative treatment (58.1; 95% CI, 47.2–69.1). A lower proportion of patients had gastrointestinal symptoms after laparoscopic surgery (9%; 95% CI, 4%–14%) than conservative treatment (36%; 95% CI, 27%–45%) in all cohorts and in 1 trial comparing these treatments (odds ratio, 0.35; 95% CI, 0.16–0.7). The proportion of patients with chronic abdominal pain after elective laparoscopy was 11% (95% CI, 1%–21%) compared with 38% (95% CI, 19%–56%) after conservative treatment.**

CONCLUSIONS: **On the basis of a systematic review and meta-analysis, patients have better QOL and fewer symptoms after laparoscopic surgery vs conservative treatment. However, studies of PROs for treatment of diverticulitis were of low quality.**

Keywords: Colon; Complication; Drug; Therapy.

Diverticulosis coli of the sigmoid and descending colon is a common condition in Western countries. An estimated 4% of patients with diverticulosis will develop diverticulitis.[1] The number of patients with diverticulosis and diverticulitis will continue to rise as the population expands and ages.[2] Uncomplicated recurrent diverticulitis can be treated by conservative means or by surgery. Recent epidemiologic data show that recurrent episodes of diverticulitis are seldom complicated, which has led to a marked shift from surgical treatment toward conservative treatment.[3] Early results of conservative treatment are often satisfactory and avoid the risk of adverse events from elective surgery.[4] However, approximately 25% of patients suffer from additional episodes of

Abbreviations used in the paper: CGQL, Cleveland Global Quality of Life; CI, confidence interval; GRADE, Grading of Recommendation, Assessment, Development and Evaluation; PRO, patient-reported outcome; QoL, quality of life; RR, relative risk; SF-36, short-form health survey (36 items).

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diverticulitis and chronic abdominal complaints.[2,4] The incidence of recurrent and chronic complaints might be lower after surgery.[5–7] Moreover, surgery for diverticulitis has become less invasive and safer.[8] The progress in both conservative medical and surgical treatment has fuelled the discussion regarding the best treatment, particularly for recurrent diverticulitis.

Nevertheless, the patients' perspective on the risk of recurrences and persistent bowel symptoms associated with surgical or conservative treatment is seldom studied. This is surprising considering the large health burden, the recurrent and chronic character of diverticulitis, the controversy about the optimal treatment strategy associated with the treatment of recurrent diverticulitis, and the increased recognition of quality of life (QoL) and other patient-reported outcomes (PROs) as relevant clinical outcomes of medical interventions, especially in chronic disease.[3,9–11] This prompted us to undertake a systematic review and meta-analysis addressing the impact of conservative or operative treatment for diverticulitis on QoL and PROs, with emphasis on comparing conservative treatment with elective surgery in uncomplicated diverticulitis.

Materials and Methods

Search Strategy and Selection Criteria

The full research protocol and search strategy of this review were prospectively registered in PROSPERO (CRD42013005854) and can be found in the Supplementary Appendix. Two researchers (C.S.A., R.B.) searched the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, and PsycInfo databases made from January 1990 to May 25, 2014. Searches included the following MeSH descriptors: "Diverticulitis", "Diverticulitis, Colonic", ("Diverticulum" AND "Inflammation"), ("Diverticulosis, Colonic" AND "Inflammation"[Mesh]), "Quality of Life", "Health Status", "Questionnaires", "Symptom Assessment", "Defecation", "Chronic Pain", "Pain Measurement", "Faecal Incontinence", "Disability Evaluation", "Activities of Daily Living", "Return to Work", and "Satisfaction".

Studies were retrieved and selected by 2 independent reviewers (C.S.A., R.B.) in 2 rounds on the basis of the title and abstract and on the basis of the full text measured against pre-specified criteria. Randomized controlled trials and cohort studies with a minimal follow-up of 3 months were considered eligible for inclusion. We included cohorts of elective surgical treatment or conservative treatment in adult patients with a radiologically or endoscopically proven episode of diverticulitis, classified as Hinchey stage I to II or Hansen/Stock stage I to IIb and reporting on QoL or other PROs. Surgical cohorts in which staging was not reported were only included if the interval between diagnosis and surgery was at least 6 weeks to ensure that elective surgery was performed for chronic or recurrent symptoms and not surgery for complications in the acute phase. Cohorts of patients with chronical abdominal complaints but no prior episode of diverticulitis (symptomatic uncomplicated diverticular disease) were excluded (Supplementary Table 1). Studies reporting on patients with any stage of diverticulitis or colorectal surgery for a variety of indications were excluded if we could not extract results for the subgroup of patients meeting our inclusion criteria.

