Operative delay to laparoscopic cholecystectomy: Racking up the cost of health care

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BACKGROUND: Health care providers are increasingly focused on cost containment. One potential target for cost containment is in-hospital management of acute cholecystitis. Ensuring cholecystectomy within 24 hours for cholecystitis could mitigate costs associated with longer hospitalizations. We sought to determine the cost consequences of delaying operative management.

METHODS: The Nationwide Inpatient Sample (2003–2011) was queried for adult patients (≥16 years) who underwent laparoscopic cholecystectomy for a primary diagnosis of acute cholecystitis. Patients who underwent open procedures or endoscopic retrograde cholangiopancreatography were excluded. Generalized linear models (GLMs) were used to analyze costs for each day's delay in surgery. Multivariable analyses adjusted for patient demographics, hospital descriptors, Charlson comorbidity index, mortality, and length of stay.

RESULTS: We analyzed 191,032 records. Approximately 65% of the patients underwent surgery within 24 hours of admission. The average cost of care for surgery on the admission day was $11,087. Costs disproportionately increased by 22% on the second hospital day ($13,526), by 37% on the third day ($15,243), by 52% on the fourth day ($16,822), by 64% on the fifth day ($18,196), by 81% on the sixth day ($20,125), and by 100% on the seventh day ($22,250) when compared with the cost of care for procedures performed within 24 hours of admission. Subset analysis of patients discharged 24 hours or earlier from the time of surgery demonstrated similar trends.

CONCLUSION: After controlling for patient- and hospital-related factors, we noted significant costs associated with each day's delay in operative management. Cost containment practices for acute cholecystitis justify consideration of same-day or next-day surgery where the diagnosis is straightforward. (*J Trauma Acute Care Surg*. 2015;79: 15–21. Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Economic and value-based analysis, level III.

KEY WORDS: Cost; laparoscopic cholecystectomy; acute cholecystitis; delayed operative management.

As health care costs rise and third-party payers seek to limit unnecessary spending, physicians are increasingly responsible for their role in cost containment.[1] Simultaneously, surgeon reimbursement from third-party payers such as the Center for Medicare and Medicaid Services (CMS) is trending toward pay-for-performance and incentivized compensation plans in an effort to condense costs and improve efficiency.[2,3] The recent push toward health care reform and legislation has been largely motivated by the burgeoning cost of health care, bringing the issue of the US high spending to light.[4–6] Efforts such as the 2010 Affordable Care Act are postulated to have far-reaching implications but will take time to influence the costs seen among patients seeking care within the general population.[7]

One potential target for cost containment is in-hospital management of acute cholecystitis. Inflammatory gall bladder disease is one of the most common surgical disorders with more than 700,000 cholecystectomies performed per year in the United States.[8,9] For the last 20 years, laparoscopic cholecystectomy has been the favored operative technique because patients recover faster and costs are lower than those seen with open cholecystectomy.[10] Studies have previously reported improved survival benefit from immediate or same-day laparoscopic cholecystectomy.[11–13] Johansson et al.[11] found a significantly lower rate of complications and decreased costs for patients in Sweden who underwent the procedure on the day of admission when compared with patients who waited overnight. Similar data on the economic benefits of early intervention, which extrapolate to the US health care system, are largely lacking in the literature.

It is known that length of stay (LOS) influences hospital costs. Given that patients with acute cholecystitis frequently present with nonemergent, although necessary, operative indications, timing to the operating room for laparoscopic cholecystectomy may be arbitrary. Time delays may further incur significant, incremental cost impacts, a fact arguably unappreciated by many health care providers. To better elucidate the

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potential importance of these considerations, the study used a nationally representative sample of US patients to determine the cost consequences of delaying operative management of laparoscopic cholecystectomy.

PATIENTS AND METHODS

The National Inpatient Sample (NIS) is the largest all-payer inpatient database in the United States. It represents a 20% stratified sample of hospitals selected based on geographic region, ownership control, urban or rural location, teaching status, and number of hospital beds. It includes modifiers (weights) that enable extrapolation of the included patient population to a national scale. It is part of the Healthcare Cost and Utilization Project, sponsored by the Agency for Healthcare Research and Quality as part of the federal-state industry partnership initiative. The database consists of hospital data used for billing purposes and is essentially administrative in nature. The sampling frame consists of 90% of all hospital discharges. Available data elements include information on patient age, sex, race/ethnicity, primary payer, LOS, total charges, disposition, and up to 15 DRG International Classification of Diseases—9th Rev.—Clinical Modification (ICD-9-CM)–defined procedure and diagnosis codes.

