Cholecystectomy in Emilia-Romagna region (Italy): A retrospective cohort study based on a large administrative database



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Fausto Catena^{*}, Rita Maria Melotti^{**}, Daniel Louis^{**}, Daniela Fortuna^{**}, Luca Ansaloni^{***}, Federico Coccolini^{***}, Salomone Di Saverio[°], Massimo Sartelli^{°°}, Antonio Tarasconi^{°°°}, Gianluca Baiocchi^{°°°}, Nazario Portolani^{°°°}, Josephine Napoli^{**}, Belinda De Simone^{*}, Rodolfo Catena^{*}, Rossana De Palma^{**}

*Department of Emergency and Trauma Surgery, Parma University Hospital, Parma, Italy **Emilia-Romagna Regional Health Agency, Italy

***General, Emergency and Trauma Surgery, Hospital Papa Giovanni XXIII, Bergamo, Italy

"Emergency Surgery and Trauma Surgery Unit, Maggiore Hospital Trauma Center, Bologna, Italy

"Department of Surgery, Macerata Hospital, Macerata, Italy.

°°°Department of Medical and Surgical Sciences, Surgical Clinic, University of Brescia, Italy

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BACKGROUND: The aim of this study was to ascertain the variability and to identify a trend for the outcome of cholecystectomy surgery when used to treat cholelithiasis and acute cholecystitis.

METHODS: This was a large retrospective cohort study following patients up to 11 years post surgery, based on administrative data collected from 2002 to 2012 in the Emilia-Romagna Region (Northern Italy) and comparing the effectiveness and efficiency of surgical activity (laparoscopic (LC) and open cholecystectomy (OC)). Analyses included patient characteristics, length of hospital stay, type of admission and mortality risk. Outcomes considered were death from all causes (during the index hospital admission or thereafter), hospital readmissions with cholecystitis or cholelithiasis as principal diagnosis and time to surgery.

RESULTS: A total of 84,628 cholecystomies were performed from 2002 to 2012 out of 123,061 admissions with primary diagnostic category of cholecystitis or cholelitiasis. Laparoscopic procedure was used in 69,842 patients. Over time there was a rising linear statistically significant trend in the use of LC. Mortality rate at 1 year of OC treated patients showed a statistically significant difference compared to LC treated patients (using a cohorts match with propensity score). Only a small number of patients with acute cholecystitis was operated according guidelines within 72 hours.

CONCLUSIONS: The analysis of aggregate administrative data is a powerful tool to support regional health management, improve the quality of medical care, and assess the appropriateness of therapeutic or diagnostic approaches. It is important to stress a short hospital stay for laparoscopic cholecystectomy patients (50% less than open surgery): this shorter hospital stay leads to a significant economic advantage. Moreover, mortality is significantly higher in open surgery for acute cholecystitis. Interestingly, the same finding was confirmed after 30 days and 1 year, probably due to comorbidities that are more evident in open surgery.

KEY WORDS: Cholecystitis, Cholelithiasis, Delivery of health care, Disease management, Surgical

Introduction

Ever since it was introduced by Langenback in 1882, open cholecystectomy (OC) has been the treatment of

choice for symptomatic cholelithiasis and acute cholecystitis ¹.

It soon became one of the most frequently performed surgical procedures and the surgical technique remained virtually unchanged for over a century because of it's therapeutic efficacy and low morbidity and mortality rates ².

The evolution of endoscopic surgery led to the idea that cholecystectomy could be performed laparoscopically (LC), a procedure first described by Muhe in 1985 ³.

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Correspondence to: Fausto Catena, Consultant General Surgeon, Parma University Hospital, Italy (e-mail: faustocatena@gmail.com)

The recent Cochrane Collaboration review compared the diagnostic and therapeutic effects of LC and the conventional OC ⁴. It found that in clinical settings where surgical expertise and equipment are available and affordable, LC has various advantages over OC ⁴.

Conventional cholecystectomy should not be considered "wrong", because the difference between the two techniques are in favor of LC, and it should be considered as a valid surgical option and used when indicated.

There is some debate on the use of LC. Considering the strong evidence of better outcomes for LC, this surgical technique is highly recommended (except for particular categories of patients). In fact, a recent study pointed out the widespread use of LC 5 .

It seemed worthwhile to further investigate the sources of variability in the choice between laparoscopy and the open approach for cholecystectomy and the trend of the usage of these procedures in current practice to analyze the clinical performance on this common disease in a large population.

The aim of this study was therefore to ascertain the variability and the 11-year trends in the use of laparoscopic surgery for symptomatic cholelithiasis and cholecystitis, using data from a large administrative database to compare the effectiveness and efficiency of LC and OC, and to establish evidence-based recommendations for the use of these two options.

Materials and Methods

This was a retrospective cohort study based on administrative data collected from 2002 to 2012 in the Emilia Romagna Region (Northern Italy) database of all Emilia-Romagna Region residents.

