Laparoscopic cholecystectomy decreases extra surgical site morbidity compared with open cholecystectomy: A propensity matched analysis

La cholécystectomie par cœlioscopie diminue la morbidité extra pariéto-abdominale comparée à la cholécystectomie par laparotomie: Analyse aidée par le score de propension.

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RÉSUMÉ

Prérequis : L'idéal pour mettre en évidence l'effet d'un traitement est de réaliser un essai thérapeutique avec tirage au sort ce qui constitue le "Gold standard" de la Chirurgie avec niveaux de preuves. En pratique, toutes les études en chirurgie ne peuvent pas avoir un tel plan d'étude (essai randomisé) pour des raisons éthiques ou même pratiques. Le but de cet article a été de comparer la cholécystectomie coelioscopique à la cholécystectomie classique (par voie sous costale droite), en utilisant des données d'une base administrative analysées à l'aide du score de propension.

Méthodes : Ont été inclus tous les patients porteurs de lithiase vésiculaire admis dans le service de chirurgie B entre 1er juin 2008 et 31 décembre 2009. Dans cette étude, le score de propension représentait la probabilité qu'un patient soit traité selon une procédure en se basant sur des variables connues qui influent sur la prescription de cette procédure. Ce score de propension émane d'une régression logistique faite pour apparier les patients qui ont eu une cholécystectomie coelioscopique à des patients contrôles qui ont eu une cholécystectomie par voie classique. Le critère de jugement principal était la morbidité qui correspond au nombre de patients ayant une ou plusieurs complications survenant lors du séjour hospitalier ou durant les 30 après le retour au domicile.

Résultats : En respectant, la règle de l'intention de traiter, 535 patients ont eu une voie coelioscopique et 60 patients ont eu une voie classique par laparotomie du fait de tare cardiaque associée, d'antécédents de laparotomie ou lorsqu'une lithiase de la voie biliaire principale (VBP) était suspectée, cependant la cholangiographie per opératoire avait montré une VBP libre. Selon le score de propension, 28 patients du groupe laparotomie ont été appariés à 58 du groupe coelioscopie. La comparaison entre les deux groupes avant et après l'appariement par le score de propension avait montré que le groupe laparotomie était associé à un taux plus élevé de complications extra pariéto abdominales (p= 0.010), et une durée médiane Page 4/25 Tunisie Medicale plus longue de l'intervention, du séjour post-operatoire et du séjour global (p= 0. 0001).

Conclusion : La voie coelioscopique doit être indiquée de 1ère intention pour traiter chirurgicalement une lithiase vésiculaire quitte à faire une conversion imposée par les données opératoires.

Mots-clés

Données administratives, qualité de soins, score de propension, étude comparative, cohorte, morbidité

SUMMARY

Background : The ideal way to show treatment effectiveness is through randomized controlled trials the 'gold standard' in evidence-based surgery. Indeed, not all surgical studies can be designed as randomized trials, sometimes for ethical and otherwise, for practical reasons. This article aimed to compare laparoscopic cholecystectomy to open cholecystectomy, according to data from an administrative database, managed by a propensity matched analysis.

Methods : Were included all patients with cholelithiasis admitted in Department B between June 1st, 2008 and December 31st, 2009. In this study, the propensity score represented the probability that a patient would be treated by a procedure based on variables that were known or suspected to influence group assignment and was developed using multivariable logistic regression used here to match patients who had laparoscopic cholecystectomy to a control patient who had open cholecystectomy. The main outcome measure was morbidity. This was expressed as the number of patients with 1 or more complications occurring during the hospital stay or within 30 days following discharge.

Results: According to intention to treat, 535 patients had a laparoscopic approach (LC group) and 60 patients had a traditional open approach (OC group) regarding associated cardiac disease, previous laparotomy or when choledocholithiasis was suspected, however intra operative cholangiography showed that there was no choledocolithiasis. According to the propensity score, 28 patients in OC were matched with 58 in LC. Comparison between OC and LC before and after propensity matched analysis showed that OC was associated with a higher rate of Extra Surgical Site morbidity (p= 0.010), a longer median duration of intervention, post-operative stay and overall hospital stay (p= 0. 0001).

