

The Risk Paradox: Use of Elective Cholecystectomy in Older Patients Is Independent of Their Risk of Developing Complications

Taylor S Riall, MD, PhD, FACS, Deepak Adhikari, MS, Abhishek D Parmar, MD, MS, Suzanne K Linder, PhD, Francesca M Dimou, MD, Winston Crowell, BA, Nina P Tamirisa, MD, Courtney M Townsend Jr, MD, FACS, James S Goodwin, MD

- BACKGROUND:** We recently developed and validated a prognostic model that accurately predicts the 2-year risk of emergent gallstone-related hospitalization in older patients presenting with symptomatic gallstones.
- STUDY DESIGN:** We used 100% Texas Medicare data (2000 to 2011) to identify patients aged 66 years and older with an initial episode of symptomatic gallstones not requiring emergency hospitalization. At presentation, we calculated each patient's risk of 2-year gallstone-related emergent hospitalization using the previously validated model. Patients were placed into the following risk groups based on model estimates: <30%, 30% to <60%, and \geq 60%. Within each risk group, we calculated the percent of elective cholecystectomies (\leq 2.5 months from initial episode) performed.
- RESULTS:** In all, 161,568 patients had an episode of symptomatic gallstones. Mean age was 76.5 ± 7.3 years and 59.9% were female. The 2-year risk of gallstone-related hospitalizations increased from 15.9% to 41.5% to 65.2% across risk groups. For the overall cohort, 22.3% in the low-risk group, 20.9% in the moderate-risk group, and 23.2% in the high-risk group underwent elective cholecystectomy in the 2.5 months after the initial symptomatic episode. In patients with no comorbidities, elective cholecystectomy rates decreased from 34.2% in the low-risk group to 26.7% in the high-risk group. Of patients who did not undergo cholecystectomy, only 9.5% were seen by a surgeon in the 2.5 months after the initial episode.
- CONCLUSIONS:** The risk of recurrent acute biliary symptoms requiring hospitalization has no influence, or even a paradoxical negative influence, on the decision to perform elective cholecystectomy after an initial symptomatic episode. Translation of the risk prediction model into clinical practice can better align treatment with risk and improve outcomes in older patients with symptomatic gallstones. (J Am Coll Surg 2015;220:682–690. © 2015 by the American College of Surgeons)

Disclosure Information: Nothing to disclose.

Support: Study was supported by grants from the UTMB Clinical and Translational Science Award #UL1TR000071, NIH T-32 Grant #5T32DK007639, and AHRQ Grant #1R24HS022134. Drs Riall, Adhikari, Dimou, and Tamirisa are supported by the Cancer Prevention Research Institute of Texas, RP1400020.

Presented at the Southern Surgical Association 126th Annual Meeting, Palm Beach, FL, November 30–December 3, 2014.

Received December 8, 2014; Accepted December 9, 2014.

From the Departments of Surgery (Riall, Adhikari, Parmar, Linder, Dimou, Crowell, Tamirisa, Townsend) and Internal Medicine (Goodwin), The University of Texas Medical Branch, Galveston, TX, the Department of Surgery, The University of California, San Francisco-East Bay, Oakland, CA (Parmar, Tamirisa), and the Department of Surgery, The University of South Florida, Tampa, FL (Dimou).

Correspondence address: Taylor S Riall, MD, PhD, FACS, Department of Surgery, University of Texas Medical Branch, 301 University Blvd, Galveston, TX 77555-0541. email: tsriall@utmb.edu

The prevalence of gallstones increases with age from approximately 8% of people younger than 40 years of age to >50% of people 70 years and older.¹ Gallbladder disease is the most common cause of acute abdominal pain in older patients and accounts for one third of abdominal operations in patients older than 65 years.^{1,2} Left untreated, approximately 1% to 4% of patients per year will have symptoms due to their gallstones.^{3–11} Once symptoms occur, acute cholecystitis will develop in approximately 14% of patients, gallstone pancreatitis will develop in 5% of patients, and common duct stones will develop within a year in 5% of patients.¹²

Current guidelines recommend elective cholecystectomy to prevent gallstone-related complications in