We considered the discharge records (HDRs) from 2002–2012 of public and accredited private hospitals containing personal details and data on hospital stays (date and ward of admission, date and ward of discharge, data of surgical procedures and patients comorbidities and vital status at discharge).

The records indicate one principal diagnosis at discharge and up to five secondary diagnoses; up to six medical or surgical procedures were recorded. Since 2002, all diagnoses and procedures have been classified according to the coding system of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM, 1997 version).

Using the HDR database, we analyzed all discharge records for patients who were admitted for cholelithiasis, acute- chronic cholecystitis, and/ or underwent cholecystectomy from January 1, 2002, to December 31, 2012 in Emilia- Romagna Region.

All hospital admissions during which LC or OC were performed to treat symptomatic cholelithiasis and acute or chronic cholecystitis were identified by means of the appropriate diagnosis and procedure codes as specified

by the ICD-9-CM. For the disease, we considered the main ICD-9 diagnosis codes for symptomatic cholelithiasis and acute or chronic cholecystitis (diagnosis, first three digit of ICD9-CM codes: '574', '575'). For the surgery, we considered the main ICD-9 procedure codes for laparoscopic cholecystectomy (51.23) and open cholecystectomy (51.22). Patients who underwent incidental cholecystectomy were excluded from our analysis. Hospital admissions are classified as medical or surgical based on the DRG assigned according to type of the ward (surgery or medicine).

Analyses included patient characteristics, length of hospital stay, and type of admission and mortality risk.

Outcomes considered were death from all causes (during the index hospital admission or thereafter), hospital readmissions with cholecystitis or cholelithiasis as principal diagnosis and time to surgery.

Data about death were retrieved through the regional mortality registry and the regional hospital admission database. We compared surgical admission vs. medical, laparoscopic vs. open , acute vs. not acute, and one day vs. ordinary surgery in our analyses. Trends were determined using the Cochrane-Armitage test; trends with a significance level of five percent were considered statistically significant.

Prevalence of risk factors and demographic and clinical features of the patients in compared groups were evaluated by the Mann-Withney test or chi-square test. When comparing the effectiveness of laparoscopic vs open treatment on large cohorts of patients with similar probability of treatment assignment, Propensity score (PS) matching was used to reduce the effect of treatment-selection bias.

PS – the probability of treatment assignment based on observed baseline characteristics – was estimated by multivariate logistic regression analysis with a binary dependent variable representing laparoscopic versus open procedures.

Independent variables included demographics, the available clinical potential risk-factors and year of procedure. Patients were matched on the logit of the PS using a caliper of width equal to 0.25 standard deviations of the logit of PS.

Appropriateness of the specification of the PS was assessed by examining the degree to which the estimated PS resulted in a matched sample in which the distribution of measured baseline covariates was similar between the two types of treatment.

To detect imbalances in baseline covariates, standardized differences were used. Standardized differences represent the difference in means between the two groups in units of standard deviation; therefore standardized differences do not depend on the unit of measurement and are not influenced by sample size. Standardized differences of less than 0.10 (10%) are likely to indicate a negligible imbalance between the two groups.

Kaplan-Meier estimates were used to plot the rates of the 1 year mortality, and differences between risk curves were assessed using the Klein-Moeschberger test for matched pairs.

The hazard ratio of laparoscopic vs. open was estimated through Cox proportional hazard models with robust standard errors, to account for clustering in matched pairs.

Potential risk factors related to 30-day mortality post procedure were estimated through a stepwise logistic regression model with patients' characteristics at baseline and type of procedure as covariates.

For the subgroup of patients with acute diagnosis, the evaluation of cumulative waiting time from medical to surgical admission was performed through Kaplan-Meier curves to take into account patients deaths.

All statistical analysis was performed using SAS 9.1.

Results

From 2002 to 2012, we had a total of 123061 admissions with primary diagnostic category of cholecystitis or cholelitiasis in the Emilia Romagna Region.

Fig. 1 shows a linear increasing trend in the rate of admissions from 2002 to 2012 both for medical ward or surgical ward admissions but only for surgical admissions there was a statistically significant increasing trend (p < 0.0001).

There was also a linear declining trend in the number of patients with at least one surgical re-admission within 30 days of medical ward discharge after conservative treatment (p = n.s.) (Fig. 2a).

Only a small percentage of patients with acute cholecystitis had a time to surgery within 72 hours of diagnosis (Fig. 2b).

Moreover 1 day surgical ward admission increased from 10.34% in 2002 to 15.23% in 2012 (trend p < 0.0001) whereas there was a decreasing trend of 1 day medical ward admission; medical and surgical ordinary admissions with a length of stay greater than 1 day remained stable during years (Fig. 3).



