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Thirty-day complications after laparoscopic or open cholecystectomy: a population-based cohort study in Italy

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ABSTRACT

Objective: The objective of the study is to evaluate short-term complications after laparoscopic (LC) or open cholecystectomy (OC) in patients with gallstones by using linked hospital discharge data.

Design: Population-based cohort study.

Setting: Data were obtained from the Regional Hospital Discharge Registry Lazio Region in Central Italy (around 5 million inhabitants) in 2007–2008.

Participants: All patients admitted to hospitals of Lazio with symptomatic gallstones (International Classification of disease, 9th Revision, Clinical Modification (ICD-9-CM)=574) who underwent LC (ICD-9-CM 51.23) or OC (ICD-9-CM 51.22).

Outcome measures: (1)'30-day surgical-related complications' defined as any complication of the biliary tract (including postoperative infection, haemorrhage or haematoma or seroma complicating a procedure, persistent postoperative fistula, perforation of bile duct and disruption of wound). (2) '30-day systemic complications' defined as any complications of other organs (including sepsis, infections from other organs, major cardiovascular events and selected adverse events).

Results: 13 651 patients were included; 86.1% had LC, 13.9% OC. 2.0% experienced surgical-related complications (SRC), 2.1% systemic complications (SC). The OR of complications after LC versus OC was 0.60 ($p<0.001$) for SRC and 0.52 ($p<0.001$) for SC. In relation to SRC, the advantage of LC was consistent across age categories, severity of gallstones and previous upper abdominal surgery, whereas there was no advantage among people with emergency admission (OR=0.94, p=0.764). For SC, no significant advantage of LC was seen among very old people (OR=0.99, p=0.975) and among those with previous upper abdominal surgery (OR=0.86, p=0.905).

Conclusions: This large observational study confirms that LC is more effective than OC with respect to 30-day complications. Population-based linkage of administrative datasets can enlarge evidence of treatment benefits in clinical practice.

ARTICLE SUMMARY

Article focus

- The advantage of the laparoscopic cholecystectomy (LC) approach for the treatment of gallstones versus open surgery has been shown from randomised controlled trials and observational studies.
- The use of linked administrative health records has become one of the most powerful tools in observational studies aimed at comparing treatments.
- We compared laparoscopic and open cholecystectomy in terms of 30-day complications using routinely collected databases in the Lazio Region (Italy).

Key messages

- This population-based cohort study contributes to the enlargement of evidence on the effectiveness of LC in a real-life setting.
- In relation to surgical-related complications, the advantage of LC was consistent across age categories, severity of gallstones and previous upper abdominal surgery, while there was no advantage among people with emergency admission.
- For systemic complications, no significant advantage of LC was seen among very old people and among those with previous upper abdominal surgery.

Strengths and limitations of this study

- Population-based design, 30-day outcomes, large numbers and robustness of analytical procedures are the main strengths.
- It contributes to the debate on the complex methodology to estimate the risk of adverse events after surgery using secondary databases to monitor the quality of care.
- The use of ICD-9-CM codes in the definition of severity of disease presentation and of complications is a major limitation.

BACKGROUND

Comparative effectiveness research is becoming central in monitoring real-life impact of treatments and supporting public health decisions.[1 2] Although the basic concept of comparing therapies is not new, over the last few years many initiatives have been implemented in several countries to provide large-scale evidence on the benefits and harms of different treatments.[3–5] The use of linked administrative health records has become one of the most powerful tools in observational studies aimed at comparing treatments. They include hospital inpatient records, birth and death registrations, outpatient care records, dispensed pharmacy drugs.[6–9]

In the Lazio Region (around 5 000 000 inhabitants), the P.Re.Val.E. Project (Regional Outcome Evaluation Program) was launched in 2005. Its aims are: to measure the quality of healthcare provided in the Lazio Region, to describe variability of care provision across institutions and populations and to compare the effectiveness of treatments for different medical and surgical conditions.[10 11] Over 60 outcome indicators are calculated based on data obtained from record-linkage procedures of different health systems. The results are periodically updated and publicly disseminated with discussion on critical methodological points.

