The Spectrum and Cost of Complicated Gallstone Disease in California

Robert E. Glasgow, MD; Michael Cho; Matthew M. Hutter, MD; Sean J. Mulvihill, MD

Hypothesis: We hypothesized that complications of gallstone disease are more common than previously recognized and are related to treatment delay.

Design: Retrospective review.

Patients: Data for 248 consecutive patients from a university hospital in 1995-1996 and 40,571 patients identified through the 1996 California Office of Statewide Health Planning and Development database who underwent cholecystectomy for gallstone disease were reviewed.

Main Outcome Measures: Diagnosis, length of hospital stay, hospital mortality, type of admission, type of surgical procedure, hospital cost, and interval of delay between onset of initial symptoms, ultrasound diagnosis, and cholecystectomy.

Results: The spectrum of gallstone disease included biliary colic in 56%, acute cholecystitis in 36%, acute pancreatitis in 4%, choledocholithiasis in 3%, gallbladder cancer in 0.3%, and cholangitis in 0.2%. Community hospitals, public or county hospitals, and academic health centers had a similar distribution of diagnoses. Patients undergoing cholecystectomy for biliary colic had a significantly shorter length of hospital stay, lower operative mortality rate, were more likely to have their operations completed laparoscopically, and had lower hospital charges than patients undergoing cholecystectomy for complications such as acute cholecystitis. Over half of the patients requiring cholecystectomy for complications of gallstones initially presented with biliary colic. Patients with gallstone complications had an average delay from ultrasound confirmation to surgery of 6 months.

Conclusion: Complications of gallstone disease are (1) common, (2) costly, and (3) potentially preventable.

Arch Surg. 2000;135:1021-1027

GALLSTONE DISEASE is a common problem in the United States. Approximately 10% of the population in Western societies have gallstones, with a 5-year incidence of 2% to 4%.1-3 In the United States, about 600,000 cholecystectomies are performed annually for symptomatic gallstone disease, making this one of the most common abdominal operations performed. Longitudinal studies show that most patients with gallstones are asymptomatic and remain so, with fewer than 20% of the patients requiring surgery for biliary colic or gallstone-related complications during a 20-year follow-up period.4,5 Decision analyses support an expectant, nonoperative approach in most patients with asymptomatic gallstones.6,7 In contrast, most patients with symptomatic gallstones remain symptomatic and it is estimated that 1% to 3% per year develop complications of their gallstones, such as acute cholecystitis.8 Based on these observations, cholecystectomy has been widely advocated for patients with symptomatic gallstones.

The current standard of care for the treatment of patients with symptomatic gallstones is laparoscopic cholecystectomy. Convincing data support the contention that laparoscopic cholecystectomy is superior to the open approach in terms of reduced patient morbidity and mortality and decreased health care resource utilization.9-12 Since the introduction of laparoscopic cholecystectomy in the late 1980s, population studies from Maryland, Connecticut, and Pennsylvania suggest that the rate of cholecystectomy has

See Invited Critique at end of article

From the Department of Surgery, University of California, San Francisco.
PATIENTS, MATERIALS, AND METHODS

DATA SOURCES

The study design was a retrospective analysis of data derived from 2 sources, the medical records of patients treated at a large, academic medical center, the University of California–San Francisco (UCSF) from January 1, 1995, to December 31, 1996, and the California OSHPD database. The OSHPD database contains standardized discharge data abstracts for every patient hospitalization from each acute care facility in the state of California. Each abstract includes demographic and clinical data that summarizes the hospital course of individual patients. The OSHPD database uses diagnostic and procedural codes derived from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), issued by the US Department of Health and Human Services. All discharge abstracts from January 1, 1996, through December 31, 1996, were reviewed to identify all patients who underwent laparoscopic cholecystectomy (ICD-9-CM code 51.23) or open cholecystectomy (ICD-9-CM code 51.22). From this group, all patients undergoing cholecystectomy for cholelithiasis or its complications were selected (ICD-9-CM codes 574.X, 576.X, and 156.0). Hospitals were characterized as academic health centers, community or private hospitals, or public or county hospitals.

