Original article

Population-based trend analysis of 2813 patients undergoing laparoscopic sigmoid resection

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Background: The use of laparoscopic sigmoid resection for diverticular disease has become increasingly popular. The objective of this trend analysis was to assess whether clinical outcomes following laparoscopic sigmoid resection for diverticular disease have improved over the past 10 years.

Methods: The analysis was based on the prospective database of the Swiss Association of Laparoscopic and Thoracoscopic Surgery. Some 2813 patients undergoing elective laparoscopic sigmoid resection for diverticular disease from 1995 to 2006 were included. Unadjusted and risk-adjusted analyses were performed.

Results: Over time, there was a significant reduction in the conversion rate (from 27·3 to 8·6 per cent; $P_{trend} < 0·001$), local postoperative complication rate (23·6 to 6·2 per cent; $P_{trend} = 0·004$), general postoperative complication rate (14·6 to 4·9 per cent; $P_{trend} = 0·024$) and reoperation rate (5·5 to 0·6 per cent; $P_{trend} = 0·015$). Postoperative median length of hospital stay significantly decreased from 11 to 7 days ($P_{trend} < 0·001$).

Conclusion: This first trend analysis in the literature of clinical outcomes after laparoscopic sigmoid resection, based on almost 3000 patients, has provided compelling evidence that rates of postoperative complications, conversion and reoperation, and length of hospital stay have decreased significantly over the past 10 years.

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Introduction

Sigmoid diverticular disease represents one of the most frequent colonic pathologies in North America and Europe, affecting approximately one-third of the population above the age of 45 years and two-thirds of persons older than 85 years[1,2]. The high prevalence of diverticular disease has an important public health impact with over 200 000 hospitalizations per annum[3]. Less than 20 years ago the only treatment for patients with recurrent episodes of acute diverticulitis was open sigmoid resection, but the advent of laparoscopy has revolutionized colonic surgery for diverticular disease. Some of the first described laparoscopic colonic resections were performed in 1991 by Fowler and White[4]. Over the past decade, the use of laparoscopic colonic surgery has become increasingly popular and is now considered the standard of care in many centres. Several high-quality studies have demonstrated significant advantages for laparoscopic colonic resection over the conventional open procedure[5–8].

Despite the compelling evidence favouring laparoscopic resection of diverticular disease, the majority of these studies included primarily surgeons with specialized expertise in laparoscopic surgery. The impact of introducing this new technology at a population-based level, with surgeons who lack subspecialty training in laparoscopy, is less clear. This is of particular importance given the history of laparoscopic cholecystectomy introduction; after marked enthusiasm by surgeons with little or no training in this

procedure, the prevalence of complications rose rapidly over several years[9].

With the introduction of a new technology, surgeons, researchers and health policy makers must rigorously examine the trends in important outcomes over time to ensure that the technology is being applied safely and effectively. To the authors' knowledge, a large, rigorous, population-based trend analysis of clinical outcomes following laparoscopic sigmoid resection has not been performed. The objective of the present trend analysis, based on a large national prospective cohort, was to assess whether clinical outcomes of laparoscopic sigmoid resection for diverticular disease have improved over the past 10 years.

Methods

This analysis utilized the database of the Swiss Association of Laparoscopic and Thoracoscopic Surgery (SALTS), a prospective database of consecutive patients undergoing laparoscopic procedures in Switzerland. Overall, 73 hospitals participated; 56 (77 per cent) were teaching hospitals and 17 (23 per cent) non-teaching private hospitals. This database is complete, although only about two-thirds of Swiss surgeons enrol their patients undergoing a laparoscopic procedure[10].

All patients with diverticular disease undergoing an elective laparoscopic sigmoid resection or a laparoscopic resection that was converted to an open procedure between 1995 and 2006 were included in the present analysis. Patients were excluded from the analysis if they: underwent sigmoid resection for a malignancy or any diagnosis other than diverticular disease; underwent any colonic resection other than sigmoidectomy; underwent a primary open colonic resection; or did not undergo an operation with primary anastomosis (for example, Hartmann's procedure).