Cholecystectomy is one of the most common abdominal surgical procedures in developed countries. Since its introduction in the late 1980s, laparoscopic cholecystectomy (LC) has replaced open cholecystectomy (OC) as the treatment of choice for symptomatic gallstones.[12 13] Beneficial effects of LC have been demonstrated in studies showing the advantages from real-life settings using secondary databases.[9 14–19] In the present study, we aimed at developing a methodology to measure short-term complications after LC or OC using large administrative databases on behalf of the P.Re.Val.E. Second, we tested the hypothesis that the advantages of LC versus OC could vary according to age and clinical patients' characteristics.

METHODS

Source of data

Data were derived from the Lazio Hospital Information System (HIS), which provides information on patients' demographic data (gender, age, place of birth and place of residence), admission and discharge dates, discharge diagnoses (up to 6) and medical procedures or surgical interventions ((up to 6) according to the International Classification of disease, 9th Revision, Clinical Modification (ICD-9-CM), status at discharge (alive, dead or transferred to another hospital), ward(s) of stay, date(s) of inhospital transfer, and a regional code corresponding to the admitting facility for patients discharged from all public and private hospital of the Lazio Region).

Study population

All hospital admissions with a primary or secondary diagnosis of gallstones (ICD-9-CM=574) and a procedure code of cholecystectomy (ICD-9-CM 51.22, 51.23), which occurred in private and public hospitals of the Lazio Region between January 2007 and September 2008, were included, making a total of 16 432 cases (age 18+ years). We a priori decided not to include codes for partial cholecystectomy (ICD-9-CM 51.21 and 51.24) to increase the specificity of our exposure. Information was retrieved from the HIS. In order to increase the case specificity, several exclusion criteria were applied including long-term hospitalisations, rehabilitations, day-hospitals, hospitalisations for delivery or trauma or cancer, hospitalisations with abdominal surgical procedures other than cholecystectomy. The final population consisted of 13 651 individuals (figure 1). See the online supplementary data (Part 1) for details on the exclusion criteria and ICD-9-CM codes. According to the Regional Law, the present study, which was based on anonymous computer records from health information systems, did not require ethical approval.

Patient-level risk factors

The following characteristics were considered for each patient: age (<70; 70–79; ≥80 years old); gender; severity of gallstones: it was classified as *low* (not complicated), *moderate* (presence of cholecystitis or biliary tract obstruction) and *high* (presence of both inflammation and obstruction of the biliary tract); previous upper abdominal surgery (based on previous 2-year hospitalisations); comorbidities (based on previous 2-year hospitalisations) following validated algorithms[20 21]; type of admission: either *elective* or *emergency*. See the online supplementary data (Parts 2–4) for details on the ICD-9-CM codes. The choice of *cut-off* for age category was based on previous studies to distinguish adult and old people.[22–24]

Outcomes

We identified various complications within 30 days after the intervention and grouped them in two categories: (1) '30-day surgical-related complications' defined as any complication of the biliary tract (including post-operative infection, haemorrhage or haematoma or seroma complicating a procedure, persistent post-operative fistula, perforation of bile duct, disruption of wound); (2) '30-day systemic complications' defined as any complications of other organs (including sepsis, infections from other organs, major cardiovascular events and selected adverse events). The complete list of complications with ICD-9-CM codes is reported in the online supplementary data (Part 5). Among the various complications, we included some conditions reported in the list of Patient Safety Indicators developed by the Agency for Healthcare Research and Quality, while other items were specifically created on the basis of scientific literature on digestive surgery.[14–19 25 26] Depending on the type of complication, some ICD-9-CM codes were searched in the index admission as well as the following ones in the 30-day period after the surgery, whereas others were searched only in later hospitalisations. For example, peritonitis or acute pancreatitis was not counted as complications when reported in the index admission. See the online supplementary data (Part 5) for details on the ICD-9-CM codes. In case of a