Conclusion: LC should be considered as first-line therapy to treat cholelithiasis surgically even if it becomes necessary to convert to OC because of intra operative findings.

Key-words

Administrative data, quality of care, propensity score, comparative study, cohort, morbidity

The objective of surgical outcomes research is to assess the effectiveness, and costs of surgical care. The ideal way to show effectiveness is through randomized controlled trials the 'gold standard' in evidence-based surgery. However, Horton in 1996 wrote in Lancet a provocative editorial when he described surgical research as a comic opera because only 7% of all surgical articles reported results from randomized trials, whereas 46% were cases series reports with a low level of evidence (1). Indeed, not all surgical studies can be designed as randomized trials, sometimes for ethical and otherwise, for practical reasons (2).

There are several alternatives to deal with this difficulty. Using large observational samples arising from administrative database is one. Outcomes research based on administrative data represents a specific subset of clinical research. Administrative data have been defined as large, computerized data files generally compiled in billing for health care services such as hospitalizations, but contain little information for scientific research (3). However, because of the design of these large samples data and conclusions may be biased linked to confounding variables. Multivariable analysis (MVA) is another solution. MVA is a tool for determining the relative contributions of different causes to a single event. Propensity scores constitute another a powerful alternative to multivariable analysis in the assessment of observational, non-randomized surgical studies (2). The propensity score represents the probability that a patient would be treated by a procedure based on variables that were known or suspected to influence group assignment.

This article aimed to compare laparoscopic cholecystectomy to open cholecystectomy, according to data from an administrative database, managed by a propensity matched analysis.

METHODS

A questionnaire was prepared with the objective of collecting data to classify patients' records, evaluate department activity and to prepare billing in the department B of general surgery at Charles Nicolle, El Manar University hospital - Tunis, Tunisia. This questionnaire included 111 variables concerning demographics, pre- operative, intra-operative, post-operative variables and cost evaluation.

Eligibility criteria : Were included all patients with cholelithiasis admitted in Department B between June 1st, 2008 and December 31st, 2009 without exception regarding age, gender, previous diseases, emergent situations and/or surgical techniques.

Non Eligibility criteria: Were not included patients who underwent cholecystectomy incidentally for cancer, chronic pancreatitis, or other disease than cholelithiasis.

Procedures: All cholecystectomies were performed under general anesthesia with the same procedural steps; intraoperative cholangiographies were performed selectively according to the Lacaine and Huguier score validated in our department with a prospective study (4). Laparoscopic cholecystectomy was planned initially for all patients except those who had associated cardiac disease, previous abdominal surgery or when choledocholithiasis was suspected.

Questionnaire

Pre-operative variables

These included: 1) age; 2) gender; 3) BMI [calculated as weight in kilograms divided by height in square meters] ; 4) American Society of Anesthesiologists Physical Status Classification System (ASA score) (5); 5) New York Heart Association Functional Classification – The Criteria Committee of the New York Heart Association (NYHA score) (6); 6) previous health conditions; 7) initial disease; 8) obesity (defined as Body Mass Index > 30 Kg/m²); 9) moment of intervention (elective or emergent operation) ; 10) Health condition at admission; 11) type of emergency (trauma or not)

Per-operative variables

Per operative variables concerned 1) surgeon status (senior or resident), 2) operating room (aseptic or septic), 3) type of anesthesia (general or local), 4) antibiotic-prophylaxis, 5) surgical approach (laparoscopy versus laparotomy), 6) evaluation of different operative costs.

Post-operative variables

Were included post-operative recovery (with or without undesirable events), surgical complications with or without re-operation, extra surgical site complications, different procedures in Intensive care unit, or death or end of life.

Outcome measures: The main outcome measure was morbidity. This was expressed as the number of patients with 1 or more complications occurring during the hospital stay or within 30 days following discharge (7). Postoperative morbidity was defined according to the Centers for Disease Control and Prevention classification by Horan et al. (8) with some modifications. Overall postoperative morbidity was modified to include 1) extra surgical site (ESS) morbidity corresponding to nosocomial infections including broncho-pneumonia, unexplained postoperative fever, septicemia, superficial phlebitis and lymphangitis arising during hospitalization; 2) incisional surgical site (ISS) morbidity (abscess, hematoma) with or without re operation; 3) organ/space surgical site (O/SSS) morbidity, including intra-abdominal abscess and generalized peritonitis; anastomotic leakage; hemoperitoneum; intestinal occlusion with or without re operation.