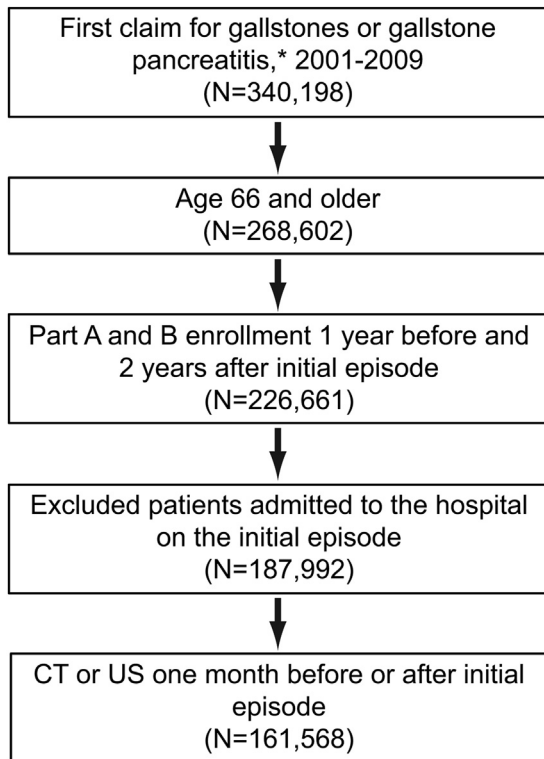


Figure 1. Cohort selection. Inclusion criteria: symptomatic cholelithiasis defined by primary diagnosis of ICD-9-CM code 574 of 575 or primary diagnosis of acute pancreatitis (577.0) and a secondary diagnosis of 574 or 575; patients aged 66 years and older; patients with Medicare Part A and Part B 1 year before and 2 years after the initial episode; patients not admitted to the hospital on the incident episode; and patients who underwent CT and/or ultrasound (US) in the month before or after diagnosis were included.

patients with symptomatic gallstones.¹² Despite these recommendations, older patients are less likely to undergo cholecystectomy.^{13,14} This might be due to the increased morbidity and mortality of elective cholecystectomy in older patients. However, if cholecystectomy is not performed, older patients are at an increased risk of gallstone-related complications developing. In addition, older patients are more likely to present with life-threatening complications from their gallstones; >20% of older patients with acute cholecystitis have gangrenous cholecystitis, empyema of the gallbladder, gallbladder perforation, or emphysematous cholecystitis at presentation.^{15,16} Once complications occur and urgent hospitalization and/or cholecystectomy is necessary, the morbidity and mortality are significantly increased.^{14,17-19}

We recently developed and validated a nomogram, PREOP-Gallstones (Predicting Risk of Complications in Older Patients with Gallstones) that accurately predicts the 2-year risk of acute gallstone-related hospitalization occurring in older patients who present with an initial

symptomatic episode of gallstones.¹⁴ Although the data demonstrate that fewer than one quarter of older patients with symptomatic gallstones undergo elective cholecystectomy,¹⁴ it is not known if current decisions about elective cholecystectomy in this population are based on risk. The goals of this study were to apply the model in a unique cohort of older patients and evaluate whether the decision to perform cholecystectomy was associated with the risk of 2-year gallstone-related hospitalization.

METHODS

This study was determined to be exempt from review by the IRB at the University of Texas Medical Branch.

Data source

We used 100% Texas Medicare claims data from 2000 to 2011, including inpatient claims (MEDPAR [Medicare Provider Analysis and Review]), physician billing claims (Carrier files), and outpatient claims (Outpatient Standard Analytic File).²⁰ Medicare claims data include patient demographic information, enrollment information, outpatient visits, physician services, and hospital admissions.²¹

Cohort selection

We used identical methodology to our previous article to identify a cohort of older patients with symptomatic gallstones who were eligible for elective cholecystectomy.²²

The cohort selection is illustrated in Figure 1. We identified all patients who were admitted to a hospital, saw a physician in the outpatient setting, or visited an emergency department (ED) for a primary diagnosis of gallstone disease between 2001 and 2009. The ICD-9-CM codes 574* or 575* capture all gallstone disease (Table 1). A patient was considered to have gallstone pancreatitis if he or she had a primary diagnosis of acute pancreatitis (ICD-9-CM 577.0) and a secondary diagnosis of ICD-9-CM 574* or 575*, or vice versa.¹⁷ When patients had more than one claim for gallstones, the first claim was considered the “incident episode.”

Patients were included if they were aged 66 years or older and had Medicare Parts A and B fee-for-service and no HMO for 1 year before and 2 years after the incident claim, or until death. This enabled us to identify incident cases (no cases in the previous year), to identify patient comorbidities from the claims data the year before the incident episode, and to follow all patients for at least 2 years after the date of the incident episode. We excluded

*Denotes any number 0–9 in ICD-9-CM extension code, which specifies the diagnosis.

Table 1. International Classification of Diseases, 9th Revision, Clinical Modification Diagnosis and Current Procedural Terminology Codes

Description	ICD-9-CM diagnosis codes or CPT procedure codes
Cholecystectomy	CPT: 49310, 56340, 56342, 47562, 47564, 47600, 47610, 47612, 47620, 49311, 56341, 47563, 47605
Initial diagnosis	
Gallstone pancreatitis	577.0 and any secondary diagnosis starting with 574*/575* OR 574* or 575* and a secondary diagnosis code for pancreatitis
Acute cholecystitis	574.0*, 574.1*, 575.0*, 575.1*, 575.2*, 575.3*, 575.4*
Common bile duct stones	574.3*, 574.4*, 574.5*, 574.6*, 574.7*, 574.8*, 574.9*
Biliary colic/biliary dyskinesia	575.8*, 574.2*
Diagnostic tests	
Computed tomography	CPT codes 74150, 74160, 74170
Ultrasound	CPT codes 76705, 76700, 76770, 76705
Evaluation and management	CPT codes
Emergency room evaluation	99281–99285
Physician visit	99201–99205, 99211–99215, 99241–99245

*Denotes any number 0–9 in ICD-9-CM extension code, which specifies the diagnosis.

patients who were admitted to a hospital or underwent cholecystectomy at the time of the incident episode.

