The Pennsylvania State University
The Graduate School

ACUTE GALLSTONE PANCREATITIS AND EARLY CHOLECYSTECTOMY
DURING INDEX HOSPITALIZATION

A Thesis in
Public Health Sciences
by
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ABSTRACT

**Background:** Cholecystectomy at index hospitalization for acute gallstone pancreatitis is recommended to prevent morbidity, mortality and costs related to recurrent pancreatitis. The aims of this study were to characterize patients with acute gallstone pancreatitis undergoing cholecystectomy and endoscopic retrograde cholangiopancreatography (ERCP) during index hospitalization in the US and determine predictors of index hospitalization cholecystectomy.

**Methods:** Discharge data was aggregated from the Healthcare cost and Utilization Project Nationwide Inpatient Sample (NIS) database for the years 2007-2011. ICD-9 codes were used to identify adult patients (>18 years) discharged with a clinical diagnosis of acute pancreatitis and cholelithiasis. We excluded patients with a diagnosis of alcohol abuse, complicated pancreatitis, and severe pancreatitis.

**Results:** 496652 patients were identified with mild gallstone pancreatitis (females: 61.5%; Age: 56.8 ± 20.4; 64% whites, 18.8% Hispanics, 10% African American (AA)). The overall rate of cholecystectomy was 56.5%. The cholecystectomy rate was highest among Hispanics (63%) and lowest in AA (52%). Cholecystectomy group had significantly more females (58.7% vs. 41.3%; p<. 0001) and younger patients (54.06 ±20.1 vs. 60.16 ±20.2; p.0001) when compared to non-cholecystectomy group. Overall, 27% of the patients with a diagnosis of acute gallstone pancreatitis underwent ERCP. Patients undergoing ERCP with biliary stent placement had lower cholecystectomy rate (46.8% vs. 58.7%; p<. 0001). On multivariate analysis, the odds of cholecystectomy was higher in Hispanics (OR 1.11, 95%CI 1.06-1.16), and lower is AA (OR 0.82, 95%CI 0.77-0.86) compared to whites. The odds of cholecystectomy was also higher in...
large size hospitals (OR 1.16, 95%CI 1.10-1.21) compared to small hospitals, and lowers in teaching hospitals (OR 0.89, 95%CI 0.86-0.92), compared to non-teaching hospitals. The Odds of receiving a cholecystectomy was also higher in the southern region (OR 1.89, 95%CI 1.82-1.98) compared to the northeast region and also in patients with private insurance (OR 1.22, 95% CI 1.17-1.28) compared to Medicare beneficiaries. Mortality was lower in patients undergoing cholecystectomy compared to the non-cholecystectomy group (0.2% vs. 0.9%, p<0.0001)

**Conclusion:** Cholecystectomy rates at index hospitalization continue to be low among patients with acute gallstone pancreatitis. Factors related to low cholecystectomy rates include male gender, older age and African American race, small size hospital, and uninsured status. These findings are concerning for suboptimal healthcare delivery.
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ACKNOWLEDGEMENT

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INTRODUCTION

In the United States, acute pancreatitis is the most common gastrointestinal disease requiring admissions and accounts for more than 274,000 hospitalizations each year\(^1\). The most common causes are gallstone disease and alcohol use. Gallstone disease is the leading cause of acute pancreatitis worldwide and accounts for 40-60% of cases of acute pancreatitis in developed countries\(^2\,3\).

Gallstone pancreatitis (GPS) is most common among women older than 60 years. The number of cases reported annually is increasing worldwide, possibly as a result of the worsening obesity epidemic\(^4\,5\,6\). The burden of acute pancreatitis from all causes in the United States exceeds $2.2 billion per year and it is responsible for 300,000 inpatient admissions and 20,000 deaths per year\(^7\,8\,9\).

Acute pancreatitis occurs in 3–8% of all patients with symptomatic gallstones\(^10\,11\), and may be the first manifestation of gallstone disease in up to 40% of patients with gallstones\(^12\).