DATA ANALYSIS

Patients were grouped according to the diagnosis at the time of admission for cholecystectomy. Patients with symptomatic cholelithiasis or biliary colic (ICD-9-CM codes 574.1, 574.2, 574.7, and 574.9) were categorized as having biliary colic. Patients seen with acute calculus cholecystitis (ICD-9-CM codes 574.0, 574.3, 574.6, and 574.8), gallstone pancreatitis (ICD-9-CM code 577.0), cholecystitis (ICD-9-CM codes 574.4 and 574.5), gallbladder cancer (ICD-9-CM code 156.0), or cholangitis (ICD-9-CM code 576.1) were categorized as having complicated gallstone disease. Outcome measures analyzed for each patient included the type of hospital admission (elective or emergency), length of hospital stay (LOS), total hospital charges, type of surgical procedure (laparoscopic or open cholecystectomy), and in-hospital mortality.

For the 248 patients who underwent cholecystectomy for gallstone disease at UCSF in 1995-1996, complete medical records were available for 217. Outcome measures analyzed for each patient included the LOS, total hospital cost, type of surgical procedure (laparoscopic or open cholecystectomy), and in-hospital mortality. In addition, the interval of delay between the onset of the patient’s initial symptoms of gallstone disease to the date of surgery and the interval of delay between the first ultrasound that documented the presence of cholelithiasis to the date of surgery were determined for each patient. Comparisons were made between patients with complicated and biliary colic. To evaluate the statistical significance of these differences, the t test was used for continuous variables and the χ² analysis of variance was used for nominal variables. P<.05 was considered statistically significant.

Table 1. Spectrum of Gallstone Disease in California in 1996

<table>
<thead>
<tr>
<th>Disease</th>
<th>No. of Patients</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biliary colic</td>
<td>22,923</td>
<td>56.5</td>
</tr>
<tr>
<td>Acute cholecystitis</td>
<td>14,586</td>
<td>35.9</td>
</tr>
<tr>
<td>Acute gallstone pancreatitis</td>
<td>1576</td>
<td>4.0</td>
</tr>
<tr>
<td>Cholecystolithiasis</td>
<td>1260</td>
<td>3.1</td>
</tr>
<tr>
<td>Gallbladder cancer</td>
<td>141</td>
<td>0.3</td>
</tr>
<tr>
<td>Cholangitis</td>
<td>65</td>
<td>0.2</td>
</tr>
<tr>
<td>Total</td>
<td>40,571</td>
<td>100</td>
</tr>
</tbody>
</table>

THE SPECTRUM OF GALLSTONE DISEASE

Of the 248 patients treated at UCSF, 140 (56%) presented electively with biliary colic, 71 (29%) had acute cholecystitis, 15 (6%) had gallstone pancreatitis, 12 (5%) had cholecystolithiasis, and 10 (4%) had other diagnoses such as gallbladder cancer or porcelain gallbladder. In 1996, 40,571 patients underwent cholecystectomy in California for symptomatic gallstone disease, for an approximate rate of 1.3 per 1000 population. As seen in Table 1, 56.5% of patients were treated electively for biliary colic and 44% (the sum of all the mean biliary colic) underwent cholecystectomy for complications of gallstones. The most common complication seen was acute cholecystitis, followed by gallstone pancreatitis. The spectrum of gallstone disease seen at academic health centers, community hospitals, and public or county hospitals did not differ significantly. Academic health centers treated a slightly higher percentage of patients with pancreatitis, while public or county hospitals treated a higher number of patients with acute cholecystitis; however, these differences were not statistically significant (Table 2). The source of payment for the hospitalization, however, differed significantly among the different practice envi-
The outcome of the 248 patients with symptomatic gallstone disease treated at UCSF in 1995-1996 is summarized in Table 3. The 138 patients treated electively for biliary colic were far more likely to undergo a laparoscopic, as opposed to an open cholecystectomy than the 79 patients treated for complications of gallstones. The LOS of the electively treated group was significantly shorter and their hospital cost was significantly lower than the patients with complications of gallstones. One hospital death was observed in each group (not statistically significant).