Nine years of NIS data (2003–2011) were reviewed for patients 16 years and older with an ICD-9-CM primary diagnosis of acute cholecystitis (540, 540.1, and 575.0) and a procedure code for laparoscopic cholecystectomy (ICD-9-CM procedure codes 51.23 and 51.24). Only patients admitted via the emergency department with the diagnosis and procedure of interest were reviewed. Patients transferred in from similar nonfederal acute care hospitals and patients discharged to similar acute care facilities were excluded to ensure that each patient record represented a single complete hospital stay. Patients who underwent endoscopic retrograde cholangiopancreatography or whose operation was converted to an open cholecystectomy were excluded, as were patients with missing information on cost or other variables of interest. Costs were top-coded to the 99th percentile to reduce the effect of outliers on outcome assessment. Figure 1 shows the derivation of the final study population.

Information was collected on patient demographics (age, race/ethnicity, sex, median household income quartile for a patient's residential zip code, and insurance status), hospital characteristics (urban vs. rural location, teaching status, geographic region, and hospital bed size), weekend versus weekday admission, ICD-9-CM diagnostic codes, total charges, hospital-specific all-payer cost-to-charge ratios, lengths of stay following the procedure, mortality, and comorbidities as measured by the Charlson comorbidity index (CCI). Cost-to-charge ratios were developed using standardized hospital information on all-payer inpatient cost and charge reported by hospitals to the Center for Medicare and Medicaid Services. The CCI describes comorbidity and mortality risk calculated based on a predetermined weighted formula.[14,15] Age was categorized into the following groups: 16 to 25, 26 to 35, 36 to 45, 46 to 55, 56 to 65, 66 to 75, 76 to 85, and older than 85 years. Because of the prevalence of missing race/ethnicity data (approximately 20% in NIS), patients with missing race/ethnicity information were coded as "missing" and included in the final analysis. Race/ethnicity was classified as white, black, Hispanic, missing, or other. Median household income quartile for a patient's residential zip code was categorized by NIS according to annual income percentiles such that quartile 1 (Q1) always corresponded to percentiles 0 to 25, quartile 2 (Q2) to percentiles 26 to 50, quartile 3 (Q3) to percentiles 51 to 75, and quartile 4 (Q4) to percentiles 76 to 100 within a given year. In 2011, the predetermined cutoff points were $1 to $38,999 (Q1), $39,000 to $47,999 (Q2), $48,000 to $63,999 (Q3), and $64,000+ (Q4) in 2011 dollars. Insurance status was categorized as private primary payer, government primary payer, uninsured, and unknown. Geographic region was predetermined by NIS to include hospitals located in the Northeast, Midwest or North Central, South, and West. The number of short-term acute stay beds, classified by NIS to be either "small," "medium," or "large,"

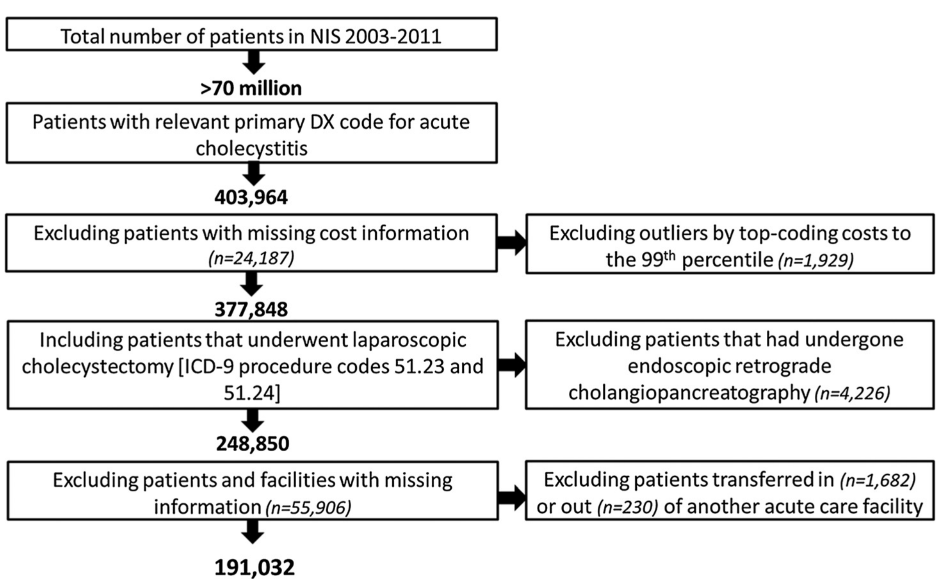


Figure 1. Flow diagram of patient inclusion/exclusion criteria.