Data Extraction

Two reviewers (R.B., R.P.G.t.B.) extracted and checked the data. We extracted information on the study design, patient characteristics, number of participants, and outcomes reported. Any discrepancies were resolved by discussion or by a third reviewer (C.S.A.). If the dataset was incomplete, the authors were contacted by e-mail for the missing data.

Outcome measures were extracted from the literature. Eight PROs were defined and graded by clinical relevance (critical for decision-making, important for decision-making, or of limited importance), as suggested by the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) working group.[12] PROs critical for decision-making included gastrointestinal QoL (Gastrointestinal Quality of Life Index [GIQLI]) and general QoL (short-form health survey [36 items] [SF-36], European Organisation for Research and the Treatment of Cancer quality of life survey, Cleveland Global Quality of Life instrument [CGQL]). Disability (defined as an inability to perform the activities of daily living, physical activities, and the activities necessary to return to work) was also graded as critical for decision-making.

Chronic abdominal pain, fecal incontinence, and patient satisfaction were graded as PROs important for decision-making. Chronic abdominal pain was defined as the persistence of abdominal pain after 3 months of follow-up. Studies that used a visual analogue scale to score pain were included. Fecal incontinence was assessed either on a fecal incontinence scale or by the percentage of patients who complained of incontinence. Patient satisfaction was assessed either by a satisfaction score or as the percentage of patients expressing good to excellent satisfaction with the treatment.

PROs of limited clinical relevance were persistent bowel symptoms (ie, hypogastric pain or bloating, diarrhea, constipation, flatulence, painful defecation, and rectal bleeding) and urogenital symptoms (ie, erectile dysfunction, ejaculation difficulties, diminished libido, and urinary and sexual dysfunction) (Table 1, Supplementary Appendix Section C).

Risk of Bias Assessment

Two reviewers (C.S.A., R.B.) independently assessed the methodological quality of articles. Any discrepancies

Table 1. Summary of Main Findings of Direct Comparison of PROs Between Surgical and Conservative Treatment Cohorts

Outcome (references)	GRADE	Elective surgery	Conservative treatment	Difference	*P* value
Gastrointestinal-related QOL	⊕⊕⊕				
GICLI score (mean difference ± 95% CI)		NA	NA	NA	NA
General QOL	⊕⊕⊕				
SF-36 (mean difference ± 95% CI)		NA	NA	NA	NA
CGQL (mean difference ± 95% CI)		NA	NA	NA	NA
Disability	⊕⊕⊕				
Prevalence		NA	NA	NA	NA
Chronic abdominal pain[18]	⊕⊕				
Prevalence, RR (95% CI)		4/36 (11%)	6/52 (11%)	0.96 (0.29–3.17)	.95
Fecal incontinence	⊕⊕				
Prevalence		NA	NA	NA	NA
Satisfaction	⊕⊕				
Prevalence		NA	NA	NA	NA
Gastrointestinal symptoms[5]	⊕				
Overall, RR (95% CI)		10/113 (9%)	10/40 (25%)	0.35 (0.16–0.79)	.01
Constipation, RR (95% CI)		10/113 (9%)	10/40 (25%)	0.35 (0.16–0.79)	.01
Diarrhea, RR (95% CI)		4/113 (4%)	5/40 (13%)	0.28 (0.08–1.00)	.05
Flatulence, RR (95% CI)		10/113 (9%)	10/40 (25%)	0.35 (0.16–0.79)	.01
Painful defecation, RR (95% CI)		10/113 (9%)	9/40 (23%)	0.39 (0.17–0.90)	.03
Bloating, RR (95% CI)		5/113 (4%)	9/40 (23%)	0.28 (0.07-0.55)	.01
Urogenital symptoms	⊕				
Prevalence		NA	NA	NA	NA