Most cases of gallstone pancreatitis are mild\(^2\), but up to 20% can develop severe disease resulting in an overall mortality rate for gallstone pancreatitis of approximately 8-15%\(^13\). Mild pancreatitis constitutes 80% of all cases. It involves mild pancreatic inflammation, which resolves in 1-2 days and is associated with a low mortality of 1-3%\(^3\,11\,13\). On the other hand, severe pancreatitis usually involves fulminant pancreatic necrosis and carries a mortality of up to 30%\(^11\,13\,3\). It is often associated with organ failure, sepsis, or systemic inflammatory response syndrome (SIRS).
Interval (delayed) cholecystectomy after mild biliary pancreatitis is associated with a substantial risk of readmission for recurrent biliary events, especially recurrent biliary pancreatitis. The risk of recurrence of GSP ranges from 18% to 63% \(^3\) \(^{11}\). Recurrent GSP may be graver than the initial presentation and between 4% and 50% of cases are reported as severe \(^{13}\).

Same admission (early) cholecystectomy in the setting of mild biliary pancreatitis is associated with significantly less biliary complications and readmission and it can decreases the risk of recurrence to as low as 8% \(^{13}\) \(^{14}\) \(^{15}\). The need for a second ERCP in increased in patients with delayed cholecystectomy beyond 8 weeks \(^{15}\).

Evidence-based guidelines developed during the 2013 International Association of Pancreatology (IAP) and American Pancreatic Association state that cholecystectomy during index admission for mild biliary pancreatitis appears safe and is recommended \(^{16}\). They have also recommended that patients with biliary pancreatitis who have undergone sphincterotomy and are fit for surgery, cholecystectomy should be performed in the same admission \(^{16}\). Similar guidelines were published almost a decade prior to that by the IAP \(^2\).

The goal of our study is to examine the current status of cholecystectomies during index hospitalization for mild biliary pancreatitis using a nationwide database, to assess predictors of index hospitalization cholecystectomies, and also to examine the effect of index hospitalization ERCP on the rate of cholecystectomies.
METHODS

Data
We utilized the Nationwide Inpatient Sample (NIS) between 2007 and 2011 as the source of our data. The NIS is the largest all-payer database of national hospital discharges, maintained as part of the Healthcare Cost and Utilization Project (HCUP) by the Agency for Healthcare Research and Quality (AHRQ). The NIS is a database of hospital inpatient stays derived from billing data submitted by hospitals to statewide data organizations across the U.S. The NIS covers all patients, including individuals covered by Medicare, Medicaid, or private insurance, as well as those who are uninsured. The NIS approximates a 20-percent stratified sample of discharges from U.S. community hospitals, excluding rehabilitation and long-term acute care hospitals.

Each record in the NIS represents a single hospital discharge and includes a unique identifier, demographic data (age, gender, and race), primary and secondary diagnoses (up to 15), primary and secondary procedures (up to 15), length of stay (LOS), and hospital characteristics (region, urban vs. rural location, bed-size, teaching status).

Weighted sample
The NIS database provides annual weights to calculate national estimates. To obtain nationwide estimates, discharge weights have been developed to extrapolate NIS sample discharges to the discharge universe. NIS discharge weights are calculated by dividing the number of universe discharges by the number of sampled discharges within each NIS stratum. Historically, the number of universe discharges had been estimated using data from the AHA annual hospital survey.
The discharge weights are constant for all discharges within a stratum, where the stratum is defined by hospital characteristics: census division, rural/urban location, bed size, teaching status, and ownership.

**Inclusion Criteria**

We searched all hospital discharges between the years of 2007 and 2011 with the following criteria: (i) a primary diagnosis of acute pancreatitis identified by the Clinical Modification of the International Classification of Diseases, 9th Revision (ICD-9-CM) code of 577.0; and (ii) a concurrent diagnosis of cholelithiasis (574.x) or cholangitis (576.1).