To improve the specificity of our algorithm for identifying patients with symptomatic gallstones, we excluded patients if the diagnosis of gallstones was not associated with a claim for abdominal ultrasound or CT in the 1 month before or after the incident claim. Computed tomography and ultrasound were identified in the Carrier and Outpatient Standard Analytic File claims files using CPT codes (Table 1).

Patient and disease characteristics

Patient age was classified as 60 to 69 years, 70 to 74 years, 75 to 79 years, or 80 years and older. We also calculated mean ± SD age. We recorded sex, race/ethnicity (non-Hispanic white, black, Hispanic, other), Elixhauser comorbidity index, and diagnosis at initial claim for symptomatic cholelithiasis (biliary colic/biliary dyskinesia, acute cholecystitis, common bile duct stones, and gallstone pancreatitis; Table 1). Diagnosis was classified in a hierarchical manner as follows: any patient who

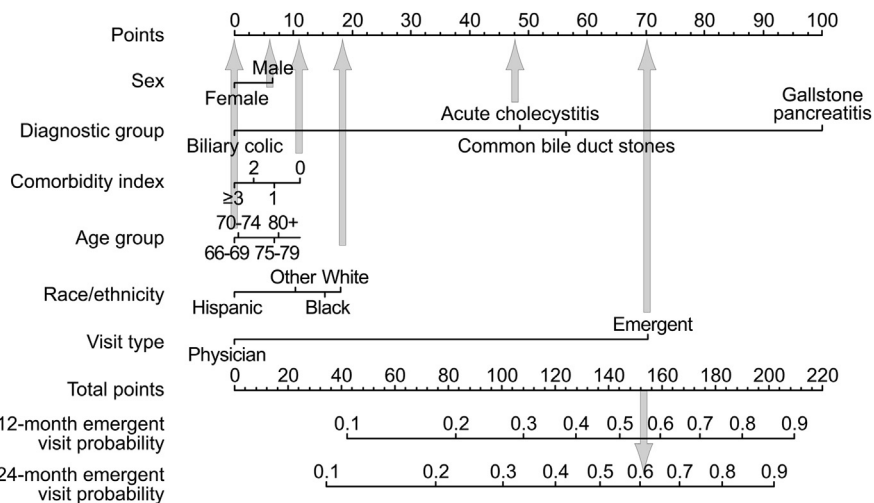


Figure 2. Sample of risk calculation using the PREOP-Gallstones (Predicting Risk of Complications in Older Patients with Gallstones) model nomogram. To use the nomogram, a vertical line is drawn from each factor to the corresponding position on the “Points” line. Points are summed for each factor and a line is drawn (downward arrow) from this position on the “Points” line to the “Emergent Visit Probability” lines to determine a patient’s 12-month and 24-month risk or emergent gallstone-related complications developing.¹⁴

Table 2. Cohort Characteristics and Cholecystectomy Rates Based on Characteristics

	Overall cohort	Undergoing cholecystectomy	p Value
Overall cohort, n (%)	161,568	35,967 (22.3)	—
Age, y, mean (SD)	76.5 (7.3)	74.1 (6.2)	<0.0001
Age group, y, n (%)			<0.0001
66–69	33,522 (20.8)	10,247 (30.6)	
70–74	38,966 (24.1)	10,521 (27.0)	
75–79	36,076 (22.3)	7,983 (22.1)	
80+	53,004 (32.8)	7,216 (13.6)	
Sex, n (%)			<0.0001
Female	96,809 (59.9)	23,261 (24.0)	
Male	64,759 (40.1)	12,706 (19.6)	
Race, n (%)			<0.0001
White	135,711 (84.0)	32,037 (23.6)	
Black	11,294 (7.0)	1,405 (12.4)	
Hispanic	11,316 (7.0)	1,998 (17.7)	
Other	3,247 (2.0)	527 (16.2)	
Elixhauser Comorbidity Index, n (%)			<0.0001
0	25,633 (15.9)	8,461 (33.0)	
1	31,991 (19.8)	9,919 (31.0)	
2	29,543 (18.3)	7,552 (25.6)	
≥3	74,401 (46.1)	10,035 (13.5)	
Initial diagnosis, n (%)			<0.0001
Biliary colic	109,043 (67.5)	20,271 (18.6)	
Acute cholecystitis	40,980 (25.4)	13,534 (33.0)	
Common bile duct stones	7,143 (4.4)	1,259 (17.6)	
Gallstone pancreatitis	4,402 (2.7)	903 (20.5)	
Location of initial visit			<0.0001
Physician visit	145,650 (90.2)	32,659 (22.4)	
Emergency room visit	15,918 (9.8)	3,308 (20.8)	

had a primary code for pancreatitis and a secondary diagnosis code for gallstones or vice versa was classified as having gallstone pancreatitis. The remaining patients were classified as having common duct stones, acute cholecystitis, or biliary colic based on the codes listed in Table 1. The number of Elixhauser comorbidities was used as a measure for patient comorbidity.²³ Type of initial visit was classified as ED or physician office visit based on the evaluation and management CPT codes for the visit (Table 1).