The second end point was postoperative mortality, defined as any and all deaths occurring during hospital stay or within 30 days after discharge (7)

Other outcome measures were: overall hospital stay; pre-operative hospital stay; duration of intervention; post-operative stay.

Definitions

The propensity score represents the probability (between 0 and 100 per cent) of receiving treatment A rather than treatment B (or the treatment rather than the control intervention) for patients in a non-randomized study, and is based on observed baseline characteristics (potential confounders).

In our study, the propensity score represented the probability that a patient would be treated by a procedure based on variables that were known or suspected to influence group assignment and was developed using multivariable logistic regression used here to match patients who had laparoscopic cholecystectomy to a control patient who had open cholecystectomy.

Calculations and statistics:
A matching procedure selected matched pairs initially identical to five decimal places of probability (9). If no match existed at five decimal places, then that patient was excluded from the study. Data were culled and analyzed with SPSS software (Statistical Package for the Social Science, SPSS, Inc; version 15.0). Univariate analysis was performed on all factors with the chi-square test and Fisher's exact test for qualitative variables and the Student's t-test for quantitative variables, as appropriate. When the distribution was not Gaussian, the Mann-Whitney U test was used. All variables with a p value ≤ 0.05 were entered into multivariable step-by-step analysis, according to non-conditional logistic regression. The maximal likelihood was expressed by odds ratios (OR) with their 95% confidence intervals (95% CI).

RESULTS

Descriptive analysis
Of 4690 admissions to Department B of general surgery during the stated study period, included in an administrative data base, we identified 837 patients (17.8%) treated for cholelithiasis (complicated or not). The medical records and similar prospectively recorded data of 595 patients (71.1%) undergoing cholecystectomy as final treatment were retrieved prospectively. Demographic data are presented in table 1.

Table 1: Demographic data of 595 cholecystectomies: descriptive analysis

variables	N=595	%
Age (years)		
≤ 59	400	67.2%
60-75	160	26.9%
≥ 76	35	5.9%
Gender		
Women	469	78.8%
Men	126	21.2%
Obesity	116	19.5%
Corticoids/immunosuppressors	21	3.5%
Melitus diabete	90	15.1%
Cardiac disorders	177	29.7%
Respiratory disorders	17	2.9%
Renal disorders	6	1%
Other disorders	70	11.8%
ASA Score		
ASA 1	369	62%
ASA 2	206	34.6%
ASA 3	19	3.2%
ASA 4	1	0.2%
Re hospitalization	19	3.2%
ICU stay	29	4.9%
Admission in ICU during 48 first hours	14	2.4%
Intervention		
Emergent	222	37.7%
Elective	373	62.7%
Antibiotic prophylaxis	387	65%
Surgical approach		
Open surgery	60	10.1%
Laparoscopy	535	89.9%
Biliary lithiasis		
Gallbladder lithiasis	383	64.4%
Cholecystitis	184	30.9%
Other	28	4.7%
Postoperative course		
Uneventful	581	97.6%
Complicated	14	2.4%
Intra surgical complication	6	1%
Extra surgical site infection	17	2.8%
Re intervention	0	0%
Post-operative death	6	1%

Comparison between OC versus LC groups
Table 2 summarizes the comparison between OC and LC before and after propensity matched analysis.

Baseline characteristics before propensity matching
According to intention to treat, 535 patients had a laparoscopic approach (LC group) and 60 patients had a traditional open approach (OC group) regarding associated cardiac disease, previous laparotomy or when choledocholithiasis was suspected, however intra operative cholangiography showed that there was no choledocolithiasis. Baseline demographics, preexisting medical conditions, relevant preoperative, and intra-operative variables in the unmatched study population are summarized in Table 2. Patients were significantly younger in LC; there were more women in LC. Several epidemiologic and clinical differences between LC and OC groups existed in the unmatched cohort. The baseline prevalence of cardiac failure, previous abdominal surgery, complicated presentation (acute cholecystitis and others), ICU stay, admission in ICU during the first 48 hours and prescription of antibiotics was higher in the OC group (Table 2).

