

Canadian Association of General Surgeons Evidence Based Reviews in Surgery. 7. Quality of life after bile duct injury during laparoscopic cholecystectomy

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CAGS Evidence Based Reviews in Surgery

In September 2000, the Canadian Association of General Surgeons (CAGS) initiated a program entitled "CAGS Evidence Based Reviews in Surgery" (CAGS-EBRS) to help practising clinicians improve their critical appraisal skills. During the academic year, 8 clinical articles are chosen for review and discussion. Both methodologic and clinical reviews of the article are performed by experts in the relevant areas. The *Canadian Journal of Surgery* will publish 4 of these reviews each year. Each review will consist of an abstract of the selected article and a summary of the methodologic and clinical reviews. We hope that readers will find these useful and learn skills that can be used to evaluate other articles. For more information about the CAGS-EBRS or information about participating in the program, send an email to mmckenzie@mtsinai.on.ca.

Selected article

Boerma D, Rauws E, Keulemans Y, Bergman J, Obertop H, Huibregtse K, et al. Impaired quality of life 5 years after bile duct injury during laparoscopic cholecystectomy: a prospective analysis. *Ann Surg* 2001;234(6):750-7.

Abstract

Objective: To assess the impact of bile duct injury (BDI) sustained during laparoscopic cholecystectomy on physical and mental quality of life (QOL). **Methods:** One-hundred and six consecutive patients (75 women, median age 44 yr [standard deviation 14 yr]) were referred between 1990 and 1996 for treatment of BDI sustained during laparoscopic cholecystectomy. Outcome was evaluated according to the type of treatment (endoscopic or surgical) and the type of injury. Objective outcomes (interventions, hospital admissions and laboratory data) were evaluated, a questionnaire was filled out and a QOL survey was performed (Medical Outcomes Study Short

Form Health Survey [SF-36]). Risk factors predicting a worse outcome were assessed. QOL results were compared to those of a healthy control group and another group who had undergone uncomplicated laparoscopic cholecystectomy more than 2 years previously. **Results:** There were 36 type A injuries (leaks of the cystic duct or duct of Lushka), 24 type B injuries (major or minor BDI), 15 type C and 31 type D injuries (major BDIs). Median follow-up time was 70 (range from 37–110) months. Following endoscopic treatment ($n = 69$), outcome was excellent in 94% and following surgical treatment outcome was excellent in 84% but depended on the timing of treatment. Five patients underwent interventional radiology with a good outcome. Eighty-two completed the QOL assessment. Despite the excellent objective outcome, QOL was significantly reduced compared with controls in all subscales and was not dependent on the type of treatment or the severity of the injury. The duration of the treatment was an independent prognostic factor for a worse mental QOL. **Conclusion:**

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Despite the excellent functional outcome after treatment of BDI during laparoscopic cholecystectomy, the occurrence of a BDI has a negative impact on the patient's QOL even at long-term follow-up.

Commentary

BDIs continue to occur as occasional complications of laparoscopic cholecystectomy. The mechanisms of these injuries have been well described, with more complex patterns than those occurring during open cholecystectomy. Several studies have addressed long-term objective outcomes, demonstrating excellent results based on laboratory investigations and patency rates for repairs of the injured common bile duct, but there is very little information on the impact of these injuries on patient QOL.

In this study, Boerma and associates set out to explore the impact of BDI sustained during laparoscopic cholecystectomy on long-term QOL in patients who suffered biliary tract injuries during laparoscopic cholecystectomy in the Netherlands between 1990 and 1996. They looked at 106 referrals to a tertiary care centre for the treatment of BDIs sustained during laparoscopic cholecystectomy. These injuries were classified using the Amsterdam Criteria. Unfortunately, this classification system is too general and does not give an accurate description of the injury. Type A (cystic duct or duct of Lushka leaks) injuries are minor and should not have been included as a BDI since there was no actual injury to the bile duct. This was the largest category of injury seen, occurring in 36 patients. Type B injuries can be either major or minor, but the patients were not further described in the paper. Types C and D are major injuries to the bile duct. The Strasberg Classification may have been a more appropriate system to use, since it classifies injuries more precisely. It allows differentiation of bile

leaks, partial or complete transections and late strictures.

The main strength of this paper is that it went beyond traditional outcome measures and recognized the importance of patient-centred outcomes as an important component in defining the success of an intervention. The instrument used by these investigators was the SF-36, which is a well-validated and widely used instrument. The instrument has 8 subscales, covering all aspects of physical and mental functioning. Prior work with this instrument has verified that it measures the items that matter to patients. Since the instrument contains questions about many aspects of health, it is almost certain to elicit information about health problems that concern the patient.