determined hospital size based on predetermined values that vary by geographic region considered. Hospitals were also described based on rural versus urban location and teaching versus nonteaching status. The day of a patient's procedure was calculated as the difference between a patient's operation date and the date of his or her hospital admission. Categorized, it served as the primary independent or explanatory variable of interest. Patients operated on within 24 hours of admission (Day 1) were compared with patients operated on after 24 hours (subdivided into patients operated on during Days 2, 3, 4, 5, 6, and 7 as well as patients operated on after >7 days).

The primary outcome variable was cost, calculated by multiplying total charges with corresponding hospital-specific cost-to-charge ratios. Costs from 2003 to 2011 were adjusted for inflation per year and converted to 2013 dollars using appropriate Consumer Price Indices. Age group of 16 years to 25 years, female, white race/ethnicity, lowest CCI (0), lowest income quartile, private insurance, weekday admission, small bed size, Southern geographic region, rural location, nonteaching status, and patients who survived while in the hospital were used as reference categories for the respective characteristics. To compare the potential association of delayed receipt of surgery on overall costs, unadjusted and risk-adjusted, accounting for potential confounding due to these characteristics, GLMs were used to estimate predicted mean costs for each day of admission (gamma family, link log, and calculation of average marginal effects). Analogous secondary assessment of a subset of patients discharged within 24 hours was also performed.

A continuing source of concern was that patients who did not undergo surgery on the first day (late receipt of surgery) were meaningfully different from patients receiving surgery within 24 hours (early receipt of surgery) in ways not captured by the initial linear specification. To better assess these important differences, additional sensitivity analysis was conducted using propensity scores to estimate each patient's likelihood of undergoing "early surgery" on the same day as his or her admission. Based on these results, initial GLM analyses were repeated among a patient population restricted to include only the 92,245 patients (weighted to represent 478,512 patients; 358,071 early and 120,441 delayed surgery patients) with predicted propensities of having undergone early surgery (values greater than the overall median value of 0.6860). Propensity scores were calculated by temporarily dichotomizing the study population into two groups: patients who underwent early surgery (within 24 hours of admission) and those who underwent delayed operations (≥24 hours), accounting for differences in baseline characteristics including age, sex, race/ethnicity, CCI, insurance status, weekend admission, and income quartile. All statistical analyses were conducted using STATA/MP version 12.0 (StataCorp, College Station, TX). Statistical significance was defined as a two-sided $p < 0.05$. The Johns Hopkins University School of Medicine Institutional Review Board approved the study.

RESULTS

The final study population included 191,032 patient encounters, weighted by application of NIS population weights to represent 932,653 national records with complete admission and discharge information. From the nationally weighted discharge record pool, it was determined that 65.5% of the patients underwent laparoscopic cholecystectomy within 24 hours of presentation (Table 1 provides observed frequencies and weighted percentages for the patient population). Half (50.3% of the patients) were discharged within 24 hours of surgery, irrespective of operative timing or preoperative course. The mean (SD) age of the patients was 51.1 (19.1) years, with a slight female preponderance of 63.7%. The majority was white at 56.4%. Of the patients, 18.2% were Hispanic and 8.0% were black. Only 12.0% of the patients were uninsured. Table 2 provides an observed description of the demographic case mix and hospital-level characteristics of the overall study population and of the dichotomized model.