All data were collected prospectively and entered in the centralized database (Qualicare®; Qualidoc, Liebefeld-Bern, Switzerland) by a data manager, independently from the study authors. Any values missing on the datasheet were obtained by the data manager.

Baseline demographic data were extracted as well as data regarding the following clinical outcomes: conversion rate; intraoperative complications; surgical postoperative complications (for example, wound infection, wound haematoma, anastomotic insufficiency); general postoperative complications (such as pneumonia, urinary tract infection, pulmonary embolism); rates of reoperation; mortality; and postoperative length of hospital stay.

Statistical analysis

An experienced statistician (LR) with particular interest in population-based outcomes research performed all statistical computations. Rates and median values of

Table 1 Intraoperative complications, 1995–2006

	No. of complications
Inadvertent puncture of stomach/intestine	4
Inadvertent puncture of bladder	1
Inadvertent puncture of blood vessels	4
Inadvertent puncture of solid organs	1
Inadvertent trocar lesion	4
Haematoma/bleeding abdominal wall	2
Intra-abdominal bleeding	26
Haematoma/bleeding requiring transfusion	9
Solid organ lesion	24
Problems with equipment	71
Anaesthetic problems	16
Lack of exposure/vision	76
Other	90
Total	328

Table 2 Surgical postoperative complications, 1995–2006

	No. of complications
Haematoma/bleeding abdominal wall	32
Intra-abdominal bleeding	40
Haematoma/bleeding requiring transfusion	27
Wound infection	63
Abscess	20
Peritonitis	10
Anastomotic insufficiency	70
Stenosis	1
Perforation	5
Prolonged paralytic ileus	19
Obstructive ileus	10
Neurological complication	2
Other	33
Total	332

Table 3 General postoperative complications, 1995–2006

	No. of complications
Pneumonia	41
Cardiac complication	21
Deep venous thrombosis	2
Pulmonary embolism	12
Myocardial infarction	1
Positioning injury	3
Urinary tract infection	34
Other	70
Total	184

outcomes were tested for changes over time using χ^2 tests for trend for rates and generalized linear models for continuous outcomes. For the adjusted analyses, rates were modelled using a Poisson regression model that included age, American Society of Anesthesiologists (ASA) fitness scores, sex and year to ascertain whether significant differences were observed over time after adjusting for the variables in the model. For intraoperative, surgical