NA, not available.

were resolved by discussion or a third reviewer (R.P.G.t.B.). The Cochrane Collaboration's tool for the assessment of bias risk was used to assess the risk of systematic error.[13] Seven components associated with the risk of bias were assessed: the generation of the allocation sequence, the allocation concealment, the blinding of participants, the masking of outcome assessors, selective outcome reporting, incomplete follow-up, and other potential sources of bias. The incomplete follow-up component was considered adequate if fewer than 10% of the patients were lost to follow-up and a description of the loss was provided. Trials in which 1 or more of the 7 components had a high score or were unclear were defined as having a high risk of bias. Heterogeneity among baseline characteristics, clinically suspected diverticulitis without radiologic confirmation, and premature trial stoppage were considered as other biases.

Data Analysis and Presentation

The inverse variance method for the pooling of prevalence and continuous data was used. The Mantel-Haenszel method was applied for the pooling of dichotomous data, and the results were presented as the relative risk (RR) with 95% confidence interval (CI). A *P* value $<.05$ was considered statistically significant. Heterogeneity was explored by using I^2 tests, as recommended by the Cochrane Handbook for Systematic Reviews of Intervention. An I^2 value between 50% and 75% was defined as substantial heterogeneity, and an I^2 value of 75% was defined as considerable heterogeneity. A fixed-effect model was applied for the meta-analysis. In the presence of significant statistical heterogeneity, a random-effects model was used. Data were analyzed by using Review Manager 5.0 (Review Manager [RevMan] [Computer program] Version 5.1; The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, 2011) and R version 2.12.0.

Of primary relevance were the results of meta-analyzing studies comparing elective surgery with conservative treatment. Secondary were the results of all cohorts of elective surgery and conservative treatment. In addition, we analyzed the results from studies with laparoscopic or open surgery. The impact of incomplete data was explored through sensitivity analyses by using the standard deviation imputed from *P* values according to the algorithms in the Cochrane Handbook. The median was used when the mean was not available. If it was not possible to calculate the standard deviation from the *P* value or the CI, the standard deviation was imputed as the highest standard deviation noted for the group and outcome in question.

Subgroup analyses were performed for the study type (trials with low risk of bias vs trials with high risk of bias), the treatment type (conservative, elective laparoscopic surgery, elective open surgery), and the diverticulitis type (first episode vs recurrent disease).

We followed both the Meta-analysis of Observational Studies in Epidemiology and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines in reporting the results.

Results

Search Results

After deduplication, 1306 studies were identified by our searches. The manual review of the references, gray literature, and trial registers identified an additional 275 records for evaluation. We excluded 1491 studies by title and abstract screening and 69 after full-text review. Twenty-one studies were included for systematic review, with a total of 1858 patients.[4–8,14–29] Five studies were excluded from meta-analysis either for using invalidated symptom scores[16,26] or for incomplete outcome data[15,29,30] (Figure 1).

Characteristics and Quality Assessment of the Selected Studies

Supplementary Table 1 shows descriptive data for the 21 studies. Medical treatment consisted of supportive care, antibiotics for flares of diverticulitis only, and anti-inflammatory agents in combination with a poorly absorbed antibiotic (mesalazine and rifaximin). Elective surgery was generally performed at least 3 months after the last episode of diverticulitis.

All studies had a high risk of bias (Table 2, Supplementary Appendix Section C). Bias was predominantly found on the domains: blinding of outcome assessor, allocation sequence, allocation concealment, and selective reporting. The 8 predefined PROs were distributed unevenly among the studies. Table 2 summarizes the main findings for each outcome measure, sorted by treatment modality.