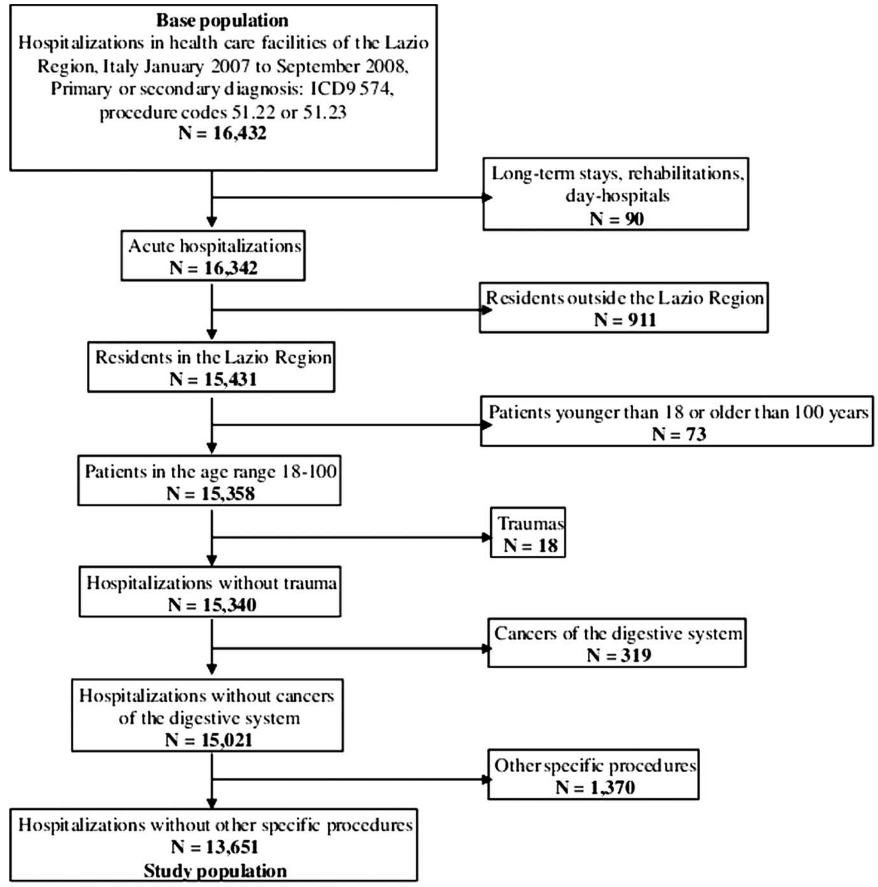

Figure 1 Selection of the study population.

subsequent hospitalisation occurred out of the study area (eg, in a region other than Lazio), we obtained information through record linkage procedure between hospital information systems. Because of the short follow-up time, this happened in a minimal proportion of cases (0.1%). The outcome variables were '30-day surgical-related complications' and '30-day systemic complications'; they were coded '1' if at least one of the complications within the group was present and '0' if none was recorded.

Type of cholecystectomy

We defined "type of cholecystectomy" as the exposure variable (LC vs OC). In case of ICD-9-CM codes for both LC and OC (5%), the patient was considered to be exposed to the open surgical procedure. We could not use the specific ICD-9 code for a case converted from LC to OC (ICD-9-CM code V 64.41) because it was highly under-reported in our region in the study period.

Statistical analysis

Multiple logistic regression models were fitted to estimate the relative risk of 30-day complications (either 'surgical-related' or 'systemic') after LC versus OC, adjusting for demographical and clinical risk factors. The two outcome variables were analysed separately. The predictive model was made of two sets of predictors: (1) variables 'a priori' chosen as confounders (age, gender, severity of gallstones, previous upper abdominal surgery and type of admission); (2) variables empirically tested (comorbidities) which were selected using iterative stepwise statistical procedures.[27] Once the 'best' predictive model was identified for each of the two outcomes, the variable 'type of cholecystectomy' was included, and the adjusted OR of LC versus open surgery was estimated, with a corresponding 95% CI and p value.