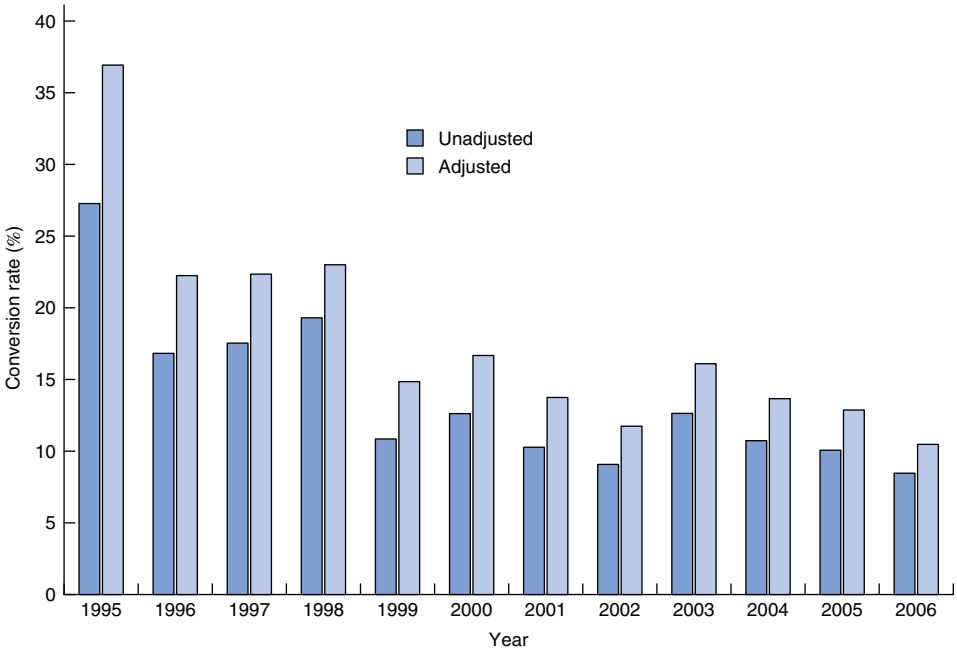

Fig. 1 Unadjusted and risk-adjusted conversion rate, 1995–2006 ($P_{trend} < 0{\cdot}001$)

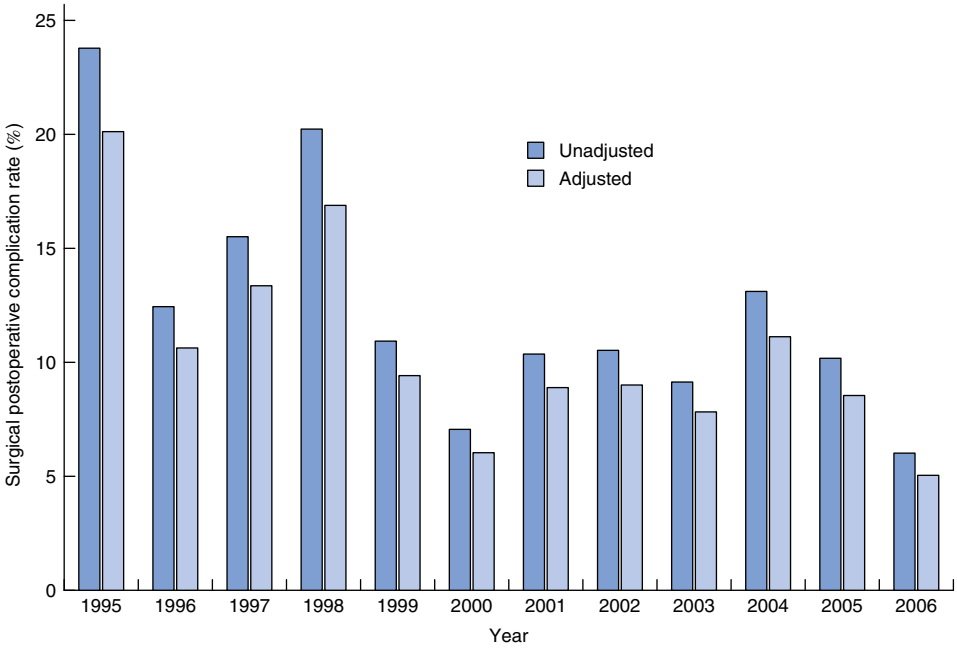

Fig. 2 Unadjusted and risk-adjusted surgical postoperative complication rate, 1995–2006 ($P_{trend} = 0{\cdot}004$)