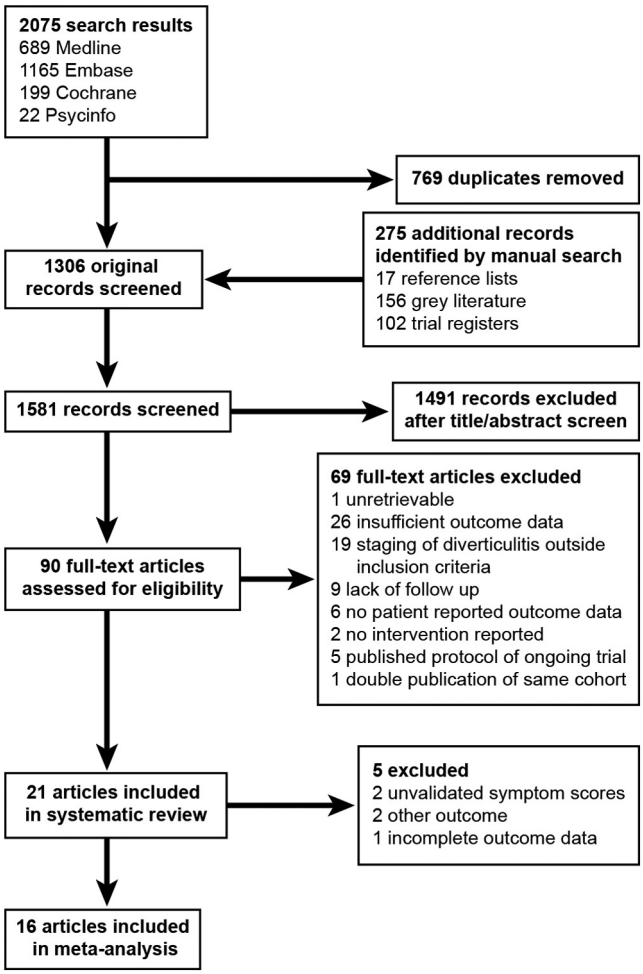

Figure 1. Study selection.

Results of Direct Comparison of Studies of Elective Surgery vs Conservative Treatment

There were no studies with direct comparison of elective surgery and conservative treatment on outcomes critical for decision-making, ie, gastrointestinal QoL, general QoL, and disability. Of outcomes important for decision-making, only chronic abdominal pain was compared between elective surgery and conservative treatment in 1 study including 36 operated and 52 conservatively treated patients, demonstrating no differences in incidences (RR, 0.96; 95% CI, 0.29–3.17).[18] Overall gastrointestinal symptoms and several subtypes of gastrointestinal complaints were compared in 1 study including 113 operatively and 40 conservatively treated patients.[5] The prevalence of gastrointestinal symptoms was lower after surgery compared with conservative treatment (RR, 0.35; 95% CI, 0.16–0.79) (Table 1, Figure 2).

Results of Non-comparative Cohort Studies of Elective Surgery and Conservative Treatment

The mean overall gastrointestinal QoL as measured by GIQLI score was 114 (95% CI, 111–116) in 2 cohorts of elective laparoscopic surgery.[6,7] Gastrointestinal QoL was not studied in open surgery or conservatively treated cohorts. The mean general QoL as measured by SF-36 was significantly higher in 1 cohort of laparoscopic surgery (73.4; 95% CI, 65.7–81.1) compared with 1 cohort of conservative treatment (58.2; 95% CI, 47.2–69.1); the difference with open surgery was not significant (67.4; 95% CI, 59.9–74.9) (Figure 3).[8,20–22] Disability was not reported. Prevalence of chronic abdominal pain was 11% (95% CI, 1%–21%) in 1 cohort of laparoscopic surgery including 113 patients[18] compared with 38% (95% CI, 19%–56%) in 4 cohorts of conservative treatment including 745 patients, but this difference was not significant.[4,18,23,27] Prevalence of fecal incontinence and satisfaction were reported in 1 surgical cohort. Overall prevalence of fecal incontinence after elective laparoscopic surgery was 11% (95% CI, 5%–16%).[5] Satisfaction with both surgical and conservative treatment was high, 95% (95% CI, 91%–98%) in 2

Table 2. Summary of Main Finding per Outcome in Non-comparative Studies Sorted by Treatment Modality