The statewide outcome data for patients with uncomplicated and complicated gallstone disease are given in Table 4. Patients with biliary colic had a significantly shorter LOS, lower total hospital charges, and lower hospital mortality rate than patients with complications of their gallstones. Patients with biliary colic were more likely to have an elective or scheduled admission, whereas patients with gallstone complications were more likely to require emergency admission. Patients with biliary colic were more likely to have a successful laparoscopic cholecystectomy than patients having complicated gallstone disease.

TREATMENT DELAY

For patients undergoing cholecystectomy for gallstone disease at UCSF, the mean (±SEM) duration of symptoms from their date of onset to the date of surgery was 523 ± 127 days. This delay was significantly shorter in patients with complications of gallstones (Table 5). The mean (±SEM) delay between the first documented abdominal ultrasound that confirmed the presence of gallstones to the date of surgery was 197 ± 57 days. There was no significant difference in delay from initial diagnosis by ultrasound to treatment in patients with biliary colic compared with those who had complications of gallstones. In over half of all patients with complications of
gallstone disease, biliary colic was the initial symptom (Table 5). Treatment delay could not be assessed in the statewide OSHPD database.

COMMENT

Our data show that 44% of all patients in California with symptomatic gallstone disease undergo cholecystectomy for complications such as acute cholecystitis, pancreatitis, choledocholithiasis, and cholangitis. A similar spectrum of disease was observed in academic health centers, including UCSF, private or community hospitals, and public or county hospitals. This high percentage of patients with complications of gallstones at the time of surgery is greater than the 15% to 20% previously observed.10-12

The care of patients with complications of gallstones is more costly in terms of patient morbidity and health care resource utilization compared with patients treated electively for biliary colic. In this study, patients treated electively for biliary colic were far more likely to have a laparoscopic, rather than an open cholecystectomy, with a shorter LOS, lower hospital costs and charges, and decreased hospital mortality compared with patients treated for complications of their gallstones. These findings are similar to previously published population studies demonstrating improved outcomes with elective vs urgent or emergent treatment.13,19 In addition, our results are consistent with those showing better outcomes in patients treated with laparoscopic, as opposed to open, cholecystectomy.10-12,21

Despite the clear benefits of performing cholecystectomy early in the disease course, most patients with symptomatic gallstone disease were treated after a prolonged period of observation. The average patient treated at UCSF with biliary colic was symptomatic for 2 years prior to treatment with cholecystectomy. The average delay between the confirmation of diagnosis by ultrasound and treatment with cholecystectomy was not statistically different between patients with biliary colic (210 days) compared with those who had complications of their gallstones (177 days). In other words, gallstones were known to be present, on average, for 6 months before patients with complications underwent urgent or emergent cholecystectomy. Half of these patients had biliary colic during this delay and in half the complication was the initial symptom.

Several possible explanations may underlie the observed delay in the treatment of patients with gallstone disease. Patients may experience symptoms but either choose not to seek medical attention or lack access to medical care. Family physicians or internists may evaluate a patient’s symptoms, but choose not to investigate. After gallstones are identified, patients or their physicians may wish to avoid surgery. Alternatively, some patients may be evaluated by surgeons, but either be felt not to be acceptable candidates or have treatment delayed because of wait lists. Our data suggest that substantial delays occur both between the onset of symptoms and the investigation with ultrasound, and the confirmation of gallstones by ultrasound and treatment by cholecystectomy. We cannot identify, from our data, which of these factors is of greatest importance in determining treatment delay. It seems, however, that payor source is not critical, as the proportion of patients operated on for gallstone complications was similar among academic health centers, private or community hospitals, and public or county hospitals, despite widely disparate payor sources.

How could treatment algorithms be modified so as to avoid the morbidity and cost associated with complications of gallstones? About 44% of all patients who underwent cholecystectomy for symptomatic cholelithiasis in California in 1996 had complications of gallstone disease at the time of surgery. Our data suggest that in about half of these patients biliary colic preceded the complication, offering the opportunity for elective treatment. If this group of patients had elective cholecystectomy at the time of their initial symptoms, they would have avoided the increased morbidity and cost associated with gallstone complications. Applied statewide in California in 1996, 9187 patients would have been spared complications of gallstones and, of these, 4 of 5 would have been successfully managed with laparoscopic cholecystectomy, with a savings of 28 patient lives, 18374 hospital days, and approximately $61 million in hospital charges. Based on these observations, we recommend that all patients with biliary colic who are suitable surgical candidates should be referred for elective laparoscopic cholecystectomy.

