

**APPENDIX C.5 GENERAL SURGERY: LAPAROSCOPIC CHOLECYSTECTOMY
LITERATURE REVIEW**

Western Canada Waiting List Project

**Literature Review – General Surgery: Laparoscopic
Cholecystectomy**

By

David Rasmusson and Cheryl M. Martin

January 2000

Table of Contents

1. Introduction
 2. Search Strategy
 3. Condition and Treatment Description
 4. Baseline Health Status Measures
 5. Surgical Outcomes
 6. Prognostic Indicators of Treatment Benefit
 - 6.1 Disease-Specific Clinical Signs and Symptoms
 - 6.2 Generic Health Status Measurement Tools
 - 6.3 Age
 - 6.4 Comorbidity and Medical History
 - 6.5 Surgeon Experience
 7. Conclusion
 8. References
- Appendix A: Search Terms
Appendix B: Article Coding Template

1. Introduction

This literature review summarizes recent study-based data concerning the outcomes of laparoscopic cholecystectomy. This review was conducted under the auspices of the Western Canada Waiting List Project for use by the general surgery panelists while developing priority criteria and associated criteria weights. Panelists will be asked to assess the extent to which the review provided meaningful assistance in this regard.

The information contained in this report will also be used to help develop a method for comparing the severity of patients' suffering and disability across different conditions, e.g., cholecystectomy versus hernia repair. This goal is compatible with the general surgery panel's decision to develop generic priority criteria, rather than procedure-specific ones as in the other WCWL panels.

This report focuses on three major questions: (1) severity of suffering and disability pre-operatively, (2) the degree to which cholecystectomy alleviated suffering and disability and (3) which pre-operative indicators were indicative or predictive of the degree of benefit experienced by patients following cholecystectomy. These are the issues most directly relevant to the task of developing criteria and for purposes of cross-treatment comparisons.

2. Search Strategy

The PubMed search service was used to search the Medline database, a system maintained by the National Library of medicine (NLM). Searches were limited to articles published between 1989 and 1999, either written in English or that had an English abstract. Articles were retrieved by combining medical search headings (MeSH) within the topic of cholecystectomy. (See Appendix A for search terms.) References from selected articles were also checked to locate additional relevant studies.

Articles were considered with respect to the three research questions listed in the Introduction, and relevant information recorded on "Article Coding Templates" or ACTs (Appendix B). This information was then used to create a database that also holds all reference information, as well as other data used for this report.

Records returned from these primary searches were screened by a Medical Librarian Specialist to eliminate any items that were not likely to have relevant information (referred to as the "false drop filter"). Abstracts for 176 remaining articles were then reviewed, and added to a custom reference database. If an abstract pertained to any of the research questions, the article was fully reviewed, and an ACT was completed. A total of 14 articles were used in preparing this report.

3. Condition and Treatment Description

Approximately 10-15% of the adult population have gallstones. The majority of people with gallstones remain asymptomatic for years and may never require treatment. However, cholelithiasis can lead to consequences that range from brief episodes of biliary pain to cholecystitis or, in rare cases, gallbladder cancer.

According to Kane et al.[1], classic gallbladder pain is in the right upper (or upper middle) part of the abdomen, and may extend to the back or right shoulder. The pain can last from 30 minutes to several hours and is constant. The attacks may be intermittent and unpredictable occurring days or months apart. Although this type of pain is the most common gallbladder symptom, the following may also be present: heartburn, vomiting, back pain, nausea, fatty food intolerance, indigestion, flatulence, bloating, jaundice, fever, and loss of appetite.[2] [3] Once gallstones symptoms appear, they tend to recur, and may lead to complications, including pancreatitis and cholecystitis. Complications may require emergency medical treatment, including emergency cholecystectomy. Thus, the NIH Consensus Statement (1992)[4] recommends that all patients with symptomatic gallstones should be treated.