Risk groups

We used our previously validated algorithm²² to calculate the expected 2-year risk of emergent gallstone-related hospitalization for each patient in the cohort. The model, PREOP-Gallstones, uses patient sex, age group (66 to 69 years, 70 to 74 years, 75 to 79 years, 80 years and older), Elixhauser comorbidity score, diagnosis at the incident episode (biliary colic, acute cholecystitis, common

duct stones, gallstone pancreatitis), race/ethnicity, and visit type (ED vs physician visit) to predict the risk of gallstone-related readmissions.

Risk was calculated using characteristics defined at the incident episode. For example, a patient who is male, had acute cholecystitis at the incident episode, no comorbidities, was 60 to 69 years old, white, and was seen in an ED on the incident episode has a total score of 156, corresponding to a 2-year gallstone-related readmission risk of approximately 63% (Fig. 2). Patients were then categorized into the following risk groups: <30% risk (low risk), 30% to 60% risk (moderate risk), and >60% risk (high risk). Risk groups were not chosen based on equal numbers of patients, but on clinical relevance.

Outcomes variables

Our outcomes of interest included elective cholecystectomy rates by risk group. Elective cholecystectomy was defined as cholecystectomy within 2.5 months of the

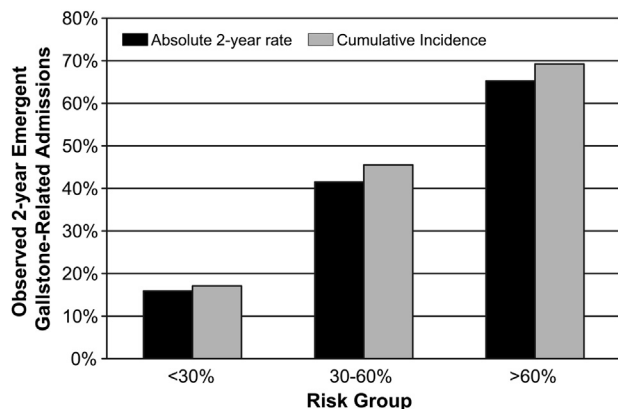


Figure 3. Two-year gallstone-related hospitalization rates in the 125,601 patients who did not undergo elective cholecystectomy in the 2.5 months after the incident symptomatic episode. The black bars represent the actual rates and the gray bars represent the cumulative incidence censored for patient deaths and elective cholecystectomy, when patients were no longer at risk for emergent gallstone-related hospitalization.

incident episode as in the previous report.²² We identified all cholecystectomies in the 2 years after the initial episode. If cholecystectomy was performed in the outpatient or inpatient setting within 2.5 months and was not classified as an urgent or emergent admission, the patient was classified as having undergone elective cholecystectomy. For each risk group, we calculated the percentage of patients who underwent elective cholecystectomy. We also calculated the percentage of patients who underwent elective cholecystectomy in the subgroup of patients who had no comorbidities. In patients who did not undergo cholecystectomy, we calculated the percentage of patients who were evaluated by a surgeon in the 2.5 months after the incident episode.

Statistical analysis

All means are reported as mean \pm SD and all categorical variables are reported as percentages. Chi-square tests were used to compare cholecystectomy rates across patient

characteristics and risk groups. To validate the risk prediction model, we calculated the actual 2-year observed gallstone-related acute hospitalizations from the date of the incident episode in patients who did not undergo elective cholecystectomy. We also used cumulative incidence curves to calculate gallstone-related acute hospitalization, censoring patients who died or underwent delayed elective cholecystectomy (after 2.5 months) and who were no longer at risk for emergent gallstone-related hospitalization.

Logistic regression models were used to identify factors associated with surgical evaluation. Any patient who underwent elective cholecystectomy and any patient who did not undergo elective cholecystectomy but was evaluated by a surgeon in the 2.5 months after the incident episode were considered to have undergone surgical evaluation. All statistical analyses were performed using SAS software, version 9.3 (SAS Institute). Statistical significance was accepted at the $p < 0.05$ level.

RESULTS

Patient characteristics and cholecystectomy rates

We identified 161,568 Medicare beneficiaries with an incident episode of symptomatic gallstones who were not admitted to a hospital on the incident episode and were potential candidates for an elective cholecystectomy. Mean age of the cohort was 76.5 ± 7.3 years. Sixty percent (59.9%) were female, 84.0% were white, and 15.9% had an Elixhauser comorbidity score of 0 (Table 2).

Elective cholecystectomy within 2.5 months of the incident episode was performed in 35,967 patients (22.3%). Table 1 demonstrates cholecystectomy rates by patient characteristics. Patients who were younger, female, white, and had fewer Elixhauser comorbidities were slightly more likely to undergo cholecystectomy. Beneficiaries who were coded as having acute cholecystitis on the incident episode were the most likely to undergo elective cholecystectomy, followed by beneficiaries with gallstone

Table 3. Patients Undergoing Elective Cholecystectomy by 2-Year Model-Predicted Risk of Requiring Gallstone-Related Hospitalization

Risk group	Total, n	Undergoing elective cholecystectomy, n (%)	p Value
Overall cohort (n = 161,568)			
<30%	147,950	33,042 (22.3)	0.002
30% to <60%	9,959	2,079 (20.9)	
>60%	3,659	846 (23.2)	
Patients with no comorbidities (n = 25,633)			
<30%	22,257	7,597 (34.2)	<0.0001
30% to <60%	2,297	576 (25.2)	
>60%	1,079	288 (26.7)	

