

Risk of surgery for inflammatory bowel disease: record linkage studies

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This month's paper

"Mortality in patients with and without colectomy admitted to hospital for ulcerative colitis and Crohn's disease: record linkage studies" by Stephen E Roberts and colleagues (*BMJ* 2007;335:1033-6; doi: 10.1136/bmj.39345.714039.55).

Abstract

Objective—To compare mortality outcomes in the three years after elective colectomy, no colectomy, and emergency colectomy among people admitted to hospital for inflammatory bowel disease, to inform whether the threshold for elective colectomy in clinical practice is appropriate.

Design—Record linkage studies.

Setting—Oxford region (1968-99) and England (1998-2003).

Participants—23 464 people with hospital stay for more than three days for inflammatory bowel disease, including 5480 who had colectomy.

Main outcome measures—Case fatality, relative

survival, and standardised mortality ratios.

Results—In the Oxford region, three year mortality was lower after elective colectomy than after either no colectomy or emergency colectomy, although this was not significant. For England, mortality three years after elective colectomy for ulcerative colitis (3.7%) and Crohn's disease (3.3%) was significantly lower than that after either admission without colectomy (13.6% and 10.1%; both $P < 0.001$) or emergency colectomy (13.2% and 9.9%; $P < 0.001$ for colitis and $P < 0.01$ for Crohn's disease). Three or more months after elective colectomy, mortality was similar to that in the general population. Adjustment for comorbidity did not affect the findings.

Conclusions—In England, the clinical threshold for elective colectomy in people with inflammatory bowel disease may be too high. Further research is now required to establish the threshold criteria and optimal timing of elective surgery for people with poorly controlled inflammatory bowel disease.

Inflammatory bowel disease, which includes Crohn's disease and ulcerative colitis, is a debilitating and sometimes life threatening disease that affects about 250 000 people in the United Kingdom. Since the 1950s Crohn's disease has become more common. Each year 2000 colectomies are performed to treat inflammatory bowel disease, with varying risk depending on the cause of the disease. Colectomy carried out as an emergency measure also carries more risk than elective colectomy surgery, at least in the short term. Currently in the UK, elective colectomy is carried out on about 40% of patients who are admitted to hospital with a severe attack of ulcerative colitis.

Given the risk associated with emergency colectomy, the authors wanted to compare the risk associated with treating inflammatory bowel disease with elective surgery, emergency surgery, or no surgery, to see if the current threshold for elective surgery is optimal. Some studies have looked at this already but have used small numbers of patients and looked at only the short term risk immediately after surgery. In this study, the authors wanted to improve the evidence by looking at many more patients with inflammatory bowel disease drawn from the general population over a longer period.

What did the authors do?

To look at large numbers of patients the authors used a record linkage method, which means that they linked different existing records about patients' health from different sources. By using records about the same patients from different times the authors could look at changes in patients' health over time: so in this case the record linkage provided longitudinal data. The records used were routine National Health Service data

recorded from hospital admissions (hospital discharge abstracts), which the authors linked to mortality data from the Office for National Statistics for each patient.

The records covered the general population of one region of England (Oxford) from 1968 to 2000; a larger dataset for the whole of England compiled later covered the period 1998 to 2000. All patients who lived in these areas during the periods covered by the records, and who were admitted to hospital with inflammatory bowel disease, were included in the study. Some of the patients were admitted to hospital on an elective basis and subsequently had surgery, and for this study these patients were categorised as having had elective surgery. Other patients were admitted to hospital as an emergency and then received surgery; they were classed as having had emergency surgery. Other patients left hospital without having surgery.

For each patient admitted to hospital, their survival during the three years after admission was checked using the linked mortality data from the Office for National Statistics. In total, 23 464 patients were included in the study, 5480 of who underwent elective or emergency colectomy. Using large numbers of patients drawn from the general population means the data can be described as "population based." This is an advantage of the study because it means the findings are likely to apply to all patients with inflammatory bowel disease in the areas covered by the records and so are highly generalisable.

Observational methods

This study uses an observational methodology because the authors used existing data that would be recorded anyway. There was no intervention as such because the authors did not change the usual care of patients

for the study. Instead they looked at what happened to patients after the normal course of treatment. Observational data from record linkage makes it relatively easy to study large numbers of participants. Another advantage is that the authors can follow up patients over a long period because no additional demand is made on patients in the study—all the data used would be recorded anyway. In this study the authors chose to follow up patient mortality in the three years after hospital admission.

The disadvantage of observational data is that you cannot be sure of the cause of any associations you find between say, elective colectomy and survival at three years, because you cannot control for all the other possible factors that might influence patients' survival. So even where an association exists you cannot say with certainty that elective surgery was the cause of the improved survival. This makes the data scientifically weaker than data from an experimental design, such as a randomised controlled trial, which uses a specifically designed intervention and randomises patients to study groups, thereby randomising all the other factors that might influence the outcome.