**Exclusion Criteria**

We excluded patients with a diagnosis of alcohol abuse (305.0 and 291.4) and chronic pancreatitis (577.1) to reduce the number of patients with alcohol related pancreatitic diseases. To be consistent with the diagnosis of mild pancreatitis and uncomplicated pancreatitis, we excluded patients with severe sepsis (995.92), severe SIRS (995.94), acute respiratory failure (518.81), acute respiratory distress syndrome (518.82), acute renal failure (584.9), and pancreatic fluid collections (577.2).

**Outcome Variables**

Data on age, race, and gender were derived from hospital administrative data. Other demographic information including geographic location, size of the hospital, location of the hospital, and teaching status of the hospital were extracted from the NIS database. The
definition of bed size for a hospital varies depending on the geographic location of where the hospital is located in.

We used ICD-9-CM procedure codes to identify laparoscopic and open cholecystectomies (51.22-23 and 51.24 respectively); ERCP (51.10); sphincterotomy and sphincteroplasty (51.85 and 51.84 respectively); endoscopic removal of stones from biliary tree (51.88), and endoscopic insertion of stent into bile duct (51.87). The accuracy of surgical and endoscopic procedures in administrative database has been previously validated which demonstrated substantial agreement between database coding and in depth review of the charts. Upon review of data, we identified 9% of the patients who had undergone ERCP with stone removal did not have a procedural code for sphincterotomy or sphincteroplasty. Since this is technically not feasible, we assumed that all patients who had ERCP with stone extraction have had sphincterotomy or sphincteroplasty. The variable was therefore recoded to reflect that.

Statistical Analysis

Data were analyzed using the IBM SPSS 20.0 software package (IBM SPSS Statistics, Armonk, New York). Pearson Chi-Square analyses were performed to compare discharge-level categorical variables. Binary logistic regression was used to calculate the association between predictor variables and the odds of receiving cholecystectomy. Logistic regression model was used to assess the association of cholecystectomy with length of stay, after adjusting for ERCP, and above mentioned predictor variables.
RESULTS

Of 2,184,821 weighted patients with acute pancreatitis, 547,951 (25.0%) had gallstone-related pancreatitis. After excluding alcohol related diseases and severe pancreatitis, 496,652 patients were included for analysis. The demographics of all discharges with a primary diagnosis of gallstone pancreatitis are shown in Table 1.

Table 1. Demographic of admissions for acute gallstone pancreatitis

<table>
<thead>
<tr>
<th>Demographic variables</th>
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<tbody>
<tr>
<td>Mean age (SD) years</td>
<td>56.84 (20.39)</td>
</tr>
<tr>
<td>Female to male ratio</td>
<td>1.71</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
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<tr>
<td>White</td>
<td>64</td>
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<tr>
<td>African American</td>
<td>10</td>
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<tr>
<td>Hispanic</td>
<td>18.8</td>
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<tr>
<td>Health insurance</td>
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<td>Medicare</td>
<td>38.6</td>
</tr>
<tr>
<td>Medicaid</td>
<td>14.0</td>
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<tr>
<td>Private including HMO</td>
<td>33.6</td>
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The rate of cholecystectomy was 56.5% among all patients. The majority of patients underwent cholecystectomy laparoscopically (91%).

On multivariate analysis, females were more likely to undergo cholecystectomy compared to males (OR 1.17 95%CI 1.14-1.21) and subjects older than 65 were less likely to undergo cholecystectomy (OR 0.61 95%CI 0.51-0.67) (Figure 1).
African-Americans (AA) were less likely to undergo cholecystectomy on index hospitalization compared to Whites (51.9% vs. 55.7%; p<0001) (Table -2). The Hispanics, however, were more likely to undergo cholecystectomy compared to the Whites (63.2% vs. 55.7%). Binary logistic regression with adjustment for other demographic, clinical, and hospital variables was performed. On multivariate analysis, Hispanics were more likely and AA and Asians were less likely to undergo cholecystectomy compared to Whites (Figure 2).

Table 2- Cholecystectomy rates based on demographic, insurance, hospital status, and regional variables.