In order to test the hypothesis of an effect modification by age, relative risk estimates for the age groups were derived by adding an interaction term between the age group and the treatment variable in the final multivariate logistic model. We obtained the OR of laparoscopic versus open surgery within each age stratum by adding the corresponding interaction term coefficients. This was accomplished by adding a coefficient from the reference category and another coefficient from the age stratum of interest, and by computing the corresponding standard error from the corresponding terms of the variance–covariance matrix. Similarly, effect modification was tested with regard to the severity of cholelithiasis, previous upper abdominal surgery and type of admission. The corresponding tests of heterogeneity of the stratum-specific risk estimates were computed.

Sensitivity analyses were performed. First, in order to guarantee adequate control of confounding factors, we identified and adjusted for all the individual factors associated with the treatment, within the propensity adjustment framework.[28] This procedure is a two-step technique: (1) it estimates the a priori probability of exposure for each individual, based on clinical and demographic characteristics and (2) it standardises them in the association between treatment and the study outcome. The individual factors related to the exposure in the present study include age, gender, severity of cholelithiasis, previous upper abdominal surgery, type of admission, cardiocirculatory disease, cerebrovascular disease, chronic obstructive pulmonary disease (COPD) or respiratory failure, chronic nephropathy and chronic disease of the liver or pancreas. Second, to take into account the potential heterogeneous experience in laparoscopic surgery across different hospitals because of the patients' clustering within a single institution, we performed a multilevel regression model with random intercepts for hospitals.[29]

All the statistical analyses were performed using SAS Software V.8.0 (SAS Institute, Inc SAS/STAT software).

RESULTS

A description of the study population, overall and by cholecystectomy procedure, is presented in table 1. Over 80% of the patients were younger than 70 years, and moderate-to-high severity of the gallstones was diagnosed for 61.7%. As compared with patients undergoing LC, those who underwent OC were more likely to be elderly men with a more severe baseline disease and more chronic conditions. Furthermore, they were operated in emergencies in most of the cases (52.4%), whereas LC was performed in elective hospitalisations much more frequently (73.9%).

Table 2 reports the relationship between demographic and clinical variables and the occurrence of complications. The adjusted risk of systemic complications increased with age and was much higher in patients with more severe baseline gallstones, whereas no clear age or severity-related differences in risk emerged with regard to surgical-related

Table 1 Study population, overall and by cholecystectomy procedure: distribution by age, gender, severity of cholelitiasis, previous upper abdominal surgery, type of admission, comorbidities—Lazio Region, Italy, January 2007–September 2008

	Laparoscopic cholecystectomy		Open cholecystectomy		Total	
Patient characteristics	N	%	N	%	N	%
Total	11 752	86.1	1899	13.9	13 651	100.0
Age (years)						
<70	9913	84.4	1162	61.2	11 075	81.1
70–79	1543	13.1	485	25.5	2028	14.9
≥80	296	2.5	252	13.3	548	4.0
Gender						
Men	4349	37.0	979	51.6	5328	39.0
Women	7403	63.0	920	48.4	8323	61.0
Severity of cholelitiasis						
Low	4767	40.6	470	24.7	5237	38.4
Moderate	6456	54.9	1200	63.2	7656	56.1
High	529	4.5	229	12.1	758	5.6
Previous upper abdominal surgery						
No	11714	99.7	1867	98.3	13581	99.5
Yes	38	0.3	32	1.7	70	0.5
Type of admission						
Elective	8690	73.9	903	47.6	9593	70.3
Emergency	3062	26.1	996	52.4	4058	29.7
Comorbidities						
Cancer	232	2.0	75	3.9	307	2.2
Diabetes	268	2.3	100	5.3	368	2.7
Obesity	115	1.0	25	1.3	140	1.0
Blood disease	146	1.2	62	3.3	208	1.5
Hypertension	842	7.2	247	13.0	1089	8.0
Ischaemic heart disease	246	2.1	107	5.6	353	2.6
Past coronary revascularisation	63	0.5	22	1.2	85	0.6
Heart failure	47	0.4	41	2.2	88	0.6
Other heart disease	158	1.3	76	4.0	234	1.7
Conduction disorders or dysrhythmia	250	2.1	95	5.0	345	2.5
Cerebrovascular disease	146	1.2	74	3.9	220	1.6
Vascular disease	91	0.8	38	2.0	129	0.9
COPD or respiratory failure	189	1.6	84	4.4	273	2.0
Chronic nephropathy	68	0.6	46	2.4	114	0.8
Chronic disease of the liver or pancreas	219	1.9	70	3.7	289	2.1

COPD, chronic obstructive pulmonary disease.