Outcome	GRADE	Overall	Elective laparoscopic surgery	Elective open surgery	Conservative treatment
Gastrointestinal-related QoL	⊕⊕⊕	2 studies,[6,7] n = 160	2 studies,[6,7] n = 160	NA	NA
GIQLI score (mean ± 95% CI)		114 (111–116)	114 (111–116)		
General QoL	⊕⊕⊕	3 studies,[8,20–22] n = 93	1 study,[8] n = 29	1 study,[8] n= 35	2 studies,[20–22] n = 58
SF-36 (mean ± 95% CI)		66.2 (60.0–72.4)	73.4 (65.7–81.1)	67.4 (59.9–74.9)	58.1 (47.2–69.1)
CGQL (mean ± 95% CI)[a]		73.0 (68.7–77.3)	NA	NA	73.0 (68.7–77.3)
Disability	⊕⊕⊕	NA	NA	NA	NA
Chronic abdominal pain	⊕⊕	4 studies,[4,18,23,27] n = 781	1 study,[18] n = 36	NA	4 studies,[4,18,23,27] n = 745
Prevalence, % (95% CI)		38 (18–57)	11 (1–21)		38 (19–56)
Fecal incontinence	⊕⊕	1 study,[5] n = 113	1 study,[5] n = 113	NA	NA
Prevalence, % (95% CI)		11.0 (5–16)	11.0 (5–16)		
Satisfaction	⊕⊕	3 studies,[7,17,29] n = 187	2 studies,[7,17] n = 163	NA	1 study,[29] n = 24
Prevalence, % (95% CI)		95 (92–98)	95 (91–98)		95 (88–100)
Gastrointestinal symptoms	⊕	7 studies,[5,21–25,27,28] n = 1197	1 study,[5] n = 113		7 studies,[5,21–25,27,28] n = 1084
Overall, % (95% CI)		33 (18–47)	9 (4–14)	NA	36 (27–45)
Constipation, % (95% CI)		13 (8–18)	9 (4–14)		25 (12–38)
Diarrhea, % (95% CI)		9 (0–18)	4 (0–7)		18 (10–26)
Urogenital symptoms	⊕	1 study,[5] n = 113	1 study,[5] n = 113	NA	NA
Ejaculation difficulties, % (95% CI)		3 (0–4)	3 (0–4)		
Urinary dysfunction, % (95% CI)		9 (4–14)	9 (4–14)		

[a]As percentage of maximum score (10).

cohorts of laparoscopic surgery[7,17] and 95% (88%–100%) in 1 cohort of conservative treatment.[29] Overall incidence of gastrointestinal symptoms was 9% (95% CI, 4%–14%) in 1 cohort of laparoscopic surgery[5] and significantly lower compared with 36% (95% CI, 27%–45%) in 7 cohorts of conservative treatment.[5,21–25,27,28] Prevalence of urogenital symptoms was only reported in 1 cohort of elective laparoscopic surgery including 113 patients.[5] Prevalence of ejaculation difficulties was 3% (95% CI, 0%–7%), and prevalence of urinary and sexual dysfunction was 9% (95% CI, 4%–14%) (Table 2).

Subgroup Analysis and Sensitivity Analyses

None of the sensitivity or subgroup analyses significantly changed the results for any outcome (Supplementary Appendix).

Discussion

Summary of Results

QoL and other PRO for treatment of diverticulitis have been poorly investigated. All studies had a high risk