<table>
<thead>
<tr>
<th></th>
<th>Cholecystectomy</th>
<th>No cholecystectomy</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD) years</td>
<td>52.9 ±20.6</td>
<td>59.4 ±20.9</td>
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<tr>
<td>Females (%)</td>
<td>58.7</td>
<td>41.3</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>White</td>
<td>55.7</td>
<td>44.3</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>51.9</td>
<td>48.1</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>63.2</td>
<td>36.8</td>
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<tr>
<td>Health insurance (%)</td>
<td></td>
<td></td>
<td>&lt;.0001</td>
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<tr>
<td>Medicare</td>
<td>49</td>
<td>51</td>
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<tr>
<td>Medicaid</td>
<td>58.5</td>
<td>41.5</td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>62.2</td>
<td>37.8</td>
<td></td>
</tr>
<tr>
<td>Geographic Region (%)</td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Region</td>
<td>Hospital size (%)</td>
<td>Teaching Hospital (%)</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>-------------------</td>
<td>-----------------------</td>
<td></td>
</tr>
<tr>
<td>Northeast</td>
<td>49.2</td>
<td>50.8</td>
<td></td>
</tr>
<tr>
<td>Midwest</td>
<td>53</td>
<td>47</td>
<td></td>
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<tr>
<td>South</td>
<td>61.2</td>
<td>38.8</td>
<td></td>
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<tr>
<td>West</td>
<td>58.6</td>
<td>41.4</td>
<td></td>
</tr>
<tr>
<td>Hospital size (%)</td>
<td>&lt;.0001</td>
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<tr>
<td>Small</td>
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<td>49.1</td>
<td></td>
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<tr>
<td>Medium</td>
<td>55.8</td>
<td>44.2</td>
<td></td>
</tr>
<tr>
<td>Large</td>
<td>58.5</td>
<td>41.5</td>
<td></td>
</tr>
<tr>
<td>Teaching Hospital (%)</td>
<td>55.2</td>
<td>44.8</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

Figure 1- AOR for receiving cholecystectomy based on Gender and Age**

** Adjusted for race, region, insurance, and hospital status
Figure 2 - Adjusted odds ratio for receiving cholecystectomy based on race**

** Adjusted for age, sex, insurance, region, and hospital status
Patients with private insurance had the highest rates of cholecystectomy at 62.2%. Medicare patients had the lowest rate of cholecystectomy at 49%. In the multivariate analysis, private insurance patients were more likely to undergo same admission cholecystectomy compared to Medicare beneficiaries (OR 1.22, 95% CI 1.17-1.28). Patients on Medicaid and uninsured patients were less likely to receive cholecystectomy compared to Medicare patients (OR 0.81, 95% CI 0.76-0.86 and OR 0.91, 95% CI 0.85-0.97 respectively) (Figure 3).

Figure 3- AOR for receiving cholecystectomy based on insurance**

** Adjusted for age, sex, race, region, and hospital status
Non-teaching hospital had higher rate of cholecystectomy compared to teaching hospitals (55.9% vs 55.2%, p<0.001). The adjusted odds ratio for cholecystectomy in teaching hospitals was 0.89 (95% CI 0.87-0.91) compared to non-teaching hospitals. Medium size and large size hospitals had a higher cholecystectomy rate compared to small size hospital (55.8% and 58.5% compared to 50.9% respectively; p<0.001). On multivariate analysis, both medium size and large size hospitals were more likely to perform cholecystectomies (Figure 4).

Figure 4- AOR for receiving cholecystectomy based on hospital status**

** Adjusted for age, sex, race, region, and insurance.
The cholecystectomy rates varied based on geographical region. The patients living in the south had the highest cholecystectomy rates (61.2%) and patients in the northeast region had the lowest cholecystectomy rates (49.2%). After adjusting for age, gender, race, insurance, and hospital type, still the patients in the south were more likely to undergo cholecystectomy (Figure 5).