Table 2 Factors related to the incidence of 30-day complications after cholecystectomy. OR crude and adjusted, p values—Lazio Region, Italy, January 2007–September 2008 (N=13 651)

	30-Day surgical-related complications (N=278, 2.0%)									30-Day systemic complications (N=280, 2.1%)								
Patient characteristics	**Per cent**	**OR_{crude}**	**95% CI**		**p Value**	**OR_{adj}**	**95% CI**		**p Value**	**Per cent**	**OR_{crude}**	**95% CI**		**p Value**	**OR_{adj}**	**95% CI**		**p Value**
Age (years)																		
<70	1.8	1.00	–	–	–	1.00	–	–	–	1.5	1.00	–	–	–	1.00	–	–	–
70–79	2.9	1.62	1.21	2.18	0.001	1.36	1.00	1.83	0.048	3.9	2.68	2.04	3.52	0.000	2.01	1.51	2.67	0.000
≥80	3.3	1.84	1.13	3.00	0.015	1.21	0.72	2.03	0.475	7.1	5.13	3.58	7.36	0.000	2.79	1.87	4.14	0.000
Gender																		
Men	2.5	1.00	–	–	–	1.00	–	–	–	2.6	1.00	–	–	–	1.00	–	–	–
Women	1.7	0.69	0.55	0.88	0.002	0.75	0.59	0.96	0.022	1.7	0.66	0.52	0.84	0.001	0.80	0.62	1.02	0.070
Severity of cholelithiasis																		
Low	1.9	1.00	–	–	–	1.00	–	–	–	1.2	1.00	–	–	–	1.00	–	–	–
Moderate	2.0	1.08	0.84	1.40	0.538	0.96	0.74	1.24	0.733	2.2	1.84	1.38	2.46	0.000	1.55	1.15	2.08	0.004
High	3.7	2.03	1.32	3.14	0.001	1.43	0.91	2.24	0.122	6.2	5.30	3.59	7.83	0.000	3.40	2.26	5.11	0.000
Previous upper abdominal surgery																		
No	2.0	1.00	–	–	–	1.00	–	–	–	2.0	1.00	–	–	–	1.00	–	–	–
Yes	5.7	2.94	1.07	8.13	0.037	2.29	0.81	6.51	0.119	4.3	2.15	0.67	6.88	0.197	1.72	0.52	5.74	0.376
Type of admission																		
Elective	1.6	1.00	–	–	–	1.00	–	–	–	1.5	1.00	–	–	–	1.00	–	–	–
Emergency	3.0	1.85	1.45	2.35	0.000	1.66	1.29	2.13	0.000	3.4	2.34	1.85	2.97	0.000	1.64	1.27	2.11	0.000
Comorbidities (presence of the condition)																		
Cancer	2.6	1.30	0.64	2.64	0.476	–	–	–	–	3.6	1.81	0.98	3.34	0.059	–	–	–	–
Diabetes	3.3	1.65	0.92	2.97	0.095	–	–	–	–	4.4	2.24	1.34	3.75	0.002	–	–	–	–
Obesity	5.0	2.57	1.19	5.55	0.016	2.35	1.29	2.13	0.034	4.3	2.16	0.95	4.94	0.067	–	–	–	–
Blood disease	5.8	3.03	1.67	5.50	0.000	2.09	1.11	3.93	0.022	7.7	4.16	2.46	7.03	0.000	1.96	1.09	3.51	0.024
Hypertension	2.9	1.46	1.00	2.13	0.050	–	–	–	–	4.0	2.20	1.58	3.05	0.000	–	–	–	–
Ischemic heart disease	2.8	1.42	0.75	2.69	0.286	–	–	–	–	7.4	4.08	2.69	6.20	0.000	1.74	1.09	2.78	0.020
Past coronary revascularization	2.4	1.16	0.28	4.74	0.836	–	–	–	–	9.4	5.08	2.43	10.62	0.000	–	–	–	–
Heart failure	2.3	1.12	0.27	4.57	0.875	–	–	–	–	4.6	2.29	0.83	6.29	0.107	–	–	–	–
Other heart disease	3.4	1.72	0.84	3.52	0.136	–	–	–	–	6.8	3.66	2.17	6.16	0.000	–	–	–	–
Conduction disorder or dysrhythmia	4.1	2.09	1.21	3.62	0.008	–	–	–	–	7.0	3.81	2.47	5.88	0.000	1.73	1.07	2.79	0.025
Cerebrovascular disease	5.9	3.12	1.76	5.54	0.000	1.98	1.09	3.60	0.025	7.7	4.19	2.52	6.98	0.000	–	–	–	–
Vascular disease	0.8	0.37	0.05	2.68	0.328	–	–	–	–	8.5	4.59	2.45	8.62	0.000	–	–	–	–
COPD or respiratory failure	2.6	1.27	0.60	2.72	0.534	–	–	–	–	7.7	4.22	2.66	6.70	0.000	2.02	1.23	3.31	0.006
Chronic nephropathy	9.7	5.31	2.82	10.00	0.000	3.24	1.65	6.36	0.001	10.5	5.82	3.16	10.72	0.000	2.27	1.15	4.46	0.018
Chronic disease of the liver or pancreas	3.5	1.75	0.92	3.33	0.087	–	–	–	–	4.8	2.51	1.45	4.35	0.001	1.97	1.11	3.48	0.020