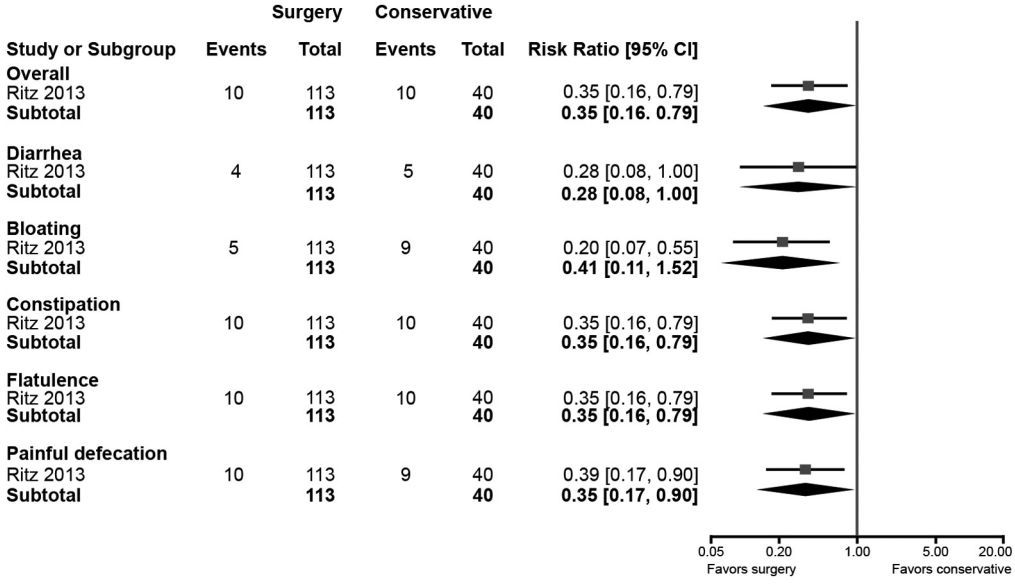

Figure 2. Direct comparison of incidence of gastrointestinal symptoms between surgical and conservative treatment cohorts.

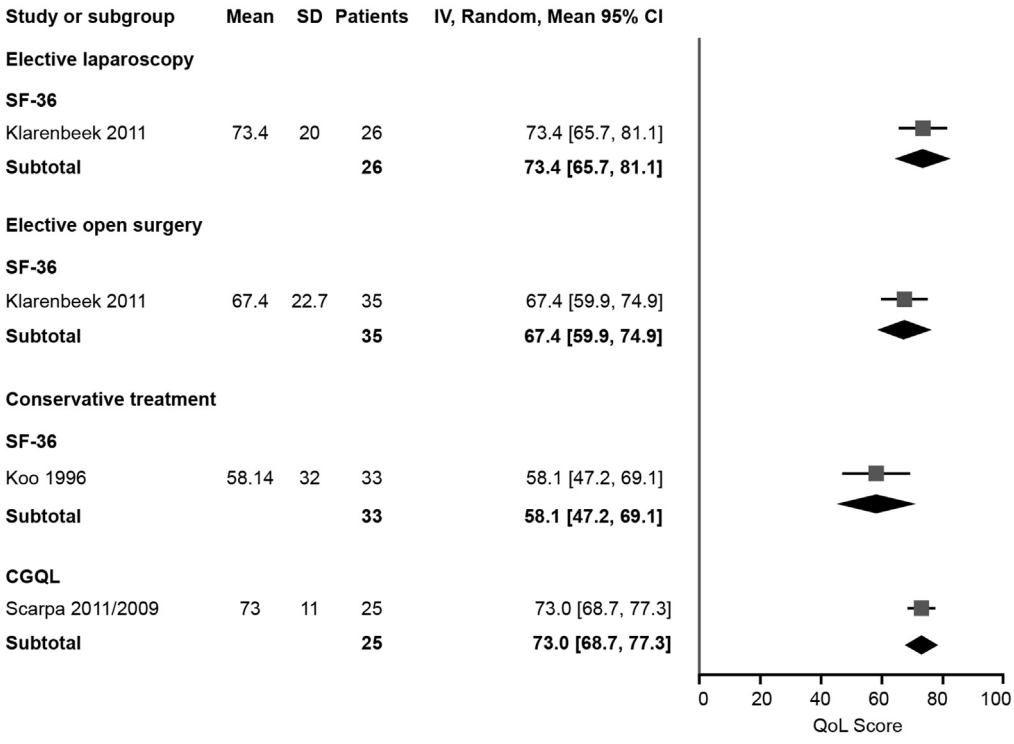

Figure 3. General QoL in non-comparative studies sorted by treatment modality. SD, standard deviation.

of bias, and most comparative studies were underpowered for comparison between different treatment modalities. In 1 comparative study a significant difference in the prevalence of gastrointestinal symptoms (which was graded of limited clinical importance) was found to favor surgical treatment. Summarizing the results of all cohort studies, general QoL was higher after elective laparoscopic surgery. However, this outcome was not assessed in direct comparison of studies, and the included studies had significant risk of bias. These results indicate that elective surgery might be beneficial for selected patient groups, but good quality data from well-designed studies are lacking.