The mean (SD) unadjusted cost for laparoscopic cholecystectomy was $12,655 ($7,913), regardless of time to operation or LOS. The mean per-person cost of laparoscopic cholecystectomy on hospital Day 1 was $11,087 (95% confidence interval [CI], $11,059–$11,115), adjusting for potential confounders. Costs increased by 22% for surgeries taking place on the second day of hospital admission ($13,526; 95% CI, 13,463–$13,588), by 37% on the third ($15,243; 95% CI, 15,142–$15,343), by 52% on the fourth ($16,822; 95% CI, 16,668–$16,976), by 64% on the fifth ($18,196; 95% CI, 17,966–$18,427), by 81% on the sixth ($20,125; 95% CI, 19,785–$20,465), and by 100% on the seventh day ($22,250; 95% CI, 21,773–$22,726), when compared with the cost of care for procedures performed within 24 hours of admission. Higher overall mean costs were seen for procedures delayed each subsequent day. Figure 2 demonstrates increased cost resulting from each day's delay in surgery. Subset analysis on patients discharged within 24 hours of surgery showed an overall mean cost of $8,552 (95% CI, 8,526–$8,579). Propensity scores applied to the sensitivity analysis showed analogous increases in risk-adjusted mean costs with each additional hospital day, as shown in Figure 3.

The median hospital LOS post procedure was 1 day (interquartile range [IQR], 1–3). The median LOS in the early group (≤24 hours) was 1 day (IQR, 1–2) compared with 2 days (IQR, 1–3) for patients in the late, delayed group (>24 hours). The crude mortality rate for patients overall was 0.3%. Fewer patients who underwent surgery within 24 hours of admission died compared with patients with delayed receipt of surgery (0.20% vs. 0.60%, $p < 0.05$).

TABLE 1. Day of Surgical Receipt (Observed Frequencies and Weighted Percentages)

Procedure Day	n (%)
1	125,288 (65.5)
2	31,416 (16.5)
3	15,115 (7.9)
4	8,092 (4.3)
5	4,467 (2.3)
6	2,465 (1.3)
7	1,507 (0.8)
>7	2,682 (1.4)
Overall	191,032 (100.0)

DISCUSSION

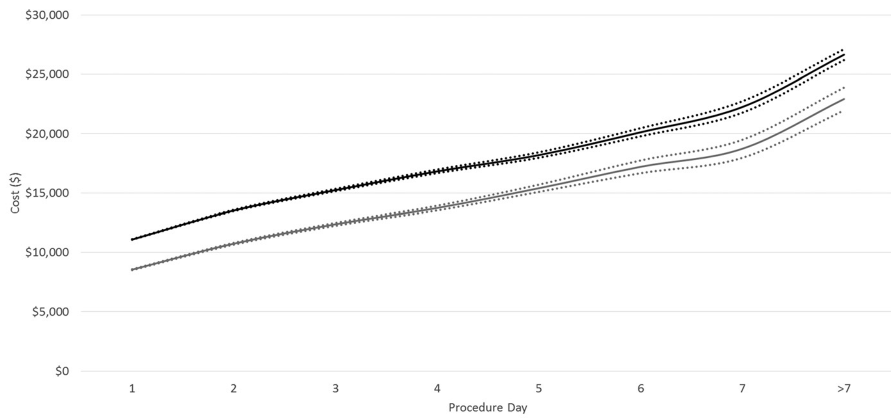
The current analysis showed that prolonged in-hospital time relating to awaiting surgical management of acute cholecystitis significantly and disproportionally increased total cost. Operative delays of more than 48 hours had significant cost consequences without clear justification for the delay. No differences in morbidity or mortality were noted when uncomplicated cholecystitis was treated early or late; however, there was a cost benefit when LOS was brief and laparoscopic cholecystectomy was pursued within hospital Days 1 or 2. For each day of extended hospital stay, incremental costs were incurred despite a lack of evidence of the operation or postoperative course being more complex. Postoperative LOS averaged 24 hours despite the length of hospitalization preoperatively; extending preoperative in-hospital time did not seem justified in the model.