Figure 5- AOR for receiving cholecystectomy based on hospital region**

** Adjusted for age, sex, race, hospital status, and insurance.
Effect of ERCP on Cholecystectomy

135993 (27%) of the patients with a diagnosis of acute gallstone pancreatitis underwent ERCP. 96.7% of patients underwent sphincterotomy or sphincteroplasty; 23% underwent biliary stent insertion; 62% had endoscopic biliary stone removal.

Patients who had undergone ERCP during their admission were more likely to undergo cholecystectomy (57.5% vs. 56.1%, p<.0001). The cholecystectomy rates were however different for those whom received different endoscopic intervention. Subjects receiving biliary stents were less likely to undergo cholecystectomy during the index hospitalization and subjects undergoing sphincterotomy with stone extraction were more likely to undergo cholecystectomy (Figure 6 and 7).
Figure 6- Frequency of cholecystectomy based in ERCP and stone removal

Figure 7- Frequency of cholecystectomy based in ERCP and stent insertion
197957 (39.9%) of the patients with acute gallstone pancreatitis had a concomitant diagnosis of choledocholithiasis (ICD-9 code: 574.5). In this subgroup, 55.6% of the patients underwent ERCP compared to 27% among all patients with gall stone pancreatitis (p<0001). This subgroup had also a significantly higher cholecystectomy rate (54.7% vs. 45.4%; p<0001). On multivariate analysis, stent insertion was associated with significant reduction in the odds for receiving cholecystectomy (Figure 8).

Figure 8- AOR for cholecystectomy based on ERCP**

** Adjusted for age, sex, race, region, insurance, and hospital status
Length of stay and Cholecystectomy

The length of stay was significantly longer in the cholecystectomy group compared to the non-cholecystectomy group (Mean 5.84 vs. 5.03, p<0.0001).

Mortality of Gallstone pancreatitis

The mortality for patients with gallstone pancreatitis was 0.6%. The mortality was significantly higher in the non-cholecystectomy group compared to cholecystectomy group (0.9% vs. 0.2%, p<0.0001).
DISCUSSION

Multiple practice guidelines from different American and European societies recommend index hospitalization cholecystectomy following an episode gallstone pancreatitis. This has been advocated to reduce the risk of recurrent pancreatitis and biliary obstruction. The recommendation has been made for patients with mild to moderate pancreatitis. Delayed cholecystectomy has been advised for patients with more severe pancreatitis or pancreatitis with complications. In recent multicenter, parallel-group, assessor-masked, randomized controlled superiority trial, of inpatients recovering from mild gallstone pancreatitis in the Netherlands it was demonstrated that compared with interval cholecystectomy, same-admission cholecystectomy reduced the rate of recurrent gallstone-related complications in patients with mild gallstone pancreatitis from 17% to 5%, with a very low risk of cholecystectomy-related complications 18.

In this nationwide study we demonstrated only half of patients admitted with gallstone pancreatitis receive cholecystectomy revealing a substantial nationwide discrepancy between published guidelines and actual clinical practice. Even after excluding patients with alcohol-induced pancreatitis and patients with evidence of severe or complicated pancreatitis, the rate did not increase significantly (56.5% vs. 51%).

The other important finding from this study was that there are disparities in utilization of cholecystectomy for those admitted with gallstone pancreatitis—a clinical indication for the procedure. These disparities were observed in race, geographical region, type and setting of hospital.
Younger patients, Hispanics, females, and patients with private insurance were more likely to undergo index admission cholecystectomy, while patients in small hospitals, patients living in northeast region of the country, and patients in teaching hospitals, were less likely to undergo cholecystectomy.

We observed that patients who undergone ERCP and stent insertion were less likely to undergo cholecystectomy. This could be in part due to concerns of surgeons to the possibility of retained stones and the need for bile duct exploration. Therefore, there might be a preference in delaying cholecystectomy.

Differences in disease severity may have also contributed to disparities in cholecystectomy rates, as there may be a tendency to delay surgery in patients with more severe disease. Unfortunately, administrative data does not contain the clinical information that would allow precise and accurate classification of pancreatitis severity.