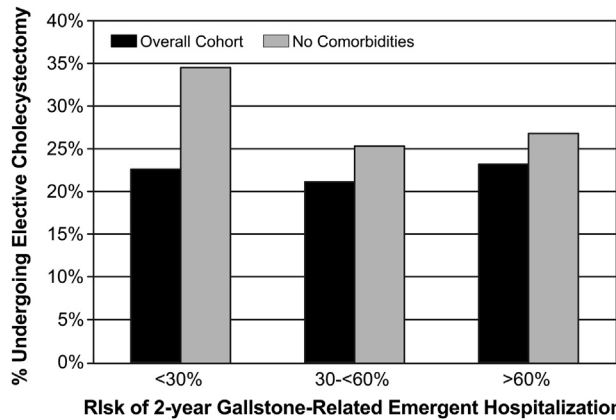


Figure 4. Percentage of patients undergoing cholecystectomy by risk group (<30%, 30%–60%, >60%). The black bars represent the percentage of the overall cohort ($n = 161,568$) and the gray bars represent the percentage of the 25,633 patients with no comorbidities undergoing cholecystectomy.

pancreatitis, biliary colic, and common duct stones. Patients seen in an ED on the incident episode were less likely to undergo cholecystectomy than those evaluated by a physician in the outpatient setting.

Risk groups and model validation

The PREOP-gallstones risk prediction model was applied to all patients in the cohort based on presenting characteristics during the incident episode. There were 147,950 patients (91.5%) with a model-predicted risk of 2-year gallstone-related emergent hospitalization of <30%; 9,959 (6.2%) had a 30% to 60% 2-year risk, and 3,659 (2.3%) had >60% 2-year risk.

The risk distribution was similar for the 125,601 patients who did not undergo elective cholecystectomy; 114,908 patients (91.5%) were in the low-risk group, 7,880 patients (6.3%) were in the moderate-risk group, and 2,813 patients (2.2%) were in the high-risk group. Of these 125,601 patients, 23,418 (18.6%) had an acute gallstone-related hospital admission in the 2 years after the incident episode. The actual 2-year acute gallstone-related hospitalizations for these patients were 15.9% ($n = 18,315$), 41.5% ($n = 3,269$), and 65.2% ($n = 1,834$) in the low-, moderate-, and high-risk groups, respectively, confirming the predictive ability of the model (Fig. 3). This increased to 17.1%, 45.5%, and 69.2%, respectively, using cumulative incidence curves with patients censored at death or after elective cholecystectomy (Fig. 3). The C-statistic in this cohort was identical to the original cohort (0.69). In patients who required emergent gallstone-related readmission, the in-hospital mortality was 6.2% and the complication rate was 53.1%.

Table 4. Multivariable Logistic Regression Model: Factors Associated with Surgical Evaluation in Older Patients Presenting with Symptomatic Gallstones

	Factors associated with surgical evaluation,* odds ratio (95% CI)
Age group, y	
66–69	1.00 (Ref)
70–74	0.89 (0.87–0.92)
75–79	0.74 (0.71–0.76)
80+	0.47 (0.46–0.49)
Sex	
Female	1.00 (Ref)
Male	0.76 (0.75–0.78)
Race	
White	1.00 (Ref)
Black	0.59 (0.65–0.62)
Hispanic	0.85 (0.81–0.89)
Other	0.62 (0.57–0.67)
Elixhauser comorbidities	
0	1.00 (Ref)
1	0.93 (0.90–0.96)
2	0.74 (0.71–0.77)
≥3	0.37 (0.36–0.38)
Initial diagnosis	
Biliary colic	1.00 (Ref)
Acute cholecystitis	2.26 (2.21–2.32)
Common bile duct stones	0.96 (0.90–1.02)
Gallstone pancreatitis	1.16 (1.08–1.25)
Location of initial visit	
Physician visit	1.00 (Ref)
Emergency department visit	0.75 (0.72–0.77)

*Surgeon evaluation defined as cholecystectomy or outpatient surgeon visit within 2.5 months of initial episode. Ref, reference value.

Elective cholecystectomy and risk

Cholecystectomy in older patients with symptomatic gallstones appeared to be independent of the risk of 2-year emergent gallstone-related hospital admission (Table 3). For the overall cohort, elective cholecystectomy was performed in 22.3% of the low-risk group, 20.9% of the moderate-risk group, and 23.2% of the high-risk group (Fig. 4; $p = 0.002$).

In a subset of patients with no Elixhauser comorbidities ($n = 25,633$) and, therefore, no clear contraindication to cholecystectomy, cholecystectomy rates actually decreased with increasing risk of emergent admission. Cholecystectomy was performed in 34.2% of patients in the low-risk group, 25.2% of patients in the moderate-risk group, and 26.7% of patients in the high-risk group (Fig. 4).

Surgical evaluation, defined as elective cholecystectomy or surgeon visit within 2.5 months of surgery, was

performed in 47,888 patients (29.5%). Only 11,921 of the 125,601 patients (9.5%) who did not undergo cholecystectomy were evaluated by a surgeon in the 2.5 months after the incident episode. This increased to only 13.8% in beneficiaries with no comorbidities.