Previous studies have shown that early cholecystectomy is associated with improved costs by directly reducing a patient's LOS.[11,16] Our findings corroborate this result and further show that each day's delay is associated with disproportionally higher costs. Despite debate on optimal timing to laparoscopic

TABLE 2. Case Mix of the Study Population and Comparison of Patients With Early Versus Late Receipt of Surgery (Observed Frequencies and Weighted Percentages)

Demographics	Overall (n = 191,032)	Early Surgery (≤24 h) (n = 125,288)	Delayed Surgery (>24 h) (n = 65,744)	p*
Age, mean (SD)	51.1 (19.1)	48.5 (18.3)	55.9 (19.7)	<0.001
Female, n (%)	121,148 (63.7)	81,045 (64.7)	40,103 (61.0)	<0.001
Race, n (%)				
White	107,488 (56.4)	70,853 (56.6)	36,635 (55.7)	0.001
Black	15,198 (8.0)	8,698 (6.9)	6,500 (9.9)	<0.001
Hispanic	34,824 (18.2)	22,825 (18.2)	11,999 (18.3)	0.859
Asian	3,505 (1.8)	2,293 (1.8)	1,212 (1.8)	0.837
Other	7,092 (3.8)	4,596 (3.7)	2,496 (3.8)	0.159
Missing	22,925 (11.9)	16,023 (12.8)	6,902 (10.5)	<0.001
Insurance status, n (%)				
Private	79,883 (41.8)	58,387 (46.6)	21,496 (32.7)	<0.001
Government	87,806 (46.0)	50,550 (40.4)	37,256 (56.7)	<0.001
Uninsured	22,915 (12.0)	16,049 (12.8)	6,866 (10.4)	<0.001
Unknown	428 (0.2)	302 (0.2)	126 (0.2)	0.030
Weekend admission, n (%)	49,102 (25.7)	28,811 (23.0)	20,291 (30.9)	<0.001
Income quartile, n (%)				
First	47,533 (25.0)	28,829 (23.0)	18,704 (28.5)	<0.001
Second	47,666 (25.0)	30,967 (24.7)	16,699 (25.4)	0.001
Third	47,883 (24.9)	32,348 (25.8)	15,535 (23.6)	<0.001
Fourth	43,861 (22.9)	30,595 (24.4)	13,266 (20.2)	<0.001
Unknown	4,089 (2.2)	2,549 (2.0)	1,540 (2.3)	<0.001
Hospital region, n (%)				
Northeast	35,258 (19.0)	22,151 (17.7)	13,107 (19.9)	<0.001
Midwest	27,464 (14.7)	18,874 (15.1)	8,590 (13.1)	<0.001
South	82,454 (42.8)	51,342 (41.0)	31,112 (47.3)	<0.001
West	45,856 (23.5)	32,921 (26.3)	12,935 (19.7)	<0.001
Urban location, n (%)	167,403 (87.7)	109,686 (88.0)	57,717 (87.8)	0.001
Teaching hospital, n (%)	65,589 (34.6)	42,123 (33.8)	23,466 (35.7)	<0.001
Hospital bed size, n (%)				
Small	23,463 (11.8)	16,170 (12.9)	7,293 (11.1)	<0.001
Medium	51,390 (26.8)	34,006 (27.1)	17,384 (26.4)	0.001
Large	115,291 (61.0)	74,521 (59.5)	40,770 (62.0)	<0.001
Unknown	888 (0.5)	591 (0.5)	297 (0.5)	0.542
CCI, n (%)				
0	130,357 (68.2)	92,867 (74.1)	37,490 (57.0)	<0.001
1	38,784 (20.3)	22,800 (18.2)	15,984 (24.3)	<0.001
2	12,347 (6.5)	5,898 (4.7)	6,449 (9.8)	<0.001
≥3	9,544 (5.0)	3,723 (3.0)	5,821 (8.9)	<0.001
LOS, median (IQR)	1 (1–3)	2 (1–3)	5 (3–7)	<0.001
Mortality, n (%)	612 (0.3)	249 (0.2)	363 (0.6)	<0.001

*Two-sided $p < 0.05$ considered statistically significant; calculated using Pearson χ^2 tests for dichotomous variables and a one-way analysis of variance for normally distributed continuous age.