Laparoscopic cholecystectomy (LC) provides safe and effective treatment for most patients and appears to have become the treatment of choice for symptomatic gallstones and cholecystitis. Approximately 90% of patients experience symptom improvement following LC.[5] LC was first performed in France in 1987[4] and requires general anesthesia and has the same risks and complications inherent to the open cholecystectomy (OC) procedure. However, LC has a shorter operating time, less preoperative pain, a brief hospital stay, and a much shorter convalescence period compared to OC. LC is associated with a slightly higher incidence of injury to the common bile duct (CBD), and a small percentage of patients are converted to the OC procedure because of unclear anatomy. Such consequences, as well as complications, appear to decrease in incidence as surgeons gain more experience.[6]

Non-invasive techniques for gallstone reduction (as opposed to removal), such as ultrasound, are less effective, and the risk for continued cholelithiasis and symptoms remains. Such treatment option may be appropriate for patients who cannot tolerate general anesthesia, or who otherwise may be at risk for complications or mortality from surgery.

4. Baseline Health Status Measures

In the literature reviewed, preoperative measures of patient health state were most often focused on the presence, and/or severity, of gallstone symptoms. This information was obtained from chart reviews, standardized or non-standardized patient interviews, and questionnaires, or from physician surveys. In fewer cases, patients were assessed before surgery with general health questionnaires, or quality of life measures. Occasionally, general health or QOL scores were obtained retrospectively, by asking the patient to think back on symptoms, health state, or quality of life before they were treated. No information was available in the studies reviewed that could be used to compare the scores of pain or function domains pre and postoperatively.

5. Surgical Outcomes

In most of the studies reviewed, investigators assessed outcome from LC in terms of primary medical measures such as length of stay (LOS), complications, morbidities, period of convalescence, and mortality. In some cases, postoperative benefit in LC patients was assessed

by the reduction of specific gallstone symptoms, typically pain, although pain scores on assessments were not provided in journal articles.

Some studies assessed the benefits of LC in terms of self-reported health status, quality of life (QOL), return to usual functioning, or patient satisfaction. Some studies seemed to assess outcome in the short-term recovery from LC, while others assessed the benefit of the surgery after recovery was complete. Barkun et al.[7] used a 0-11 point visual analog scale to rate quality of life. Out of 35 patients with a mean baseline score of 6.4, 18 patients reported a score of 9.3 at 10 days, 21 patients reported 9.9 at 1 month, and 21 reported 10.0 at 3 months.

6. Prognostic Indicators of Treatment Benefit

6.1 Disease-Specific Clinical Signs and Symptoms

Several studies have evaluated the relative benefits among patients with different presenting clinical signs and symptoms. The studies discussed in this section all evaluated outcome in terms of symptom “cure rates,” or conversely, rates of persisting symptoms. In general the findings here support practice guidelines that recommend treating patients with gallstones who show classic pain or other symptoms typical of gallbladder disease.[4]

Fenster and his colleagues at University of Washington in Seattle evaluated 225 patients before and three months after LC.[8] Patients identified which of several symptoms they were experiencing in a pre-surgical interview, and again later through a mailed questionnaire. The highest symptom cure rates were found for patients reporting pre-surgical classic biliary pain (82%), or atypical pain (81%), who also had gallstones documented by ultrasound. Non-pain symptoms (gassiness, bloating, indigestion, fatty-food intolerance, and nausea) where gallstones were present had a cure rate of 46%. However, among patients where gallstones were not documented on pre-surgical ultrasound, cure rates for the above type of symptoms were 52, 76, and 38%, respectively. Thus, the presence of gallstones and pain (even atypical) appear to be features that predict which patients will have symptom relief from LC.[8]

Gui et al.[9] at St George's Hospital Medical School, London evaluated the impact of LC on GI symptoms in 92 consecutive patients interviewed 12 to 83 months post-surgery. Pain-free outcome was predicted independently by pre-operative classic biliary pain, fatty-food intolerance, and thick-walled gallbladder on ultrasound. Logistic regression analysis suggested a potential prediction model with the following pre-surgical factors: thick-walled gallbladder, elevated gamm-glutamyl transpeptidase, body mass index <26.0, fatty-food intolerance, and normal bowel habit.