Factors predicting surgical evaluation

In a multivariable model (Table 4), increasing Elixhauser comorbidities, white race, and uncomplicated biliary colic at presentation were associated with lower rates of surgical evaluation, consistent with the factors associated with lower risk of acute gallstone-related hospitalization. However, the other associations in the model were counter to the risk prediction model. Patients who were male (odds ratio [OR] = 0.76; 95% CI, 0.75–0.78), older (80 years and older vs 66 to 69 years; OR = 0.47; 95% CI, 0.46–0.49), and seen in an ED on the incident episode (OR = 0.75; 95% CI, 0.72–0.77) were less likely to undergo surgical evaluation, despite increased risk in these situations.

DISCUSSION

Using the previously validated PREOP-Gallstones risk prediction model, our data demonstrate that current decision making about elective cholecystectomy in older patients with symptomatic gallstones is independent of patients' risk of requiring 2-year acute gallstone-related hospitalization. In the overall cohort, elective cholecystectomy was performed in <25% of patients in the low- (<30%), moderate- (30%–60%), and high- (>60%) risk groups. Even more striking, in older patients with no comorbidities and no clear contraindication to cholecystectomy, elective cholecystectomy was performed in 35% of patients at lowest risk and only 27% of patients at highest risk for acute hospitalization. Receipt of cholecystectomy seems largely determined at the level of the primary care physician or nonsurgeon practitioners, as <10% of patients who did not undergo cholecystectomy were evaluated by a surgeon in the 2.5 months after the incident episode.

The 2002 Society of American Gastrointestinal and Endoscopic Surgeons' guidelines include symptomatic cholelithiasis as an indication for laparoscopic cholecystectomy, with few relative or absolute contraindications.²⁴ These recommendations are based on level II, grade A evidence and supported by a later Cochrane review demonstrating decreased risk for conversion, operative time, and length with early vs delayed cholecystectomy in the setting of symptomatic gallstones.¹² Despite these guidelines, only 22% of fee-for-service Medicare beneficiaries in Texas underwent elective cholecystectomy after an initial

episode of symptomatic gallstones, reflecting uncertainty about the risks and benefits of cholecystectomy in this population.

The PREOP-Gallstone nomogram accurately predicts the risk for 2-year gallstone-related acute hospitalization in patients with symptomatic gallstones. Created from a 5% national sample of Medicare patients, the model can be applied at the time of initial presentation in older patients with gallstones. In addition, the model is based on the following readily available patient characteristics: sex, age, race, comorbidity, diagnosis at initial presentation (biliary colic, acute cholecystitis, common duct stones, or gallstone pancreatitis), and whether the patient was seen by a physician or in an ED. The model performs well in this unique cohort of Texas Medicare beneficiaries with an observed 2-year hospitalization rate of 17%, 46%, and 69% in the <30%, 30% to 60%, and >60% risk groups, respectively.

In the PREOP-Gallstone model, the risk of gallstone-related hospitalization is largely driven by the diagnosis at initial presentation and the site of the initial visit, both of which are surrogates for the severity of the gallbladder disease. Consistent with the model, patients were more likely to be evaluated by a surgeon and undergo cholecystectomy if they had complicated disease on the initial presentation, suggesting that primary care physicians and surgeons recognize that the severity of disease increases the risk for future episodes. However, patients were less likely to be evaluated by a surgeon if they were seen in an ED on the incident episode. This seems counterintuitive, and might represent a system problem in which patients seen in the ED are not provided adequate follow-up. Patients who were white and had more Elixhauser comorbidities were less likely to be evaluated by a surgeon, which is also consistent with the risk prediction model. However, surgical evaluation decreased with increasing age despite data that demonstrate increased probability of gallstone-related complications in older patients and poorer outcomes once complications occur.

Once cholecystectomy is performed in the acute setting, the morbidity and mortality rise sharply.^{14,18,19,25-29} Although elective cholecystectomy can be performed safely in older patients, limited data in this population suggest higher rates of comorbid illness, higher conversion rates, longer lengths of stay, increased need for ICU care, and more complications in this population.^{18,19,30-34} In a recent study of 81 octogenarians, Lupinacci and colleagues¹⁹ reported a 34% mortality rate, 51% complication rate, and an 11-day mean length of stay when cholecystectomy was performed in the acute setting (n = 30); 77% of these patients required ICU care and the mean ICU stay was 9.4 days. This is in contrast to elective/nonurgent cholecystectomy

(n = 51), for which there was no mortality, a 12% to 14% complication rate, and a mean length of stay <3 days. Although 31% percent of patients in this group required ICU admission, the mean ICU stay was only 1 day. Likewise, Uecker and colleagues²⁹ reported outcomes in 53 patients 80 years and older who presented in the ED with acute complications of gallstones. Sixty-six percent required open cholecystectomy. The mortality rate was 13% and 28% had complications, with a mean length of stay exceeding 11 days. We similarly observed substantial morbidity and mortality in older patients admitted emergently after an initial symptomatic episode.