Overall ($ [95% CI])	11,087 [11,059-11,115]	13,526 [13,463-13,588]	15,243 [15,142-15,343]	16,822 [16,668-16,976]	18,196 [17,966-18,427]	20,125 [19,785-20,465]	22,250 [21,773-22,726]	26,649 [26,199-27,098]
Stay ≤ 24 hours ($ [95% CI])	8,552 [8,526-8,579]	10,742 [10,676-10,808]	12,375 [12,260-12,491]	13,735 [13,545-13,925]	15,398 [15,096-15,700]	17,207 [16,670-17,745]	18,728 [17,963-19,492]	22,930 [21,964-23,895]

Figure 2. Risk-adjusted predicted mean cost for each procedure day (overall) and among patients discharged within 24 hours of surgery (patients were assumed to have no ongoing issues requiring prolonged hospital stays).

cholecystectomy, it is likely that patients are being delayed longer than clinically indicated for a variety of reasons. Surgeon and staff resource limitations, constraints of the operating room resources, and correlation of patient symptoms to presentation all influence delays to laparoscopic cholecystectomy, which translate to increased costs and extended lengths of stay for patients. The average postoperative stay following laparoscopic cholecystectomy is 24 hours, emphasizing the lack of advantage to long preoperative LOS.[16] Delays in operative management have not been directly attributed to perioperative morbidity, complications, or mortality; however, evidence exists that high-volume, well-resourced centers experience more complications following nighttime laparoscopic cholecystectomy.[17] Consideration should be given to resource availability when scheduling these cases with attention to limiting delay. The only true emergent indication for cholecystectomy is overt sepsis, and these patients more often undergo immediate open cholecystectomy or interval operation following use of a percutaneous tube for source control.[18] In most cases, patients with acute cholecystitis can be temporized to operative convenience, thus, increasing operative timing.

In cases where patient morbidity necessitates preoperative optimization, it may be more economical to obtain clearance and schedule the procedure as an outpatient operation to limit both the preoperative and postoperative lengths of stay. Cochrane reviews on the subject have shown no difference in major outcomes for people undergoing early versus late operations, including conversion to open operation, return to work, and postoperative morbidity and mortality.[19] On the basis of these findings, there seems to be limited reason to suspect that the reason for a patient's delayed receipt of laparoscopic cholecystectomy will affect the outcomes that a patient experiences. It could, however, influence cost. Significant baseline differences in patients undergoing early versus delayed surgery were reported in our sample. While the actual reason for delayed receipt of operative intervention is beyond

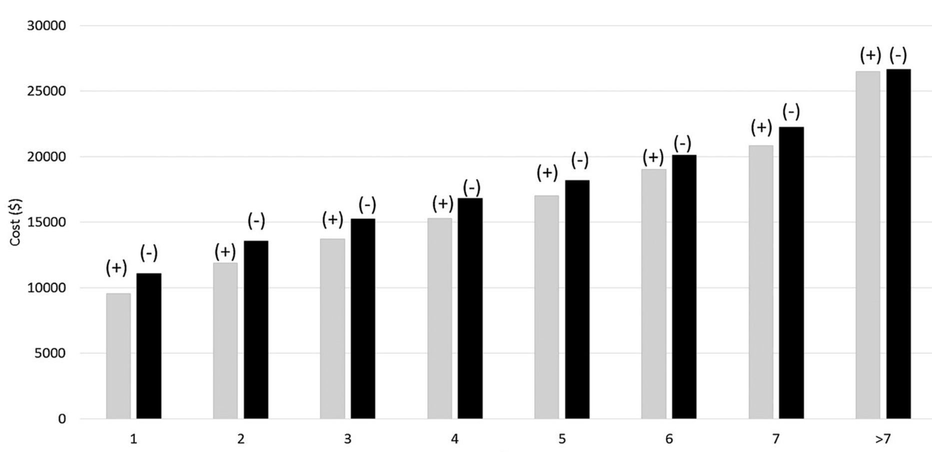


Figure 3. Comparison of risk-adjusted predicted mean costs of surgery overall (+) and among a restricted population with higher than median propensity of having undergone surgery on the same day as admission (−).

the scope of the data to assess, implementation of risk adjustment and secondary assessment using propensity scores to account for patients who could have undergone operations earlier (based on available information) did not appreciably change the noted increase in incremental costs. Future studies are warranted to further explore how various indicators for delayed receipt of care influence specific aspects of cost.

The time at which the patient decides to present to the emergency department with symptoms is an important factor in the management of cholecystitis.[20] Patients who present days after the onset of symptoms pose a surgical dilemma, since the ongoing inflammatory response yields a more difficult operative field.[21] Late operations reportedly result in higher conversion rates, more postoperative infections, and longer hospital stay.[22,23] It is possible that experience with difficult gallbladders influences surgeon timing to operation. Other factors that may contribute to delays include the practice of using antibiotics to "cool down" inflammatory responses, surgeon availability, time of admission (day vs. night), or admitting day of the week (weekend vs. weekday presentation). System modification and resource availability could enhance access and allow for faster operative intervention.