Luman et al.[3] at the Western General Hospital in Edinburgh administered patient-completed questionnaires to 100 patients before and 6 to 10 months after LC. The investigators found that 13 out of 97 patients completing the procedure had persistent pain. Only one of those patients had cholecystitis, where as the other 30 patients presenting with cholecystitis experienced symptom relief. Bloating was reported as a presurgical symptom in

12 of the 13 patients with persisting pain, whereas 36 of the 84 (43%) patients with surgical benefit reported bloating. Eight of the 13 patients with persisting pain had been taking psychotropic medications (antidepressants or anti-anxiolytics) at the time of the surgery. Thus, symptoms that confirm typical gallbladder disease seem to predict a greater likelihood of symptoms relief from LC.

6.2 Generic Health Status Measurement Tools

The American Society for Anesthesia (ASA) scale and the APACHE II score are measures of preoperative medical severity. The ASA is often administered to identify patients at high risk for complications or mortality in association with surgical procedures requiring general anesthesia. ASA grades range from 0 (no risk) to IV (highest risk). Many studies of LC exclude patients with grades III or IV. The simplified APACHE II (as used by Clavien et al.[10]) assigns points for older age and concomitant disorders, and has a maximum score of 11. Both of these measures score higher among older patients who tend to have greater health problems; the APACHE II score is, in part, determined by age.

Studying 1200 patients in total from two surgical centers (Mt Sinai in Toronto and Geneva University Hospital), Clavien et al.[10] assessed predictors of complications resulting from open cholecystectomy (OC) procedure. Although higher risk for any type of complication was found for patients with higher ASA grades (III or IV) and higher APACHE II scores (10 or 11), both were significant in the Toronto series (OR=4.1; CI=2.2-7.8 and OR=8.1; CI=4.1-15.7, respectively) and only Apache II was significant for the Geneva series (OR = 2.0, CI, 1.2-3.5). Similarly, Cullen et al. reported increased operation-specific complication rates among 376 OC patients for ASA grade III and IV. However, complication rates were quite low, and even among the ASA grade III and IV the rate was 0.27%.[11] Thus, although complications contribute to patient satisfaction in LC patients,[5] they occur at lower rates even among high risk patients, and may not be a robust measure of treatment outcome. Complications of all types appear to be nearly seven times more frequent in OC compared to LC.[12]

6.3 Age

A number of studies have investigated surgical outcomes among LC patients in different age groups. Although it has been reported that older patients have higher rates of complications following OC[10, 11] and LC[13], Maxwell et al.[13] concluded that LC may be performed safely among octogenarians. In relation to OC, the reduced invasiveness, lower rate of complications, and shorter recovery time of LC, makes surgical treatment of older patients with gallbladder disease more acceptable.[12]

6.4 Comorbidity and Medical History

Several specific comorbid conditions have been studied as potential risk factors for reduced efficacy, or increased complications. Because of the relationship between health and aging, these are also indirectly assessed in the studies described above on Health Status and Age. Nevertheless, two important conditions deserve special mention.

Clinical trials and other studies of LC have often excluded patients with prior abdominal surgery, or specifically upper abdominal surgery. However, only one study in the literature seems to have systematically evaluated the effect of prior abdominal surgery on LC complications.[6] In a consecutive case series of 504 patients undergoing LC, 175 had a history of prior abdominal surgery, 21 of which had upper abdominal surgery. The study found that complications were not increased in this group of patients, and conversion to OC was low (7/175). Five of the seven conversion of the prior abdominal surgery group were due to dense adhesions in regions of needle or trocar placement.

As mentioned in an earlier section, Luman et al.[3] found 13 of 97 patients had persisting pain 6 months after LC. Eight of the 13 patients had been taking psychotropic medications (antidepressants or anti-anxiolytics) at the time of the surgery. Although patient psychiatric history is not described in the study, it is possible that some of the patient symptoms were somatic symptoms resulting not from gallbladder disease, but from psychiatric illness.

6.5 Surgeon Experience

One study systematically evaluated the effects of surgeon experience on complication rates in LC. Kane et al[14] evaluated patient records and obtained functional status for 2,481 cases undergoing LC or OC procedure during the period that LC was introduced in the Minnesota health care system. The result suggested a learning curve for surgeons performing LC. Both operative and general complications reduced as surgeons performed more LC procedures. After the 50th LC procedure, complication rates were below 2% for all types of complications.