Presented at the 71st Annual Session of the Pacific Coast Surgical Association, San Francisco, Calif, February 20, 2000.

Corresponding author: Sean J. Mulvihill, MD, Department of Surgery, University of California–San Francisco, 533 Parnassus Ave (U-122), San Francisco, CA 94143-0788 (e-mail: mulvihills@surgery.ucsf.edu).

REFERENCES

12. Trondsen E, Reiersen O, Andersen OK, Kjaersgaard . Laparoscopic and open...
L. William Traverso, MD, Seattle, Wash: The literature indicates that we have overused cholecystectomy in the laparoscopic era. Four population-based studies said the use of cholecystectomy and the expenditures on this operation increased since the inception of laparoscopic cholecystectomy. In Connecticut they noted a 29% increase in the overall cholecystectomy rate along with a 9% increase in expenditure. The increase is speculated to be due, among other possibilities, a backlog of reluctant patients or referring physicians that developed a lower threshold for surgical intervention. Today the group from UCSF tells us that cholecystectomy is not used soon enough because they found too many complicated cases. What is the cause for this surprisingly high incidence of complicated cases?

The authors studied a smaller group of their own UCSF patients during the same time period that had more clinical details in their case records. In 217 cases with cholecystectomy they found that 36% were complicated cases. Most interesting was the natural history of gallstone disease in these UCSF patients. About half of the UCSF complicated patients had no symptoms until they developed a complication, that is, no preceding biliary pain before having to rapidly go on to cholecystectomy. The remaining patients in the complicated group had an average of only 142 days before needing surgery compared with the uncomplicated group's 728 days. What we learn here is that all gallstones do not act the same clinically. There are the protracted clinical courses of the uncomplicated cases and the immediate clinical courses of the complicated cases. In our studies we found a higher risk of conversion to open cholecystectomy in men—many of whom did not have a prodrome of symptoms. Therefore, did the authors note any sex differences in the complicated group with no prodrome of symptoms vs the other subgroup of complicated cases that had a short period of biliary symptoms? There is more we can learn here. Early referral will not help the patient who has no phase of biliary colic before a severe complication.

There is a caveat. The definitions of the following terms are very important to the accuracy of this study. These terms are “biliary colic” and “acute cholecystitis.” The hospital ICD-9-CM coders assign these diagnoses—do you trust them to do as good a job as you in determining that the patient was symptomatic with biliary colic or that the patient had acute cholecystitis? We are developing a Web-based Outcomes Initiative through SAGES [Society of American Gastrointestinal Endoscopic Surgeons]. In this burgeoning outcomes database base ICD-9 codes are assigned by the surgeon at the time of surgery for their own gall bladder, ingunal hernia, and antireflux procedures. We believe this database will be more accurate than the population-based databases of Connecticut, New York, etc, that are dependent on ICD-9 coders for accuracy.

Finally, let us return to the question: why is there a high incidence of complicated gallstone disease in this study? Is it a falsely high incidence because of inaccurate coding? What about the delay in patients with biliary colic? The answer is the same as the reason why cholecystectomy has been more frequently used in the laparoscopic era—the threshold of the patient and the referring physician for surgery. Today the group from UCSF tells us that cholecystectomy is not used soon enough because they found too many complicated cases. What is the cause for this surprisingly high incidence of complicated cases?

The authors need to differentiate between those cases of gallstones with complications and those that are symptomatic. I wonder if they can differentially diagnose stones in the common duct vs those in the gallbladder. In one case it is cholelithiasis and in the other cholecystalgia. The whole term “biliary colic,” meaning pertaining to the colon, is rather out of date. Would you address the semantics of this and whether your differentiation of complicated and uncomplicated might be symptomatic vs asymptomatic?