Baseline characteristics after propensity matching
According to the propensity score (table n°2), 28 patients in OC were matched with 58 in LC. The c statistic for the propensity derivation model was 0.763. The range of the propensity scores was similar in both groups (0.71796– 0.98676, each) (table 3). The matching process eliminated all significant differences that existed between OC and LC regarding patient demographics, epidemiologic factors, preexisting medical conditions, or relevant clinical variables except for ICU stay (Table2).

Outcome Measures
Comparison between OC and LC before and after propensity matched analysis showed that OC was associated with a higher rate of Extra Surgical Site morbidity (p= 0.010), a longer median duration of intervention, post-operative stay and overall hospital stay (p= 0. 0001) (Table n° 4).

DISCUSSION

LC should be considered as first-line therapy to treat cholelithiasis surgically even if it becomes necessary to convert to OC because of intra operative findings. LC decreases the rate of Extra Surgical Site morbidity (p= 0,010), median duration of intervention, median postoperative stay and median overall hospital stay (p= 0, 0001) compared to OC. No statistical difference was observed between the two groups concerning the other outcome measures.
Our administrative database helped us to perform a comparison between LC and OC using the propensity score. As propensity analyses have been shown to effectively reduce bias in baseline characteristics when assessing treatment effects (10), all significant baseline differences between studies groups were adequately reconciled using this method. Propensity score analysis is an important tool in the analysis of surgical non-randomized studies and represents a good alternative to regression analysis in controlling for differences in baseline characteristics between treatment groups (2).
Two other studies used the same design. Harboe et al. (11) showed

Table 2: Unmatched and propensity score-matched baseline characteristics

	Unmatched cohort			Propensity Matched Cohort		
	OC* n=60	**LC** n=535**		**OC* n=28**	**LC** n=58**	
Risk Factors	**n (%)**	**n (%)**	**p**	**n (%)**	**n (%)**	**p**
Age (years)						
≤ 59	24 (40%)	376(70.3%)		13(46.4%)	31(53.4%)	
60-75	25(41.7%)	135(25.2%)	0.000	13(46.4%)	25(43.1%)	0.676
≥ 76	11(18.3%)	24(4.5%)		2(7.1%)	2(3.4%)	
Gender						
Women	40(66.7%)	429(80.2%)	0.015	23(82.1%)	51(87.9%)	0.515
Men	20(33.3%)	106(19.8%)		5(17.9%)	7(12.1%)	
Obesity	14(23.3%)	102(19.1%)	0.429	5(17.9%)	7(12.7%)	0.076
Corticoids/immunosuppressors	4(6.7%)	17(3.2%)	0.152	3(10.7%)	1(1.7%)	0.099
Melitus diabetes	10(16.7%)	80(15%)	0.725	3(10.7%)	11(19%)	0.534
Cardiac disorders	31(51.7%)	146(27.3%)	0.000	12(42.9%)	23(39.7%)	0.777
Respiratory disorders	1(1.7%)	16(3%)	1.000	0(0%)	2(3.4%)	1.000
Renal disorders	2(3.3%)	4(0.7%)	0.115	1(3.6%)	1(1.7%)	0.548
Other disorders	9(15%)	61(11.4%)	0.412	5(17.9%)	6(10.3%)	0.327
Patient previously admitted	12(20%)	32(6%)	0.001	1(3.6%)	1(1.7%)	0.548
Origin						
Consultation	29(48.3%)	310(57.9%)	0.320	13(46.4%)	30(51.7%)	
Emergency	23(38.3%)	158(29.5%)		11(39.3%)	20(34.5%)	0.891
Other	8(10.3%)	67(12.5%)		4(14.3%)	8(13.8%)	0.548
Re hospitalization	2(3.3%)	17(3.2%)	1.000	1(3.6%)	1(1.7%)	0.013
ICU stay	10(16.7%)	19(3.6%)	0.000	5(17.9%)	1(1.7%)	0.246
Admission in ICU during 48 first hours	6(10%)	8(1.5%)	0.001	2(7.1%)	1(1.7%)	
Intervention						0.525
Emergent	25(41.7%)	197(36.8%)	0.462	11(39.3%)	27(46.6%)	1.000
Elective	35(58.3%)	338(63.2%)		17(60.7%)	31(53.4%)	0.499
Distress at arrival	0(0%)	0(0%)	1.000	0(0%)	0(0%)	
Antibiotic prophylaxis	47(79.7%)	335(63.1%)	0.011	19(67.9%)	35(60.3%)	
Biliary lithiasis						0.147
Gallbladder lithiasis	34(56.7%)	349(65.2%)		16(57.1%)	35(60.3%)	0.103
Cholecystitis	15(25%)	169(31.6%)	0.000	7(25%)	20(34.5%)	
Other	11(18.3%)	17(3.2%)		5(17.9%)	3(5.2%)	
Intra operative incidents	2(3.3%)	6(1.1%)	0.189	2(7.1%)	0(0%)	