30-day complications, once other cofactors were taken into account. Women were less likely to experience both types of complications. Having had a previous intervention on the upper digestive system seemed to enhance the risk of both surgical-related and systemic complications, though results were not statistically significant owing to small power. Finally, the risk of both types of complications was more evident in emergencies as opposed to scheduled interventions. Surgical-related complications were higher among individuals with obesity, blood disease, stroke or chronic nephropathy, whereas systemic complications were associated with blood diseases, ischaemic heart disease, conduction disorders or dysrhythmias, COPD or respiratory failure, chronic nephropathy and chronic diseases of the liver or pancreas.

Table 3 shows the relationship between the types of cholecystectomy and outcomes, adjusted for the risk factors identified in table 2. We report results of the advantage of LC versus OC (OR, 95% CI) in the cohort and in each stratum of the variables tested in the models with interaction terms. The incidence of '30-day surgical-related complications' and '30-day systemic complications' was 2.0% and 2.1%, respectively. The OR of surgical related complications for patients who underwent LC as compared to patients with OC was 0.60 (p<0.001). The corresponding figure for systemic complications was 0.52 (p<0.001).

In relation to 30-day surgical-related complications, the protective effect of LC versus OC was consistent across the age category, severity of cholelithiasis and previous upper abdominal surgery, whereas among people with emergency admission, there was no advantage (OR=0.94, p=0.764). Similarly, for systemic complications, the superiority of LC versus OC was consistent, regardless of the level of cholelithiasis severity and elective/emergency admission, but for those 80+ years aged

Table 3 Association between the type of cholecystectomy and 30-day complications: OR and p values from a crude model, risk-adjusted model and models with interaction with the age group, severity of cholelithiasis, previous upper abdominal surgery and type of admission; p value of heterogeneity of the strata-specific estimates—Lazio Region, Italy, January 2007—September 2008

