

ORIGINAL ARTICLE

Mortality after a cholecystectomy: a population-based study

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Abstract

Background: The trade-off between the benefits of surgery for gallstone disease for a large population and the risk of lethal outcome in a small minority requires knowledge of the overall mortality.

Methods: Between 2007 and 2010, 47 912 cholecystectomies for gallstone disease were registered in the Swedish Register for Cholecystectomy and endoscopic retrograde cholangiopancreatography (ERCP) (GallRiks). By linkage to the Swedish Death Register, the 30-day mortality after surgery was determined. The age- and sex-standardized mortality ratio (SMR) was estimated by dividing the observed mortality with the expected mortality rate in the Swedish general population 2007. The Charlson Comorbidity Index (CCI) was estimated by International Classification of Diseases (ICD) codes retrieved from the National Patient Register.

Results: Within 30 days after surgery, 72 (0.15%) patients died. The 30-day mortality was close [SMR = 2.58; 95% confidence interval (CI): 2.02–3.25] to that of the Swedish general population. In multivariable logistic regression analysis, predictors of 30-day mortality were age >70 years [odds ratio (OR) 7.04, CI: 2.23–22.26], CCI > 2 (OR 1.93, CI: 1.06–3.51), American Society of Anesthesiologists (ASA) > 2 (OR 13.28, CI: 4.64–38.02), acute surgery (OR 10.05, CI: 2.41–41.95), open surgical approach (OR 2.20, CI: 1.55–4.69) and peri-operative complications (OR 3.27, CI: 1.74–6.15).

Discussion: Mortality after cholecystectomy is low. Co-morbidity and peri-operative complications may, however, increase mortality substantially. The increased mortality risk associated with open cholecystectomy could be explained by confounding factors influencing the decision to perform open surgery.

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Introduction

Background rationale

One of the most common procedures in routine surgical practice,¹ a cholecystectomy, for gallstone disease is generally associated with a low risk for major adverse events.^{2,3} Nevertheless, post-operative mortality after surgery for a benign condition, although rare, is considered less acceptable than mortality after surgery for a potentially lethal disease. In population-based studies, the risk for post-operative mortality after a cholecystectomy for gallstone disease has been estimated to be between 0.1% and 0.7%.^{4–8} Mortality rates were not substantially affected by the introduction of a laparoscopic cholecystectomy (LC).⁷ Factors such as high age,^{5,9}

acute admission¹⁰ and factors indicating underlying co-morbidity¹⁰ are considered risk factors for post-operative mortality after a cholecystectomy.

Previous studies have largely been based on hospital-administration databases or national registers providing limited information on patient characteristics and factors related to the surgical technique.^{4–7} Furthermore, many patients with gallstone disease undergo a cholecystectomy on an outpatient basis and may not be registered in national databases.^{4–7} Finally, it is unclear how the mortality rates found in previous studies compare with mortality in a reference general population.^{5–8}

Objectives

The aim of the present study was to evaluate the risk for post-operative mortality after a cholecystectomy using a nationwide

Data from this study were presented at the 3rd Biennial Congress of the Asia Pacific HPBA, 27–30 September 2011, Melbourne.

prospective population-based biliary surgery register, and to compare this with the Swedish general population. We also aimed to clarify the role of patient- and surgically-related factors in predicting mortality after gallbladder surgery.

Material and methods

Study design

Established in 2005, the Swedish Register for Cholecystectomy and endoscopic retrograde cholangiopancreatography (ERCP) (GallRiks) has collected standardized data on the indications, complications and outcome of gallbladder surgery on a national basis.^{11,12} Since 2007, more than 95% of all cholecystectomies performed in Sweden have been recorded in GallRiks. All cholecystectomies are registered online by the surgeon responsible for the procedure. Registered data include the unique national registration number (NRN)¹³ which identifies each resident in Sweden, gender, medical history, American Society of Anesthesiologists (ASA) classification, surgical indication, type of procedure and peri-operative complications. Patient notes are reviewed by the local coordinator at each unit in order to register the occurrence of any post-operative adverse events within 30 days after surgery. The register is validated each year by blinded reassessment of a randomly selected sample of patient notes. The prevalence of errors so far has been lower than 2%.