Cost and time to operative management have been shown to be decreased in acute care surgery (ACS) models where hospital- or system-based barriers are eliminated.[24] Proponents of ACS models tout the easy accessibility of patients to their surgeons and highlight the efficiency of these teams in caring for emergencies that were previously designated to private, general, or other specialized surgical services, juggling elective operations and necessary but nonemergent cases. With the expansion of ACS programs across the country, urgent operative management of uncomplicated surgical problems would be expected to be streamlined—a notion largely supported by the available literature. For example, ACS teams that take in-house call have improved time to surgical intervention when compared with on-call surgeons where call is taken from home.[25] Time to cholecystectomy was also reduced on ACS teams.[26] These findings argue for comprehensive care that focuses on efficiency of surgical management, bypassing time constraints of surgeons with elective, daytime practices.

Despite the finding of disproportionately increasing costs and the important impetus to carefully manage surgical timing in treatment decisions, there are several limitations to the study, which need to be considered. One notable weakness involves the study's reliance on retrospective data, which does not allow us to discern a surgeon's judgment about the merits and related timing of a given case. We have no information regarding the severity of cholecystitis at presentation, and we have no real-time view of the patient other than the included comorbidities and vital signs. However, by assaying the NIS in the manner that we did, we were able to study a large, nationally representative group of patients using readily available data thought to yield valid results for high-revenue invasive procedures, such as the type considered here.[27,28] The study made several presumptions. One was that laparoscopic cholecystectomies performed within 72 hours of admission could have been safely performed at 24 hours or 48 hours because the underlying patient characteristics and ultimate postoperative LOS were unchanged in the two groups. Cholecystitis in the stable patient population, such as the one we evaluated, likely does not require extensive testing, preoperative clearance, or other interventions—the disease, diagnosis, and treatment are straightforward and well defined, so spending more time in the aforementioned endeavors is not justified. Another was that operative time availability and surgical resources were not limiting factors; unfortunately, in most centers, operations that are not urgent are not prioritized, and time is wasted awaiting the availability of necessary operative resources. Future studies would do well to consider the need to balance the availability of the surgeon, support staff, and anesthesiology teams, all of whom play a role in the timing to operation.

Researchers outside the United States have shown hypothetical cost containment in early cholecystitis, despite being criticized for small sample size and failure to account for important patient-related factors.[15–17] In all cases, earlier cholecystectomies cost less. The present results are the first to demonstrate cost differences using a robust, nationally representative sample and the first to show that incurred costs per additional day of inpatient stay disproportionately increase. Similar to previous studies from regional health care systems,[9,11–13,16,17,19,21–23,29,30] our results reveal that among a large American cohort of patients, the findings are consistent and statistically significant: delays to operative management cost more. Related literature indicates that antibiotic therapy does not greatly influence postoperative infection rates,[31] suggesting that surgeons may not be justified in delaying operative care simply for the sake of antibiotic use. Further studies are warranted to determine the veracity of this observation.

On the basis of the findings presented here and what was previously known, we recommend that cholecystitis remain a priority for early operation. Clinically straightforward, nonemergent cholecystitis should be handled early to minimize cost. In the absence of postoperative complications, hospitalization following operative management of cholecystitis is brief.[32,33] It is, therefore, assumed that the sooner an operation can be completed, the shorter a patient's LOS is,[32,33] and correspondingly, the lower are his or her costs. Where clinically reasonable to do so, application of such an approach is likely to dramatically curtail costs otherwise incurred when straightforward cholecystitis is not managed immediately.

AUTHORSHIP

A.A.S., A.H.S., D.A.S., E.R.H., E.B.S., S.S. and D.T.E. were responsible for conceiving the study. A.A.S. and L.H.N. contributed towards dataset generation and analysis. A.A.S., A.H.S., C.K.Z., D.A.S., C.G.V. and D.T.E. made significant contributions in the writing of the manuscript. A.A.S., A.H.S., D.A.S., C.K.Z. and D.T.E. reviewed the manuscript and provided valuable insight. All authors have approved the final version of the manuscript for publication.

DISCLOSURE

The authors declare no conflicts of interest.

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