Lawrence A. Danto, MD, Stockton, Calif: At first look the results almost seem to be a no brainer, but the results in...
fact have tremendous socioeconomic implications. In California alone last year, 25,000 people lost access to health care delivery each month. The results of this study in great measure represent what happens to people who do not have access to health care delivery. That is probably the basic cause of delay that exists in our system. So my question is this: what strategies would the authors suggest to increase access to the system?

Jeffrey M. Pearl, MD, San Francisco, Calif: I have 2 questions. One is the timeframe that was picked for investigation. It is a time when there was a very heavy penetration of managed care in the state of California. I wonder if they were able to go back and look at a different period, say in the mid 1980s or mid 1970s using OSHPD data to see if managed care is playing a significant role in this delay. The second part of the question is, I believe OSHPD data only includes inpatients or admitted patients; it does not include outpatients procedures. I wonder if that adds any bias to the data.

Edward H. Phillips, MD, Los Angeles: The conclusion of this paper is very provocative, but as referred to already by Drs Organ and Collins, we should examine the flip side. That is, 25% of patients who are operated on for symptomatic gallstones still have their symptoms after surgery. The primary physician and the gastroenterologist is left with that large number of patients who are unhappy with cholecystectomy. I think that is the bias that prevents perhaps other symptomatic patients from being referred promptly. Determining who is really symptomatic is not always straightforward. We have to do a better job in defining what is truly a symptomatic patient though maybe that is an impossible task, but I think that until we can lower the 25% rate of persistent symptoms, we are going to have trouble with delayed referral for patients who truly are symptomatic and later are seen with complications.

Mark A. Vierra, MD, Stanford, Calif: The business about whether patients with symptomatic gallstones or asymptomatic gallstones should undergo operation changed with the study in the early 1980s when Gracie and Ransohoff did a decision analysis looking at a group of middle-aged university male professors. That is the origin of the notion that asymptomatic gallstones do not require operation. They subsequently revised that decision analysis looking at a couple of things that they had forgotten, such as gallbladder cancer and gallstone pancreatitis. Remember that patients do not come to see us without symptoms. So when we argue that we are inappropriately doing operations for gallstone disease, I think that is probably really not the case. The best decision analysis we have says that symptomatic gallstones probably warrant operation, and as we have seen, a lot of patients are being followed up for quite some time. There is at least one paper from the late 1980s looking at what happened before and after Gracie and Ransohoff published their article that documented a marked change in the referral patterns for cholecystectomy during that interval.

Another of my reservations has to do with the distinction between biliary colic and cholecystitis. The lecture that I give to the medical students is that perhaps the best way to distinguish the 2 is by a patient’s insurance status. (I say this partly facetiously). So for example, if you have a healthy young patient with 4 hours of abdominal pain in the emergency department and they live nearby, are reliable, and have good transportation, you may give them pain medication, send them home, and do their operation as an outpatient the next morning. On the other hand, if they have MediCal, you do not know whether their pain is going to go away, you have to admit them to the hospital. Otherwise, you send them home, submit a TARR [Treatment Authorization Request Referral], and it takes weeks to get anything done. I think the distinction between biliary colic and cholecystitis is difficult at best, and probably particularly unreliable based on ICD-9 codes.

Steven Stain, MD, Nashville, Tenn: I am not sure if the UCSF database or the state database can predict if patients with Medicaid are more likely to have complicated gallstone disease. Does your database allow you to distinguish between indemnity insurance or Medicaid?

Dr Mulvihill: Gallstone disease is such a lowly subject. All of the third-year medical students learn everything there is to know about gallstone disease, we think. Yet, we were surprised to see patterns of care that made us realize that we could do a better job. An anecdote that led us to this study was a physician of our own faculty who was admitted with gallstone pancreatitis and was advised by his internist that there was no need to consider cholecystectomy because it was a mild bout. He was going to get better in 2 or 3 days and go home. It struck us that there are either misconceptions or different attitudes amongst some of the internists about this subject that make us wonder whether we are all as educated as we think we are.