Based on these data, many authors recommend early, elective cholecystectomy in older patients as soon as they are found to be symptomatic. Our previous study,¹⁴ as well as the current study, demonstrate that this is not the current national practice. In addition, the data demonstrate that >80% of older patients who do not undergo elective cholecystectomy in the first 2.5 months do not require emergent hospitalization in the 2 years after the incident episode. This suggests that not all older patients necessarily benefit from elective cholecystectomy, but outcomes in the subset at highest risk could be improved with early cholecystectomy.

Current decisions about cholecystectomy are seemingly independent of their risk for complications developing. In the era of patient-centered outcomes research, the PREOP-gallstones risk prediction model provides a starting point for individualized care and shared decision making in older patients with gallstones. Translation of this model into clinical practice, especially at the level of the primary care physician, has the potential to improve outcomes by increasing surgical referrals and elective cholecystectomy rates in the patients at highest risk for gallstone-related hospitalization. This can avoid the morbidity associated with subsequent complicated gallstone disease in this vulnerable population. Likewise, it would allow physicians to avoid cholecystectomy in patients who are high surgical risk and at low risk for complications developing from their gallstones. Finally, in patients who are low surgical risk and have low to moderate risk of complications, where the decision for cholecystectomy is preference-sensitive, this risk information can help patients make a decision in the context of their symptoms, the impact of their symptoms on their quality of life, and their personal preferences.

CONCLUSIONS

To achieve this long-term goal of targeted surgical therapy for patients with high-risk gallstone disease, qualitative studies exploring physicians' decision-making process on

referral for (primary care physicians), or receipt of, cholecystectomy (surgeons) are necessary to understand the current range of physician practice and preferences in treating gallstone disease. Additional studies incorporating clinical data can improve the predictive ability of our model. Finally, input from primary care physicians, surgeons, and patients is needed to determine optimal strategies to incorporate the model into practice and to communicate individualized risk to patients.

Author Contributions

Study conception and design: Riall, Parmar, Linder, Dimou, Tamirisa, Townsend, Goodwin

Acquisition of data: Riall, Adhikari, Crowell, Goodwin
Analysis and interpretation of data: Riall, Adhikari, Linder, Dimou, Crowell, Tamirisa, Goodwin

Drafting of manuscript: Linder, Dimou, Crowell, Tamirisa

Critical revision: Townsend, Goodwin

Please note that coauthor Suzanne K Linder, PhD was a key member of our group and was instrumental to the development of the abstract and the article. She was killed in a car accident on October 9, 2014.

Acknowledgment: This article is dedicated to the memory of Suzanne Kneuper Linder, PhD (January 8, 1977–October 9, 2014). The coauthors recognize her for her contributions to this article and to the field of risk communication. She was a role model in her dedication to patient-centered outcomes research and her desire to improve quality and delivery of care. She is missed.

REFERENCES

1. Hendrickson M, Naparst TR. Abdominal surgical emergencies in the elderly. *Emerg Med Clin North Am* 2003;21:937–969.
2. Bugliosi TF, Meloy TD, Vukov LF. Acute abdominal pain in the elderly. *Ann Emerg Med* 1990;19:1383–1386.
3. Attili AF, De Santis A, Capri R, et al. The natural history of gallstones: the GREPCO experience. The GREPCO Group. *Hepatology* 1995;21:655–660.
4. Comfort MW, Gray HK, Wilson JM. The silent gallstone: a ten to twenty year follow-up study of 112 cases. *Ann Surg* 1948;128:931–937.
5. Festi D, Reggiani ML, Attili AF, et al. Natural history of gallstone disease: expectant management or active treatment? Results from a population-based cohort study. *J Gastroenterol Hepatol* 2010;25:719–724.
6. Friedman GD, Raviola CA, Fireman B. Prognosis of gallstones with mild or no symptoms: 25 years of follow-up in a health maintenance organization. *J Clin Epidemiol* 1989;42:127–136.
7. Gracie WA, Ransohoff DF. The natural history of silent gallstones: the innocent gallstone is not a myth. *N Engl J Med* 1982;307:798–800.