	Per cent	OR_{crude}	95% CI		p Value	OR_{adj}	95% CI		p Value	p_{het}
30-Day surgical-related complications: N=278, %=2.0										
Open cholecystectomy	3.9	1.00	–	–	–	1.00	–	–	–	–
Laparoscopic cholecystectomy	1.7	0.44	0.33	0.57	0.000	0.60	0.44	0.80	0.001	–
Age (years)										0.917
<70	1.8	0.49	0.35	0.71	0.000	0.62	0.43	0.90	0.012	–
70–79	2.9	0.45	0.26	0.76	0.003	0.57	0.33	0.98	0.043	–
≥80	3.3	0.41	0.15	1.12	0.082	0.51	0.18	1.38	0.184	–
Severity of cholelithiasis										0.053
Low	1.9	0.37	0.22	0.61	0.000	0.46	0.28	0.77	0.003	–
Moderate	2.0	0.58	0.40	0.85	0.005	0.78	0.53	1.16	0.224	–
High	3.7	0.24	0.11	0.53	0.000	0.30	0.13	0.68	0.004	–
Previous upper abdominal surgery										0.654
No	2.0	0.45	0.34	0.59	0.000	0.60	0.44	0.81	0.001	–
Yes	5.7	0.26	0.03	2.64	0.256	0.36	0.03	3.69	0.388	–
Type of admission										0.001
Elective	1.6	0.32	0.22	0.46	0.000	0.37	0.25	0.55	0.000	–
Emergency	3.0	0.76	0.51	1.13	0.178	0.94	0.62	1.42	0.764	–
30-Day systemic complications: N=280. %=2.1										
Open cholecystectomy	5.2	1.00	–	–	–	1.00	–	–	–	–
Laparoscopic cholecystectomy	1.6	0.29	0.23	0.37	0.000	0.52	0.40	0.69	0.000	–
Age (years)										0.136
<70	1.5	0.34	0.24	0.49	0.000	0.47	0.32	0.68	0.000	–
70–79	3.9	0.35	0.22	0.55	0.000	0.47	0.29	0.75	0.002	–
≥80	7.1	0.71	0.37	1.37	0.309	0.99	0.50	1.94	0.975	–
Severity of cholelithiasis										0.755
Low	1.2	0.29	0.16	0.51	0.000	0.43	0.24	0.77	0.005	–
Moderate	2.2	0.34	0.25	0.47	0.000	0.55	0.39	0.77	0.001	–
High	6.2	0.38	0.21	0.70	0.002	0.56	0.30	1.05	0.071	–
Previous upper abdominal surgery										0.702
No	2.0	0.29	0.22	0.37	0.000	0.52	0.39	0.69	0.000	–
Yes	4.3	0.41	0.04	4.69	0.470	0.86	0.07	10.40	0.905	–
Type of admission										0.545
Elective	1.5	0.33	0.23	0.50	0.000	0.48	0.32	0.72	0.000	–
Emergency	3.4	0.35	0.25	0.49	0.000	0.56	0.39	0.81	0.002	–

[c] There are no 30-day complications in patients with moderately high severity and undergoing laparotomic cholecystectomy

people there was no advantage of LC versus OC (OR 0.99, p=0.975); also, for patients with previous upper abdominal surgery, there was a much weaker advantage (OR=0.86, p=0.905).

When the association between the type of cholecystectomy and 30-day complications was adjusted with the propensity adjustment method, the results were consistent with those obtained with the risk-adjustment procedure (LC vs OC OR=0.61 and OR=0.52, respectively, for the two outcomes). Finally, the results were similar, taking into account the patients' clustering within different hospitals (data not shown).

DISCUSSION

From this large observational study based on linked administrative health records—taking into account the disomogeneous distribution of factors related to the probability of being offered open surgery—people who end up having an LC have a better short-term prognosis than those who get an OC for the treatment of gallstones. The superiority of the laparoscopic approach in terms of 30-day complications is consistent in different age categories, different severity in disease presentation and history of upper abdominal surgery.