7. Conclusions

Data regarding pain and functional disability in the articles reviewed tended to focus the existence of a symptom or the lack of it. No scores were available to compare severity of pain or functional problems before and after surgery. Regarding predictive factors, patients with typical symptoms of proven gallbladder disease, especially pain, are most likely to benefit from LC.

8. References

1. Kane, R.L., M. Maciejewski, and M. Finch, *The relationship of patient satisfaction with care and clinical outcomes*. Med Care, 1997. **35**(7): p. 714-30.
2. Vander Velpen, G.C., S.M. Shimi, and A. Cuschieri, *Outcome after cholecystectomy for symptomatic gall stone disease and effect of surgical access: laparoscopic v open approach*. Gut, 1993. **34**(10): p. 1448-51.
3. Luman, W., et al., *Incidence of persistent symptoms after laparoscopic cholecystectomy: a prospective study*. Gut, 1996. **39**(96): p. 863-6.
4. *Gallstones and laparoscopic cholecystectomy*. NIH Consens Statement, 1992. **10**(3): p. 1-28.
5. McMahon, A.J., et al., *Symptomatic outcome 1 year after laparoscopic and minilaparotomy cholecystectomy: a randomized trial*. Br J Surg, 1995. **82**(10): p. 1378-82.
6. Wongworawat, M.D., et al., *The impact of prior intra-abdominal surgery on laparoscopic cholecystectomy*. Am Surg, 1994. **60**(10): p. 763-6.
7. Barkun, J.S., et al., *Randomised controlled trial of laparoscopic versus mini cholecystectomy. The McGill Gallstone Treatment Group*. Lancet, 1992. **340**(8828): p. 1116-9.
8. Fenster, L.F., et al., *What symptoms does cholecystectomy cure? Insights from an outcomes measurement project and review of the literature*. Am J Surg, 1995. **169**(5): p. 533-8.
9. Gui, G.P., et al., *Is cholecystectomy effective treatment for symptomatic gallstones? Clinical outcome after long-term follow-up*. Ann R Coll Surg Engl, 1998. **80**(1): p. 25-32.
10. Clavien, P.A., et al., *Recent results of elective open cholecystectomy in a North American and a European center. Comparison of complications and risk factors*. Ann Surg, 1992. **216**(6): p. 618-26.
11. Cullen, D.J., et al., *ASA Physical Status and age predict morbidity after three surgical procedures*. Ann Surg, 1994. **220**(1): p. 3-9.
12. Massie, M.T., et al., *Advantages of laparoscopic cholecystectomy in the elderly and in patients with high ASA classifications*. J Laparoendosc Surg, 1993. **3**(5): p. 467-76.
13. Maxwell, J.G., et al., *Laparoscopic cholecystectomy in octogenarians*. Am Surg, 1998. **64**(9): p. 826-31; discussion 831-2.
14. Kane, R.L., et al., *The outcomes of elective laparoscopic and open cholecystectomies*. J Am Coll Surg, 1995. **180**(2): p. 136-45.

Laparoscopic Cholecystectomy Literature Review Appendix A: Search Terms

Search terms included the following:

- (cholecystectomy [majr] OR cholecystostomy [majr])

AND

- (1989:1999[dp])

AND

- (eng [la] OR hasabstract)

AND

- activities of daily living [mh]
- age factors[mh]
- age of onset[mh]
- APACHE[mh]
- cost allocation[mh]
- cost-benefit analysis [mh]
- cost control[mh]
- cost savings[mh]
- costs and cost analysis[mh]
- decision making[mh:noexp]
- Delphi Technique[mh]
- economic value of life[mh]
- evaluation studies[mh]
- geriatric assessment[mh]
- health care costs[mh:noexp]
- health care rationing[mh]
- health priorities[mh]
- health services needs and demand [mh:noexp]
- health status [mh]
- medical futility[mh]
- needs assessment[mh]
- nutritional status[mh]
- outcome assessment [mh]