8. Halldestam I, Enell EL, Kullman E, Borch K. Development of symptoms and complications in individuals with asymptomatic gallstones. *Br J Surg* 2004;91:734–738.
9. Lund J. Surgical indications in cholelithiasis: prophylactic cholecystectomy: prophylactic cholecystectomy elucidated on the basis of long-term follow up on 526 nonoperated cases. *Ann Surg* 1960;151:153–162.
10. McSherry CK, Ferstenberg H, Calhoun WF, et al. The natural history of diagnosed gallstone disease in symptomatic and asymptomatic patients. *Ann Surg* 1985;202:59–63.
11. Thistle JL, Cleary PA, Lachin JM, et al. The natural history of cholelithiasis: the National Cooperative Gallstone Study. *Ann Intern Med* 1984;101:171–175.
12. Gurusamy KS, Samraj K, Fusai G, Davidson BR. Early versus delayed laparoscopic cholecystectomy for biliary colic. *Cochrane Database Syst Rev* 2008;[4]:CD007196.
13. Bergman S, Sourial N, Vedel I, et al. Gallstone disease in the elderly: are older patients managed differently? *Surg Endosc* 2011;25:55–61.
14. Parmar AD, Sheffield KM, Adhikari D, et al. PREOP-Gallstones: a prognostic nomogram for the management of symptomatic cholelithiasis in older patients. 2014 Jul 28. [Epub ahead of print].
15. Bedirli A, Sakrak O, Sozuer EM, et al. Factors effecting the complications in the natural history of acute cholecystitis. *Hepatogastroenterology* 2001;48:1275–1278.
16. Morrow DJ, Thompson J, Wilson SE. Acute cholecystitis in the elderly: a surgical emergency. *Arch Surg* 1978;113:1149–1152.
17. Riall TS, Zhang D, Townsend CM, et al. Failure to perform cholecystectomy for acute cholecystitis in elderly patients is associated with increased morbidity, mortality, and cost. *J Am Coll Surg* 2010;210:668–677. 677–669.
18. Fukami Y, Kurumiya Y, Mizuno K, et al. Cholecystectomy in octogenarians: be careful. *Updates Surg* 2014;66:265–268.
19. Lupinacci RM, Nadal LR, Rego RE, et al. Surgical management of gallbladder disease in the very elderly: are we operating them at the right time? *Eur J Gastroenterol Hepatol* 2013;25:380–384.
20. Center for Medicare & Medicaid Services. Available at: <http://www.cms.gov/>. Accessed December 30, 2012.
21. Research, Statistics, Data & Systems. Available at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Research-Statistics-Data-and-Systems.html>. Accessed December 30, 2014.
22. Parmar AD, Vargas GM, Tamirisa NP, et al. Trajectory of care and use of multimodality therapy in older patients with pancreatic adenocarcinoma. *Surgery* 2014;156:280–289.
23. van Walraven C, Austin PC, Jennings A, et al. A modification of the Elixhauser comorbidity measures into a point system for hospital death using administrative data. *Med Care* 2009;47:626–633.
24. Society of American Gastrointestinal and Endoscopic Surgeons. Guidelines for the clinical application of laparoscopic biliary surgery. Available at: <http://www.sages.org/publications/guidelines/guidelines-for-the-clinical-application-of-laparoscopic-biliary-tract-surgery/>. Accessed August 12, 2014.
25. Chau CH, Tang CN, Siu WT, et al. Laparoscopic cholecystectomy versus open cholecystectomy in elderly patients with acute cholecystitis: retrospective study. *Hong Kong Med J* 2002;8:394–399.
26. Guerriero O, D'Amore E, Di Meo E, et al. [Laparoscopic surgery for acute cholecystitis in the elderly. Our experience]. *Chir Ital* 2008;60:189–197.
27. Kirshtein B, Bayme M, Bolotin A, et al. Laparoscopic cholecystectomy for acute cholecystitis in the elderly: is it safe? *Surg Laparosc Endosc Percutan Tech* 2008;18:334–339.
28. Moyson J, Thill V, Simoens C, et al. Laparoscopic cholecystectomy for acute cholecystitis in the elderly: a retrospective study of 100 patients. *Hepatogastroenterology* 2008;55:1975–1980.
29. Uecker J, Adams M, Skipper K, Dunn E. Cholecystitis in the octogenarian: is laparoscopic cholecystectomy the best approach? *Am Surg* 2001;67:637–640.
30. Arthur JD, Edwards PR, Chagla LS. Management of gallstone disease in the elderly. *Ann R Coll Surg Engl* 2003;85:91–96.
31. Dubecz A, Langer M, Stadlhuber RJ, et al. Cholecystectomy in the very elderly—is 90 the new 70? *J Gastrointest Surg* 2012;16:282–285.
32. Hazzan D, Geron N, Golijanin D, et al. Laparoscopic cholecystectomy in octogenarians. *Surg Endosc* 2003;17:773–776.
33. Maxwell JG, Tyler BA, Rutledge R, et al. Cholecystectomy in patients aged 80 and older. *Am J Surg* 1998;176:627–631.
34. Pavlidis TE, Marakis GN, Symeonidis N, et al. Considerations concerning laparoscopic cholecystectomy in the extremely elderly. *J Laparoendosc Adv Surg Tech A* 2008;18:56–60.

Discussion



DR JOHN CHRISTEIN (Birmingham, AL): Dr Riall, your clinical research team has often published on the use of large databases to examine important public health issues. This manuscript is no exception and unique, as it approaches a topic most of us as general surgeons treat every week. As the population ages, we will see symptomatic cholelithiasis in older patients more and more frequently.

In this study, you have applied your validated Predicting Risk of Complications in Older Patients with Gallstones (PREOP-Gallstones) model to older patients with cholelithiasis, in particular the groups undergoing and those not undergoing cholecystectomy on an elective basis after symptoms have presented.

A few questions:

1. In your analysis of the elective cholecystectomy group, and of those who did not undergo an elective cholecystectomy within the 2.5 months after the initial event, was there anything specific about these patients that would have led us to recommend an operation during their first admission? In other words, when should we operate on the older patient after the first attack?
2. What is special about 2.5 months? This seems long to me because, with the disease process of gallstone pancreatitis, we are taught to perform cholecystectomy during the initial admission or very shortly after to prevent recurrence.
3. Would you please elaborate on the group of patients you discuss who were seen in the emergency department (ED), as they were less likely to undergo cholecystectomy in the 2.5-month elective period? Is there anything in your database that indicated that perhaps these patients were not plugged into the medical system, perhaps they were using the ED more for