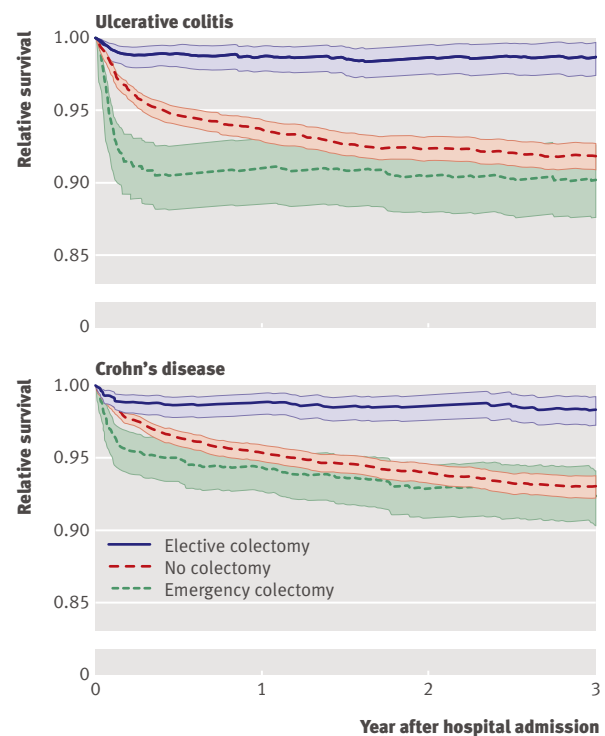
One of the drawbacks of this study is that the researchers could only analyse the information contained in the records they used, which are not very detailed. For example, the records did not include any information about the severity and past management of the patients' inflammatory bowel disease, which might affect survival after admission to hospital, whether or not the patient underwent surgery.

What was found?

The authors calculated two outcome measures. Case fatality refers to the percentage of patients with either Crohn's disease or ulcerative colitis who died within the three year follow-up period out of all patient admissions. Relative survival is a ratio of patient survival compared with the expected survival of a member of the general population, which is calculated as the standardised mortality ratio; see the figure (fig 2 in the full online version of the original paper).

The authors used regression to analyse the relation between elective surgery, emergency surgery, or no surgery and case fatality. This statistical method analyses the data to see if there is more than random likelihood that the predictor variable—in this case, type of surgery—is associated with or can predict the outcome variable—here case fatality. The authors also included sex, age, and major comorbidity in the regression model to see what influence the predictor variable has on the outcome even after these factors have been taken into account (see table 4 in the full online version of the original paper). Data on major comorbidity was taken from the NHS records and included any of several serious illnesses that the patient also had. The authors ran analyses on patients who were admitted to hospital for four days or longer, and re-ran analyses, including on patients staying fewer than four days, assuming that those patients who stayed for less time had a less severe attack of inflammatory bowel disease, and so a potentially different prognosis.

The authors found that for records of both the Oxford region and the England region, during the three years after hospital admission case fatality was lower and relative survival was greater in patients who had elective surgery than patients who had emergency surgery or no surgery. Only in the data from the England region, however, were these findings statistically significant—that is, statistical analyses confirmed that these findings have a high probability of not being the result of chance.



Relative survival during three years after elective colectomy, emergency colectomy, and no colectomy in England (1998-2000) for patients admitted for ulcerative colitis and for Crohn's disease, adjusted for age and sex and compared with general population. Survival in general population is 1. Shaded areas are 95% confidence intervals

The findings were not changed when patients who stayed for fewer than four days were included in the analysis. When major comorbidity was included in the regression the results remained largely the same, with a slightly reduced odds of mortality for patients with Crohn's disease. Survival after admission varied for patients with Crohn's disease and ulcerative colitis at different times after elective surgery, emergency surgery, and no surgery. The authors went on to look at the cause of death in patients who had died during the three year follow-up who had not had surgery, finding that almost one third died of intestinal disease. In isolation this is somewhat misleading because no findings are given as a comparison for cause specific death in patients who had received surgery.

What does the study mean?

Although it may be tempting to conclude from the associations found in the data that elective surgery improves the survival of patients with inflammatory bowel disease over emergency surgery or no surgery, the observational nature of this study does not allow conclusions of cause and effect to be drawn. It is likely that the severity and nature of each patient's disease at admission at least partially determined the treatment given, and also contributed to the survival rate of patients after leaving hospital. The data in this study indicate, however, that it would be fruitful to use additional resources in further research, in the form of a cohort study or randomised controlled trial, to establish the factors that determine which patients would benefit from elective colectomy.

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A longer version of this article with more on observational methods can be found at student.bmj.com