Fig. 1: 2002-2012 frequency of hospital admissions in the Emilia Romana Region with a primary diagnostic category of Cholecystitis or Cholelithiasis.



Fig. 2: A) Readmissions Of PATIENTS with a medical admission during the calendar year, the number and percent of PATIENTS with a surgical readmission within 30 days of discharge from medical admission: B) Time to surgery after an acute cholecystitis. Median time to surgery was 34 days.



Fig. 3: Medical and surgical ward day admissions or ordinary admissions with a length of stay of 1 day and ordinary admissions with a length of stay greater than 1 day.

With regard to frequency and severity of diagnosis related to type of admission, the majority of patients with chronic cholecystitis and cholelithiasis were admitted to a surgical ward (69%) while the majority of patients with acute cholecystitis were admitted to a medical ward (22%) (Fig. 4).

Overall, for medical ward admissions mean hospital stay was 7.7 days: for chronic cholecystitis and cholelithiasis it was 6.98 days, which was shorter than the 8.58 days needed for acute cholecystitis (Fig. 5) (p=n.s.).

Figure 6 shows a significant linear declining trend in the rate of open cholecystectomy procedures from 2002 to 2012 with increasing trend in the rate of laparoscopic

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Fig. 4: Frequency and Severity of Diagnosis by Medical and Surgical Admissions.



Fig. 5: Medical Admissions, Average Length of Stay-Hospital admissions are classified as medical or surgical based on the DRG assigned to each admission. Average length of stay for ordinary medical admissions of more than one day only (excluding in-hospital deaths).



Fig. 6: Significant linear declining trend in the rate of open cholecystectomy procedures from 2002 to 2012 with increasing trend in the rate of laparoscopic cholecystectomy in the same period (trend test p<0.0001).



Fig. 7: Frequency and Severity of Diagnosis by Type of Surgery (Laparoscopic or non-Laparoscopic).



Fig. 8: Percentage of frequency and Severity of Diagnosis by Gender and Type of Surgery (Laparoscopic or non-Laparoscopic).





cholecystectomy in the same period (trend test p<0.0001).

Focusing on type of surgery and severity of diagnosis, laparoscopic cholecystectomy was more frequently performed in cases of chronic cholecystitis and cholelithiasis (88.04%) while laparoscopic cholecystectomy was less frequently performed for acute cholecystitis (72.71%)(p < 0.0001) (Fig. 7).

We found that laparoscopic cholecystectomy was more frequently performed on female patients compared to



Fig. 10: Average Length of Stay by Stage/Severity and Type of Surgery (Laparoscopic or non-Laparoscopic) p< 0.05 lap vs open.



Fig. 11: Average Length of Stay by Year, Stage/Severity and Type of Surgery (Laparoscopic or non-Laparoscopic).



Fig. 12: In-Hospital Deaths and Deaths within 30 Days of Admission).

male patients both for chronic cholecystitis and cholelithiasis and acute cholecystitis (p < 0.001) (Fig. 8). From 2002 to 2012, LC increased both for chronic cholecystitis and cholelithiasis and acute cholecystitis, reaching 90% and 77% respectively (Fig. 9).

Overall, for surgical admissions, mean hospital stay for laparoscopic cholecystectomy was 4.3 days and for open surgery it was 11.6 days. Mean hospital stay for chronic cholecystitis and cholelithiasis treated with LC was 3.94 days, and 6.10 days for acute cholecystitis treated with LC, both with a statistically significant difference compared to open surgery (p< 0.05) (Fig. 10).

From 2002 to 2012, mean hospital stay for LC and OC was stable for all diagnosis with the exclusion of the not statistically significant increasing trend found in OC for acute cholecystitis (Fig. 11).

In-patient mortality rate was comparable for OC and LC for chronic cholecystitis and cholelithiasis, whereas it was significantly higher for acute cholecystitis treated with OC (Fig. 12). The same trend was evident for death within 30 days of admission. (p<0.0001).

Using the cohorts and propensity scores, the one year survival was significantly different in laparoscopic surgery vs. open surgery (log-rank p< 0.0001; Klein Moeschberger Test p < 0.0001) (Fig. 12).

Discussion

The present study showed a linear increasing trend in the rate of admissions for colelithiasis or cholecystitis from 2002 to 2012 (both for medical ward or surgical ward admissions) while there was a linear declining trend in the number of patients with at least one surgical admission within 30 days after medical admission (Figs 1, 2a).

This last finding is coherent with the application of the current guidelines for surgical treatment for acute cholecystitis within 72 hours ⁴ but there is still a good number of patients readmitted to surgery within one month of medical ward admission without having LC before.

This is confirmed by the time to surgery data after an acute cholecystitis: only a small amount of patients are submitted to surgery within 72 hours (Fig. 2b).