This population-based study contributes to the enlargement of evidence on the effectiveness of LC in a real-life setting by providing an example from the Southern Europe area. It supports the usefulness of observational approaches. The 30-day outcomes linked to admission represent one strength of this study. Despite randomised clinical trials (RCTs) being considered the optimal study design when comparing the efficacy of treatments, observational studies provide a picture of treatment under the usual circumstances of healthcare practice and can also answer the question 'Does it work in practice?'.[3 8] RTCs often have a small sample size and may under-represent vulnerable patient groups, including elderly patients with multiple comorbidities, children and young women, and operate in a highly controlled environment that is far from routine clinical practice. Our study supports the theory that LC is a reliable approach that is safer than OC not only in the old age group—confirming previous findings[22 30]—but also in the presence of severe disease presentation and in patients with a history of upper digestive system surgery. The beneficial effect of LC in relation to systemic complications tends to be lower in 80+ years aged people in comparison with those in younger age groups, and in patients with emergency admission in comparison to elective admissions in relation to 30-day surgical-related complications. These data add to the evidence on the complex relationship between age and outcomes after surgery.[22–24 30]

A number of potential biases are present. First of all, people in the two groups of patients analysed are not homogeneous in terms of anaesthesia risk due to a higher frequency of the elderly and more comorbidities in the open group than in the laparoscopic one. When comparing the effect of the two techniques using two different populations, the so-called indication bias may affect study validity.[8 31] To limit this problem, we run the propensity adjustment analysis to take into account the different distribution of factors strongly associated with the probability to receive open surgery in the study population. This analytical approach confirmed the advantage of laparoscopic versus open surgery obtained in the main logistic regression analysis. Another critical point is the potential different distribution of laparoscopic experience across surgeons; however, a sensitivity analysis which took this point into account led to similar results. The use of ICD-9-CM codes in the definition of severity of disease presentation and of complications is another major limit. Since discharge abstract data have little insight into clinical details and do not inform on the temporal relationship of the clinical conditions and processes, defining complications is a difficult task.[32] In this respect, we tried to improve the accuracy of our measures both by (1) applying a specific coding algorithm with subsequent hospital admissions used to retrieve adverse events and (2) excluding in the 'count' of complications specific items if reported in the index only (ie, peritonitis) because of the difficulty in determining whether it was already present at admission. Moreover, we cannot exclude an undernotification of complications—a major limit of our source of data—but it is unlikely that it is influenced by the type of surgery. Another major problem is the potential misclassification of exposure as we were not able to measure the occurrence of conversion of LC to OC. The number of individuals that were switched from LC to OC is low in comparison to the figures documented in other studies, and it may represent a severe source of bias in our study.[30 33]

Beneficial effects of the laparoscopic approach versus traditional open surgery for the treatment of gallstones come from various randomised controlled trials.[34] They found significant shorter hospital stay and quicker convalescence associated with LC but no differences in mortality, complications and operative time between the two procedures. A better trend with the laparoscopic approach, including morbidity and mortality, comes from observational studies. From a surveillance system in eight Swiss hospitals, surgical site infections were less common in the laparoscopic approach in comparison to traditional open surgery (0.5% in LC vs 1.8% in OC).[35] Significantly, a lower incidence of venous thromboembolism and surgical site-infections in laparoscopic cases versus open cases was observed in a large administrative dataset-based study in USA.[14 15] National estimates for LC in USA showed an increase in LC from 52% in 1991 to 75% in 2000 with a constantly low death rate and a decrease in biliary reconstruction rate over time.[16] On the basis of the 1997–2006 trend analysis by the same authors, LC was associated with a low death rate (mean value in the period: 0.52%) while OC was associated with a significantly higher rate (corresponding value: 4.9%).[9] In a retrospective study using Medicare beneficiaries, common bile duct (CBD) injury during cholecystectomy was associated with a significant higher risk of death in comparison to cholecystectomy without CBD injury over a 9.2-year follow-up period.[17] From a Swiss 1995–2005 hospital database analysis, the incidence rate of bile duct injury after LC was 0.3% and did not change over time.[18] The incidence of conversion to OC after LC in all hospitals in England from 2005 to 2006 was examined using Hospital Episode Statistics and recorded (4.6% for elective procedures and 9.4% for emergency procedures).[19]

Population-based linkage of routinely collected health data represents a precious tool to support large-scale and real-world practice evaluation by measuring specific outcomes and comparing them over time and across populations. Together with results from experimental research settings, the conclusions of research studies evaluating clinical outcomes through data linkage systems should be successfully incorporated into practice by clinicians/surgeons.

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