- patient satisfaction [mh]
- patient selection [mh]
- population surveillance[mh]
- predictive value of tests[mh]
- quality-adjusted life years[mh]
- quality of life [mh]
- questionnaires [mh]
- reference standards[mh]
- risk factors[mh]
- self assessment psychology [mh]
- sentinel surveillance[mh]
- severity of illness index [mh]
- social responsibility [mh]
- surgical procedures, elective/utilization [mh]
- surgical procedures,operative/standards[mh]
- time factors[mh]
- treatment failure[mh]
- treatment outcome [mh]
- waiting lists[mh]
- work capacity evaluation[mh]

NOT

- radiography [mh]
- radiography [sh]
- feasibility studies [mh]
- intraoperative care [mh]
- postoperative care [mh]
- comorbidity[mh]
- sensitivity and specificity[mh]
- case report[mh]
- comparative studies [mh]
- length of stay[mh]

Additional terms included:

- disability evaluation[mh]
- function recovery[mh]
- ADL[textword]
- disease management[mh]
- delivery of health care/standards[mh]
- outcome and process assessment (health care) [mh]

Articles were excluded which focused on technical procedures, materials, and methods, as well as articles on:

- comparison of methods;
- preoperative, perioperative, postoperative care;
- outcomes related to particular technique;
- surgical complications;
- patient guides;
- gender utilization;
- patient selection based on medical considerations only;
- rehabilitation;
- articles in foreign languages which had summaries (abstracts) too brief or general to be useful; and
- research methods (apart from subject of this project).

Separate searches were also conducted with each of the major topic groups AND to the following list of non-MeSH test names:

- SF-#36
- Short Form Health Survey
- MOS OR Medical Outcomes Study
- MGQ OR McGill Pain Questionnaire
- FSI OR Functional Status Index
- GDS OR Geriatric Depression Scale
- NHP OR Nottingham Health Profile
- Rosser Index Matrix

**Laparoscopic Cholecystectomy Literature Review Appendix B: Article Coding Template
(ACT)**

**WCWLP
Article Coding Template**

Article ID:	First Author:	Year of publication:
Title:		
Rating of overall usefulness of article to study questions:		Blank
Reviewer summary:		
Study name or center:		
Kind of study:	Case series(fol'd thrgh time, no control group)	
Sample size:		
Study methods:		
Study's Inclusion criteria:		
Study's Exclusion criteria:		
PRE-SERVICE HEALTH STATE (Baseline Measurement)		Blank
1. Does paper describe the <i>kinds of patients</i> with the condition, regarding GENERIC health state (ie QOL, functional impairment) or DISEASE SPECIFIC health state (degree of suffering, visual acuity, mobility)?		
1a. If yes, how were they measured (what questionnaire[s] were used or factors assessed)?		
1b. Did paper distinguish among patients with <i>differing levels</i> of severity (e.g., mildly, moderately, severely affected; a scoring system with 100 representing absence of any suffering or impairment)?		Blank
1b1. If yes, what were the definitions of the ratings (range of scores, description)?		

1b2. If yes, how many patients were in the categories?

1c. Does this method of grading severity allow comparison across different medical conditions? Blank

Comments about above:

HEALTH SERVICE BENEFIT (Outcome Measurement)

Blank

2. Does paper describe postoperative degree of suffering, functional impairment, quality of life, or clinical symptoms?

2a. If yes, how were they measured (what questionnaire[s] were used or factors assessed)?

2b. Did paper provide information to assess post-operative severity relative to pre-operative severity? Blank

2b1. If yes, did paper permit quantitative estimation of degree of benefit? Blank

2b2. What was the degree of quantitative benefit (either in relative or absolute terms)?

2c. Does this method of measuring outcome allow comparisons across medical services? Blank

Comments about above:

PROGNOSTIC INDICATORS

Blank

3. Did paper provide a basis for predicting which patients will benefit more or less than average (e.g., prediction models/rules for estimating small, medium, large benefit)?

If yes, what were the distinguishing factors?

Save the form as a document in the ACT Document folder. Data elements will be extracted at the end of the review by AB.