Setting

Patients registered in GallRiks between 2007 and 2010 constituted the study population. The Charlson Co-morbidity Index (CCI) was estimated by obtaining International Classification of Diseases (ICD) codes from the National Patient Register.¹⁴

Participants

Between 2007 and 2010, 50 019 cholecystectomies were registered in GallRiks. After exclusion of patients with incorrect NRN, missing information on gender, age <18 years, those with malignancy in the biliary tract and individuals undergoing subtotal cholecystectomy, 47 912 patients who underwent a cholecystectomy because of gallstone disease remained for analyses. The study was approved by the Regional Ethics Committee in Stockholm, Sweden. All participants were informed about the registration.

Data sources and measurement

Using the NRN, linkage was made to the Swedish Death Register to identify all deaths that occurred within the first 30 days after surgery.

Bias

Multivariate logistic regression analysis was used to adjust for potential confounding from variables influencing post-operative mortality.

Study size

The study size was determined by the number of procedures registered in GallRiks. The size was expected to be sufficient to

identify the most important factors influencing post-operative mortality and to calculate standardized mortality ratio.

Criteria for cause of death

As all analyses were based on anonymized files, we were not able to determine the cause of death from the death certificates. However, we had access to the ICD codes from the death certificates, which served as a base for defining cause of death. If the death certificate stated ICD codes related to gallstone disease (K80-K87) or liver failure (K72) as cause of death, the cause of death was classified as related to the gallstone disease. The same categorization was applied if the death certificate stated a non-specific cause of death (R68.8, R09.2, I16.9, I97 and J96.9) and gallstone disease (K80-K87) as a contributing factor. If septicemia (A41.9) without any other surgery-related diagnosis as contributing factor was defined as cause of death, the cause of death was classified as related to complications to the gallstone disease. If the death certificate stated chronic ischaemic heart disease (I25), myocardial infarct (I21), cerebral bleeding (I61) or pulmonary oedema (J81) as the cause of death, the main cause of death was defined as cardiovascular. If septicemia (A41.9) without any gallstone-related code was stated and no direct relation to the gallstone disease or surgical procedure was indicated, the cause of death was defined as infectious. If bleeding (R58.9), disease in the circulatory system after surgery (I97), post-operative bleeding (T81.0) or post-operative infection (T81.4) was stated as cause of death in the death certificate, the cause of death was defined as a post-operative complication. The cause of death was only attributed to the procedure per se if the death certificate stated a complication as the main cause of death or as contributing factor. If the death certificate stated a non-specific cause of death (R68.8) and gallstone disease (K80-K87) as contributing factor, the cause of death was classified as related to complications to the gallstone disease. If there was only a non-specific code, the cause of death was unclear. Where the cause was obvious from the death certificate (malignant disease, pulmonary embolism, infectious disease, chronic obstructive pulmonary disease, or bleeding duodenal ulcer or trauma), the main diagnosis was considered the cause of death.

Statistical analysis

All analyses were performed with an anonymized data file. Poisson regression was used to calculate the 30-day age- and sex-standardized mortality ratio (SMR) with the corresponding 95% confidence interval (CI) using the expected mortality rate extrapolated from the Swedish general population in 2007 as a reference.

Multivariable logistic regression was used to calculate the odds ratios (OR) and the corresponding 95% CI for the impact of each predictor on the risk for death after a cholecystectomy. The pre-defined model included gender, age (<50 years, 50–70 years and >70 years), American Society of Anesthesiologists (ASA) classification (1–2, 3–5), indication for surgery (uncomplicated gallstone

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