Even if patients may not have been fit for cholecystectomy, they should be expected to undergo ERCP with sphincterotomy. In our study patients who underwent ERCP were more likely to undergo cholecystectomy, on multivariate analysis there was no difference in the rate of cholecystectomy in patients who underwent ERCP.

The strength of our study is its substantial sample size and its geographic representativeness throughout the United States, allowing a nationwide population-based assessment of overall rates of procedural intervention for gallstone pancreatitis. We applied strict criteria to exclude patients...
with severe disease, complicated pancreatitis, and chronic pancreatitis. Given lack of clinical, radiographic, and laboratory variables on administrative data we used surrogates of disease severity, which were evidence of sepsis and organ failure. The fact that the overall mortality rate was only 0.6% that is even lower that previously reported mortality of mild pancreatitis, supports the appropriate selection of cases of mild acute gallstone pancreatitis. The mortality of patients with acute GPS who underwent cholecystectomy was even lower at 0.2%, which supports the low risk mortality for index admission cholecystectomy.

One of the main limitations of our study was lack of an ICD-9 diagnostic code for GSP. As discussed earlier we used a composite to identify patients with GPS, which could lower our accuracy of our case selection. Additionally, our definition of mild disease is arbitrary and was based on absence of markers of severe illness such as severe sepsis or respiratory failure rather using well-validated scores and calculators of disease severity of acute pancreatitis. As matter of fact the disease severity is rather a spectrum than simply two categories. Use of administrative data was prohibitive of further defining this spectrum.

Given that gallstones are the leading cause of pancreatitis in the United States and that cholecystectomy is the most common gastrointestinal surgery performed in this country\textsuperscript{20}, these findings may have substantial impact on a disadvantaged and minority population in the United States. The underlying mechanisms of disparities in cholecystectomy utilization require further elucidation in order to devise strategies to alleviate inequities in quality of care.
APPENDIX A

ICD-9-CM codes used in project

574.10: Calculus of gallbladder with other cholecystitis, without mention of obstruction

574.00: Acute cholecystitis with cholelithiasis w/out obstruction

574.01: Acute cholecystitis with cholelithiasis with obstruction

574.2: Cholelithiasis:

574.5: Choledocholithiasis

574.51: Choledocholithiasis NOS w obstruction

574.70: Calculus of gallbladder and bile duct with other cholecystitis, without mention of obstruction)

574.61: Calculus of gallbladder and bile duct with acute cholecystitis, with obstruction

576.1: Cholangitis
576.2: Bile duct obstruction

Acute cholecystitis: 575.0

Acute cholecystitis and choledocholithiasis: 574.3

Alcohol abuse: 305.0

Idiosyncratic alcohol intoxication: 291.4

571.1: Acute alcoholic hepatitis

Acute pancreatitis: 577.0

Chronic pancreatitis: 577.1

Cyst or Pseudocyst: 577.2

SIRS without acute organ dysfunction: 995.93

SIRS with acute organ dysfunction: 995.94

Sepsis without organ dysfunction: 995.91
Severe sepsis: 995.92

ARDS: 518.2

Acute respiratory failure: 518.81

Acute pulmonary edema: 518.4

Acute renal failure: 584.9
APPENDIX B

Current Procedural Terminology (CTP) codes used for the project

ERCP: 51.10

Intraoperative cholangiogram: 87.53

PTC: 87.51

Percutaneous Cholecystostomy: 51.12

ERP: 52.13

Sphincterotomy: 51.85

Sphincteroplasty: 51.84

Pancreatic sphincterotomy: 51.82

Endo Removal of stones from biliary tree: 51.88

Endoscopic insertion of stent (tube) into bile duct: 51.87
Cholecystectomy: 51.2

Open cholecystectomy: 51.22

Laparoscopic cholecystectomy: 51.23

Laparoscopic partial cholecystectomy: 51.24


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alternatives to index cholecystectomy in severe acute gallstone pancreatitis (GSP). Surg.