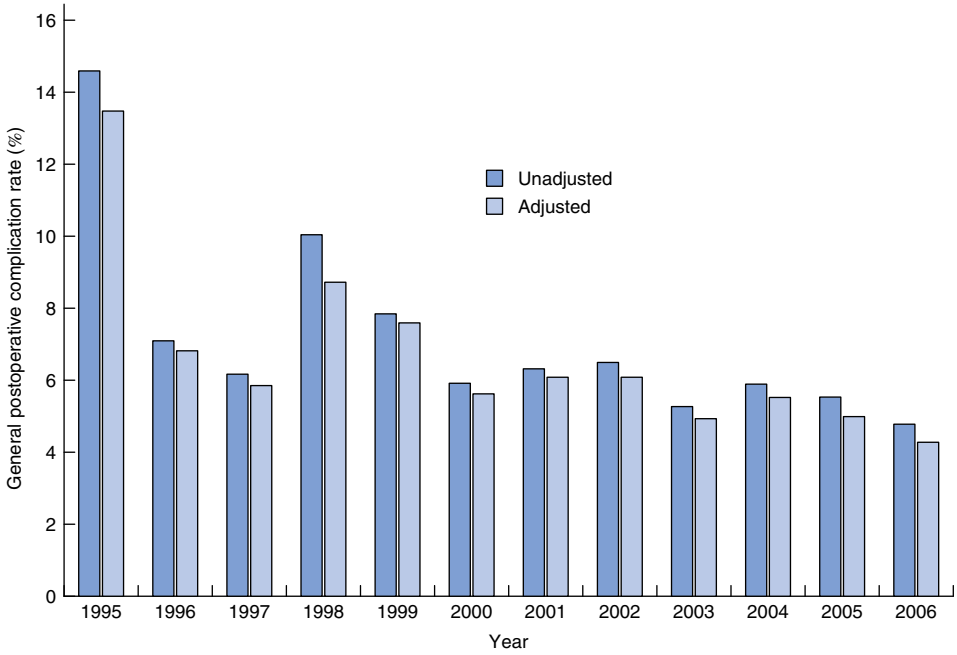

Fig. 3 Unadjusted and risk-adjusted rate of general postoperative complications, 1995–2006 ($P_{trend} = 0{\cdot}024$)

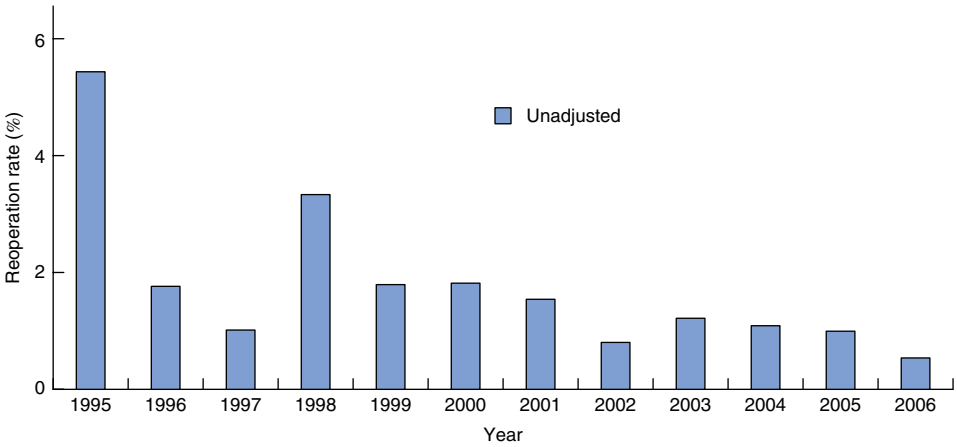

Fig. 4 Unadjusted reoperation rate, 1995–2006 ($P_{trend} = 0{\cdot}015$)

postoperative and general postoperative complications, the event of the multivariable analyses for each outcome was defined as the presence of one or more complications.

No risk-adjusted analyses were performed for the outcome 'mortality' or 'reoperation rate' as these occurred rarely (low event rate) and multivariable analysis would have been methodologically suboptimal. A significance level of $\alpha = 0{\cdot}050$ was used for all tests. All P values were two sided. All statistical analyses were performed with SAS® statistical software version 9.1 (SAS Institute, Cary, North Carolina, USA).

Results

Between 1995 and 2006, 2813 patients undergoing elective laparoscopic sigmoid resection were enrolled in the study. The median age at the time of the procedure was 60 (range 23–97) years and 58·2 per cent of patients were women. The median ASA score was 2 (range 1–4).