I appreciate all of the comments and will try to efficiently go through the questions. I appreciate all of the comments. Dr Traverso asked if there were any sex differences among the patients with or without complications. We found that the patients with complicated gallstone disease tended to be slightly older but there were no sex differences. Patients with biliary colic as the first presenting symptom who later developed a complication tended to be men. The patients who had the complication as their first sign of gallstone disease tended to be women.

He asked about the errors in coding. This is a significant issue in the statewide database. It has been shown that there are some errors in diagnosis coding in that database. But we are confident in our own data from UCSF because we had the complete clinical records on those patients. In terms of our conclusion about the delay, we were looking at data from our own hospital where we are confident about the accuracy.

Dr Collins asked about the challenge of the differential diagnosis, and I think that is clearly a problem. There are many patients with abdominal pain syndromes who do not have gallstone disease and, of course, the internist is faced with this problem in the office. We believe that patients with typical symptoms require fairly little in the way of a preoperative evaluation aside from an ultrasound. Patients with atypical symptoms such as bloating or isolated nausea require further investigation with Helicobacter pylori testing and endoscopy.

Dr Organ asked about the semantic differences about biliary colic vs acute cholecystitis. It sometimes is difficult clinically to differentiate a patient with a bad bout of biliary colic vs one with acute cholecystitis. In our study we defined the complications such as acute cholecystitis pathologically. Cholangitis and gallstone pancreatitis are usually clearly clinically.

Dr Danto asked a troubling question about strategies to increase the access of patients to care in California, and I am afraid I cannot answer. That is a difficult issue. It may play a role in the delay that we saw in this study.

Dr Pearl asked about the timeframe of this study. About 65% of California citizens during this study were part of a managed care health program. That could have an effect on the data. The OSHPD database includes only inpatient data, and I suspect that there could be variance among practice patterns in different hospitals where the patient with a laparoscopic cholecystectomy is counted as an admission or not.

Dr Phillips made the point that some patients remain symptomatic after cholecystectomy. This, of course, could lead to a referral bias on the part of the internist who manages these difficult patients after failed cholecystectomy. I agree that we should investigate those patients with atypical symptoms a
little more thoroughly. Drs Vierra and Stain asked questions regarding the Medicaid population. Our initial bias was that perhaps the medically indigent or Medicaid population was being hurt more in today’s environment than patients with higher paying insurance status, but our own data does not support that. It looks to us that payer status did not play a large role in predicting the presence or absence of complications of gallstone disease.

**Invited Critique**

When first asked by the editor to submit a critique of this study, I was supplied only with the title, and armed with this, I was confident I could trash and burn the work sufficiently to justify the editor’s confidence in me. Alas, my generally feisty mood rapidly dissipated on the review of the data that unarguably show the increased cost, in human and financial terms, of the delayed treatment of symptomatic gallstones. This is not the first study that has shown that physician delay, either rooted in medical ignorance or mandated by bureaucratic indifference, can lead to a higher incidence of complications in a group of patients who should sustain very little morbidity and negligible mortality if treated expeditiously at the onset of symptoms. These California data demonstrate that the cases of 44% of the patients treated for gallstones were complicated by the presence of acute cholecystitis or other sequelae of untreated gallbladder disease and that half of this number had premonitory biliary colic; therefore, almost one quarter of all patients could have been treated electively by laparoscopic cholecystectomy if early operation had been undertaken. If the California figures can be assumed to be representative, hundreds of millions of dollars and countless lives could be saved nationally by earlier intervention. One disturbing piece of data noted by the authors was that 25% of all elective cholecystectomies in California are still being performed as open procedures. In my opinion, this is an unacceptably high number which I suspect reflects a lack of expertise in performing laparoscopic cholecystectomy by a substantial number of surgeons practicing in that state. These data presented here throw down the gauntlet to physicians and surgeons, virtually demanding earlier laparoscopic intervention in all symptomatic patients. The medical and medicolegal implications of these data should be fully understood by practicing family physicians, internists, and gastroenterologists. Also, it should give pause to those politicians advocating a single governmental payer system in the United States as this will inevitably give rise, as noted by our friends north of the border, to rationing of care and long waiting lists for medical services. The accompanying article clearly shows that this represents inappropriate medical care for patients with symptomatic gallstones.

Jack Pickleman, MD
Maywood, Ill