The investigators set out to compare health-related QOL among 3 groups of patients. They compared patients with BDI to a control group, which consisted of healthy age- and sex-matched controls and to patients who had undergone uncomplicated laparoscopic cholecystectomy at least 2 years previously. It is important to note that the scores for the BDI patients were derived in a different way from that of the other patients. The BDI patients were each sent the SF-36 form at a median of 70 months following completion of their treatment. However, the control data were taken from a previous study in which a modified SF-36, the SF-24, was used. They describe this as the SF-20 plus the Vitality Scale from the SF-36. Thus, the scores derived by these 2 methods may not be strictly comparable.

Sixty-nine of the 106 patients in the study had endoscopic treatment of their injuries: 58 had stents placed and 11 underwent sphincterotomy. Twenty-five patients underwent hepaticojejunostomy, 6 patients underwent a variety of other operations and 5 had anastomotic dilatation after surgery done at another institution. For patients with BDI, the SF-36 scores in most subscales were

relatively uniform, suggesting that the validity of the instrument was acceptable in this group.

The follow-up QOL data were available for 82 of the 106 patients. All patients with BDI had significantly impaired QOL on all 8 subscales. Surprisingly, there were no differences among the subgroups who suffered different types of injury. It is very curious that a patient with a simple cystic duct stump leak who underwent an endoscopic sphincterotomy had the same degree of impairment as someone who underwent a hepaticojejunostomy with a subsequent stricture. In fact, those with minor injuries had a worse score in the physical functioning and bodily pain subscales than those with complete transection of the common bile duct. Those of us familiar with patients suffering these injuries would find this hard to accept. We are left wondering whether the instrument is truly measuring what it is intended to measure, calling its face validity into question. In all of the patient groups, the duration of treatment was surprisingly long. Even the most severe injuries were primarily treated endoscopically, when it would appear that the patients required surgical reconstruction.

In spite of apparently excellent objective outcomes, there was a statistically significant uniform reduction of QOL in every domain measured among those patients with BDI. The authors noted that in spite of apparently poor health, the patients had not sought medical attention in more than 5 years. Therefore it is hard to know how clinically significant this decrease in health status was to the patients, and the authors provided very little insight into this question.

One reason for the poor QOL reported by patients with type A injuries could be that the patients expected a day surgery procedure that is generally associated with a rapid recovery. The occurrence of an unexpected injury may have caused

extreme distress to the patients. It would be interesting to know whether the potential for a BDI was discussed with the patients before surgery. How the surgeon handled the problem once it occurred and the response to patient complaints in the postoperative period may also have played a major role in a patient's subjective outcome. It appears that many patients in this study had not been fully informed of the nature of the problem until referral to a tertiary centre.

The SF-36 was designed as a generic health-related QOL instrument. It has been used in hundreds of studies of patients with many different diseases. It has been most widely used in rheumatology and orthopedics. The pain score is the predominant measure associated with poor health status. As with all generic instruments, it was designed to be applicable across a wide range of populations and interventions. Therefore, the questions are by design not highly sensitive. Significant differences among various people with the same condition may be completely missed. For example, there may be no way for the SF-36 to determine the impact of jaundice on QOL, which is obviously highly relevant to patients with biliary disease.

Because generic instruments may fail to detect small but significant differences, a number of disease-specific instruments have been developed. Al-

though these are not useful for comparing patients with disparate conditions, they are very valuable for detecting differences among patients with the same disease. One example is the Gastrointestinal Quality of Life Index, which has been used to assess health-related QOL after cholecystectomy. In the present study, it may have been more appropriate to use a disease-specific instrument, since all the patients had varying degrees of the same problem. A more disease-specific instrument may have been able to detect differences between the subgroups. Many authors currently recommend that all studies employ one of each type of instrument.

The treatments these patients underwent were generally appropriate for the injuries they suffered. Since they were a convenience sample of consecutive patients, they were closely reflective of clinical practice. Unfortunately, once a BDI has occurred, the die is cast. The nature of the treatment we offer to patients is dictated by the anatomic specifics of the case. It would appear from this study that we might as well perform major biliary reconstruction for the most trivial injuries, since the long-term results are no worse. This observation is so counterintuitive and contrary to clinical experience that the evidence would need to be much stronger than shown by Boerma and associates. However, the conclusion that the occurrence of a BDI has a

great impact on QOL, even at long-term follow-up, is a reasonable one that is supported by the evidence presented. The authors have addressed the question initially posed and have shown that from the patient's viewpoint these injuries have a profound impact.

The evidence they presented does convincingly show a decreased health-related QOL in patients after BDI. However, the controls they used were problematic, since the same instrument was not used to measure health-related QOL in all groups. The fact that they could not distinguish differences in QOL in patients with trivial and extremely serious injuries based on long-term outcome is very troubling. At least part of the explanation for this is the fact that they used a generic QOL instrument when a disease-specific instrument may have been more appropriate.

The management of BDI in the era of laparoscopic cholecystectomy continues to evolve, and this paper certainly adds to the literature. The results illustrate that a more liberal use of patient-centred outcomes is imperative when we seek to assess the results of clinical interventions.

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