So it is possible to hypothesize that a significant number of patients experiencing an episode of acute cholecystitis are not operated in an acute care surgery setting, but are arbitrarily scheduled for an elective LC and recurred while waiting at home the planned operation ⁶⁻⁸.

Therefore it will be very important in Emilia Romagna Region to implement the knowledge on acute cholecystitis guidelines and to improve hospital organizational pathways ⁸⁻¹⁰. Fig. 3 depicts the declining trend of 1 day medical and surgical admission: this data can be analyzed as more accurate medical diagnosis minimizes inappropriate hospital admission ¹¹⁻¹⁵. There is a great number of patients admitted to the medical ward for acute cholecystitis (Fig. 4): again, this is a controversial finding since there is an evidence based recommendation to operate patients within 72 hours of admission; it would be advisable to admit patients directly to the surgical ward ¹⁶⁻¹⁸.

Medical ward mean hospital stay was more than one week for both chronic and acute cholecystitis: this mean hospital stay should be reduced. Chronic cholecystitis should be treated in the majority of cases on a "one day Surgery" hospital base and acute cholecystitis should be handled by surgeons directly ¹⁹⁻²².

From 2002 to 2012, there was a significant linear declining trend in the rate of open cholecystectomies performed with a concomitant increasing trend in the rate of laparoscopic cholecystectomies performed, likely due to the increasing expertise in this technique. About 70% of patients with acute cholecystitis undergo laparoscopic cholecystectomy compared to 90% of patients with chronic cholecystitis and cholelithiasis: this result can likely be explained with an improved analysis of which centers favor open surgery to treat them ²²⁻²⁵. It is worthwhile to try to achieve better results in acute cholecystitis patients where there is still the possibility to increase laparoscopic cholecystectomy rate ²¹⁻²³.

Interestingly, LC was used more often for women than for men; this result could be explained only by the greater "aesthetic concern" experienced by women^{24,25}. It is important to stress a short hospital stay for laparoscopic cholecystectomy patients (50% less than open surgery): this shorter hospital stay leads to a significant economic advantage ²¹.

Moreover, mortality is significantly higher in open surgery for acute cholecystiris and this finding is consistent with Kivuluoto paper that demonstrated an higher morbidity rate for open cholecystectomy in acute cholecystitis ²⁵.

Interestingly, the same finding was confirmed after 30 days and 1 year, probably due to comorbidities that are more evident in open surgery.

In conclusion, the administrative database is an effective system to check the quality and the appropriateness of clinical performance in benign gallbladder disease.

Riassunto

INTRODUZIONE: Questo studio si pone come obiettivo l'identificazione della variabilità nell'approccio alla colecistite acuta ed alla colelitiasi e di identificare eventuali trend nell'outcome di questi malati.

MATERIALI E METODI: Lo studio è un ampio studio di coorte retrospettivo, basato su dati estratti dai database amministrativi della Regione Emilia Romagna raccolti tra il 2002 ed il 2012 e con un periodo di follow-up fino a 11 anni, che compara l'efficacia e l'efficienza dell'attività chirurgica confrontando la colecistectomia

laparoscopica (LC) con l'approccio open (OC). Sono stati analizzati: parametri demografici e caratteristiche dei pazienti, durata della degenza, modalità di ricovero e mortalità. Sono stati considerati come indicatori di outcome la mortalità (ospedaliera e successiva al ricovero in analisi), le riammissioni con colecistite acuta o colelitiasi come diagnosi principale ed il tempo intercorso prima del trattamento chirurgico.

RISULTATI: Nel periodo 2002-2012 sono state eseguite 84.628 colecistectomie su 123.061 ricoveri con diagnosi principale di colecistite acuta o colelitiasi. L'approccio laparoscopico è stato utilizzato in 69.842 pazienti. La mortalità ad un anno per i pazienti sottoposti a OC ha mostrato un differenza statisticamente significativa se comparata con quella di pazienti sottoposti a LC. Solamente una minoranza dei pazienti è stata operata entro 72 ore dall'insorgenza dei sintomi, al contrario di quanto raccomandano le linee guida.

DISCUSSIONE E CONCLUSIONI: L'analisi di dati amministrativi è un potente strumento di supporto per la gestione della sanità a livello regionale, consentendo di migliorare la qualità delle cure e di valutare l'appropriatezza dell'approccio diagnostico-terapeutico ai pazienti. È fondamentale rilevare la minor durata della degenza per i malati trattati con tecnica laparoscopica (50% in meno rispetto ai malati trattati con approccio open): questa riduzione dei tempi di degenza porta ad un significativo vantaggio economico. Inoltre, la mortalità è significativamente maggiore per la chirurgia open per la colecistite acuta; è interessante sottolineare come questo dato sia confermato anche a 30 giorni ed 1 anno di followup, essendo probabilmente dovuto ad un maggior numero di comorbidità presente nei pazienti sottoposti a chirurgia open.

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