The following results represent the median value of the yearly average of different outcomes over the 12-year interval. The median postoperative hospital stay was 8 (range 1–90) days; the median rate of intraoperative, surgical

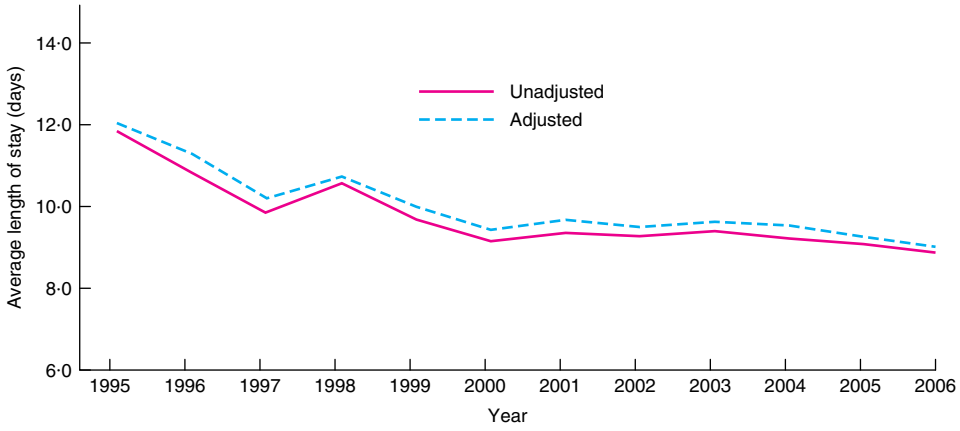

Fig. 5 Unadjusted and risk-adjusted postoperative length of hospital stay, 1995–2006 ($P_{trend} < 0{\cdot}001$)

postoperative and general postoperative complications was 9·2, 10·8 and 6·3 per cent respectively; the median rate of conversion was 11·8 per cent; and the median reoperation rate was 1·4 per cent. The overall mortality rate was 0·1 per cent (four of 2813 patients).

The frequency of intraoperative, surgical postoperative and general postoperative complications are summarized in *Tables 1–3*. The rates of both unadjusted and adjusted outcomes for each year are displayed in *Figs 1–5*.

Over time, the conversion rate significantly decreased from 27·3 to 8·6 per cent ($P_{trend} < 0{\cdot}001$), the surgical postoperative complication rate from 23·6 to 6·2 per cent ($P_{trend} = 0{\cdot}004$), the general postoperative complication rate from 14·6 to 4·9 per cent ($P_{trend} = 0{\cdot}024$) and the reoperation rate from 5·5 to 0·6 per cent ($P_{trend} = 0{\cdot}015$). The median postoperative length of hospital stay significantly decreased over time, from 11 to 7 days ($P_{trend} < 0{\cdot}001$). The rate of intraoperative complications did not change significantly over time ($P = 0{\cdot}783$).

There was no significant change over time with respect to surgeons' experience (data not shown).

Discussion

This population-based analysis of 2813 patients undergoing elective laparoscopic sigmoid resection provides clear evidence that rates of postoperative complications, conversion and reoperation, and length of hospital stay have significantly decreased over the past 10 years. To the authors' knowledge, this is the first trend analysis of outcomes following laparoscopic sigmoid resection for diverticular disease.

Several studies have been performed over the past decade comparing laparoscopic and open sigmoid resection for diverticular disease[5,7,11–14]. These studies suggest numerous perioperative advantages for the laparoscopic procedure, including less blood loss, lower rates of major and minor complications, reduced pain and shorter length of hospital stay.

Only one randomized controlled trial (RCT) has been conducted to compare laparoscopic and open sigmoid resections for diverticulitis, with only the short-term outcomes reported so far[5]. In this trial, the conversion rate was 19·2 per cent and the laparoscopic procedure significantly reduced the rate of major complications from 25·0 to 9·6 per cent.