Comparison With Other Studies and Clinical Implications

In patients with recurrent diverticulitis or persistent abdominal complaints, the need to operate and the timing of surgery are subjects of debate. The standard was to perform elective colectomy after 2 episodes of diverticulitis to prevent future complicated diverticulitis. Recent data show that recurrent cases are seldom complicated, which questions the need for prophylactic surgery also when taking into account the risk of morbidity and mortality associated with surgery.[5,31,32] As a consequence, the rate of elective surgery for recurrent episodes of diverticulitis has declined, even though the current guidelines leave room for surgical treatment to improve QoL.[33,34]

Today, physicians and surgeons tend toward conservative treatment to avoid early morbidity and need for colostomy associated with colonic resection. However, the patient's perspective on the outcome of treatment may differ from that of physicians. In a meta-analysis of trials with QoL outcomes, almost 1 in 3 trials had discordant results when comparing SF-36 results with those of the primary early outcome.[35] Therefore, the decision between surgery and conservative treatment need not only account for early morbidity and chance of stoma formation but also for long-term QoL and functional outcome of the individual patient.

Unfortunately, the impact of surgical and conservative treatment on QoL and PROs has thus far been studied very poorly. Such studies are needed to individualize the treatment approach of patients with diverticulitis. In this meta-analysis several different instruments for measuring QoL were compared. Questionnaires of general QoL such as the SF-36 and CGQL but also the gastrointestinal-related GIQLI questionnaire have the benefits of being validated instruments for measurement of QoL for use in different countries, languages, and diseases,[36–39] but they are also criticized because the typical symptoms of the lower digestive tracts are masked in these questionnaires.[40] Furthermore, by measuring general symptoms, larger sample sizes in studies are needed to reach sufficient power. Hence, we believe that the overall QoL and performance are what should determine the choice of treatment. Therefore, we defined these as the outcomes critical for decision-making.

Although the data we found were of limited quality, the tendency of a higher general QoL and significant improvement of gastrointestinal symptoms associated with laparoscopy might plea for a less conservative

approach to recurrent diverticulitis. Especially in young patients, bowel symptoms might have strong social implications, and the risk of recurrence is high, whereas they have a relatively low risk of surgical complications.[2] Furthermore, results of surgery have greatly improved in terms of early morbidity and complications since the introduction of laparoscopic surgery.[41,42] In the largest cohort of 500 laparoscopic resections for diverticulitis, conversion rate was 2.8%, incidence of anastomotic leakage was 1.4%, and overall mortality was 0.2%.[43]

Strengths and Limitations of the Study

This systematic review assessed the effects of different treatment modalities on QoL and PROs in patients with diverticulitis. A relatively large number of studies were included on the basis of an extensive literature search of different databases. The analysis of gray literature and trial registers did not reveal publication bias, and results were robust in sensitivity and subgroup analyses. This review uses the GRADE system for ranking outcomes.

Selection bias within the studies could not be excluded. Bias in selecting patients with recurrent diverticulitis for surgery and patients with functional bowel symptoms that resemble diverticulitis for a conservative treatment might explain the better outcome in general QoL in the laparoscopic surgery cohorts. The exclusion of studies conducted before 1990 may have introduced a bias, although we believe that older studies would have provided data not reflecting the current practice of laparoscopic surgery and 1-stage or 2-stage open surgery for complicated diverticulitis.

Conclusions

The available evidence on QoL and PROs in patients treated for diverticulitis is limited and of poor scientific quality. Heterogeneity among the existing studies is substantial, impeding strong conclusions on best treatment. Elective laparoscopic surgery might have benefits in terms of general QoL and gastrointestinal symptoms compared with conservative treatment in patients with disabling chronic complaints or recurrent diverticulitis. Treatment decisions should be made on an individualized basis accounting for operative risks, patient preferences, and QoL. High-quality trials focusing on PROs and QoL with well-defined patient populations of diverticulitis are needed.

Supplementary Material

Note: to access the supplementary materials accompanying this article, visit the online version of *Clinical Gastroenterology and Hepatology* at www.cghjournal.org, and at http://dx.doi.org/10.1016/j.cgh.2015.08.020.

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Conflicts of interest
The authors disclose no conflicts.