Although RCTs represent the optimal study design for comparing the efficacy of two interventions, they suffer from important limitations that may make a new technology appear better than it actually is. Patients enrolled in prospective studies tend to be healthier, and more committed to their healthcare than patients in the general population[15,16]. Furthermore, surgeons who participate in trials likely have a special interest and expertise in the interventions being studied. For these reasons it is imperative to confirm the findings of RCTs in large population-based studies that include all patients undergoing the intervention and all surgeons administering the intervention. It is also critical to assess the uptake of new surgical procedures among general surgeons, to ensure that complications do not increase over time as new surgeons begin performing these operations. The lack of rigorous oversight may have contributed to the significant increase in major complications seen in patients undergoing laparoscopic cholecystectomy during the uptake of the procedure[9].

The present investigation adds to the current literature and demonstrates that several relevant outcomes have improved over the past 10 years. Among the most important findings of this study was the significant decrease

in the conversion rate, from 27·3 to 8·6 per cent. This difference is not only highly statistically significant but also of great clinical relevance. This result can most likely be attributed to surgeons' learning curves, which have been estimated to plateau at between 40 and 80 laparoscopic sigmoid resections[17–19].

The median postoperative length of hospital stay decreased from 11 days in 1995 to 7 days in 2006, with a significant *P* value for trend. The duration of hospital stay in the early years of the investigation seems long; however, it must be emphasized that this was before the advent of fast-track surgery[20,21]. After laparoscopic sigmoid resection during the early years of the study interval, patients were often not permitted to eat for several days, and aggressive feeding was seen as potentially hazardous.

The present analysis demonstrates that laparoscopic sigmoid resection is a safe procedure. The mortality rate was low, with only four perioperative deaths over the entire study period. The rate of reoperation was also low, with a median of 1·4 per cent, and is within the range of published data[11–14].

As there was no significant change over time with respect to surgeons' experience, part of the improvement in clinical outcomes described here was certainly due to better equipment, such as the advent of the harmonic scalpel. Moreover, although surgeons' experience did not change over time, overall knowledge and experience regarding laparoscopic sigmoid resection and associated potential complications and pitfalls did increase during the study interval. This may be the driving factor for improved patient outcomes.

Ongoing surveillance of quality measures is critical as more surgeons begin performing laparoscopic colonic surgery routinely. Between 2000 and 2004, the proportion of laparoscopic colonic resections performed for benign disease in a large USA-based analysis increased from 4·6 to 8·2 per cent[22]. Although this was found to be a significant increase, it still represented only a minority of the total operations for benign conditions. Laparoscopic colonic resections are more likely to be performed in teaching and urban hospitals, and by high-volume surgeons[22,23]. This disparity, coupled with the strong evidence that surgeons with more experience in laparoscopic sigmoid colectomy achieve better outcomes, provides justification for careful monitoring[24,25].

This study was most limited by the lack of long-term data. For instance, from this database the authors were unable to ascertain the incidence of trocar hernias or small bowel adhesions. Further research is needed to assess the long-term advantages and potential drawbacks of the laparoscopic approach to sigmoid resection, and how these are changing over time. Second, although risk adjustment of the outcomes was performed for a variety of potential confounders, including age, sex and co-morbidity, no risk adjustment was possible for Hinchey stage. However, the vast majority of patients with Hinchey stage III and IV disease underwent emergency surgery and were excluded from the present investigation. Finally, it would be interesting to assess similar clinical outcomes for elective open colectomy for diverticular disease in Switzerland from 1995 to 2006. However, the prospective database used for this investigation (SALTS) does exclusively contain laparoscopic procedures and the authors are thus unable to provide such data.

There were several strengths to the study. First, the sample size was large and the statistical power to detect clinically relevant differences high. Second, the data, which were gathered prospectively, were complete. Third, the study was population based and thus had excellent generalizability. Although the study was based on Swiss patients only, the authors believe that the results can be generalized to all countries where the standard of laparoscopic surgery is high. Finally, and most importantly, this is the first trend analysis assessing clinical outcomes after laparoscopic colonic surgery over time.

This study has provided compelling evidence that postoperative complication, conversion and reoperation rates, and length of hospital stay, have decreased significantly over the past 10 years. Clearly, important patient outcomes after laparoscopic sigmoid resection for diverticular disease have much improved over time.

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