*OC: Open cholecystectomy **LC: Laparoscopic cholecystectomy

that administrative data issued from the Danish national register were useful as results for cholecystectomy derived from the review of medical records serving as the “gold standard” with a concordance ranging between 97.1% and 100% and a kappa indice varying from 0.73 to 1. Dolan et al (12), used logistic regression to show that the mortality rate was higher for OC (Odds Ratio: 4.57; 95% CI, 4.37-4.79, p< 0.001).

As concerns propensity matched analysis, Kuwabara et al (13) concluded that LC decreased post-operative complications compared to OC for elderly patients. Two other prospective and comparative studies concluded in the same way (14, 15). Two retrospective and comparative studies (16, 17) concluded that LC was associated with less post-operative complications and a shorter post-operative stay than OC.In another study, again using the same methodology (administrative database associated with propensity score analysis), Kuawabara et al. (18) assessed laparoscopic abdominal surgery in Japan with a Japanese administrative database. Laparoscopic surgery safety was confirmed; laparoscopic cholecystectomy was associated with shorter length of stay and lower total charge.

In contrast, Porte et al. (19) reported a prospective study comparing LC to OC after adjustment of age and gender showing that there was no significant statistical difference regarding post-operative complications; however post-operative stay was significantly shorter in LC (p< 0,001).

Table 3: Predicted probability according abdominal approaches

	Abdominal approaches		
Predicted probabilities	**OC***	**LC****	**total**
.71796	1	5	6
.72558	1	1	2
.73486	1	1	2
.77945	1	2	3
.79614	1	1	2
.81475	1	1	2
.83071	1	1	2
.83576	1	1	2
.85482	1	1	2
.86364	1	2	3
.86489	1	1	2
.88104	1	3	4
.88481	1	1	2
.88847	1	4	5
.88862	1	2	3
.89217	1	4	5
.89562	1	3	4
.89898	1	1	2
.90849	1	1	2
.92256	1	1	2
.92761	1	3	4
.93235	2	2	4
.94678	1	4	5
.96011	2	2	4
.97734	1	4	5
.98676	1	6	7
Total	28	58	86

*OC: Open cholecystectomy **LC: Laparoscopic cholecystectomy

Table 4 : Outcomes measures

	Unmatched cohort			Propensity Matched Cohort		
	OC* n=60	**LC** n=535**		**OC* n=28**	**LC** n=58**	
Postoperative factors	**n (%)**	**n (%)**	**p**	**n (%)**	**n (%)**	**p**
Post-operative death	2(3.3%)	4(0%)	0.115	0(0%)	0(0%)	1.000
ISS morbidity	0(0%)	2(0.4%)	1.000	0(0%)	0(0%)	1.000
O/SSS morbidity	2(3.3%)	4(0.7%)	0.115	0(0%)	1(1.7%)	1,000
ESS morbidity	7(11.7%)	10(1.9%)	0.001	4(14.3%)	0(0%)	0,010
Duration of intervention: median (range)	2:00(0:40-5:00)	1:00(0:20-5:15)	0.000	2:05(0:40-4:35)	1:10(0:20-3:10)	0,000
Post-operative stay: Median (range)	3(1-18)	1(0-12)	0.000	3(1-18)	1(0-12)	0,000
Hospital Stay: Median (range)	6(2-29)	3(1-45)	0.000	8(2-9)	3(1-21))	0,000

*OC: Open cholecystectomy **LC: Laparoscopic cholecystectomy
ISS: incisional surgical site O/SSS: Organ/Space surgical site ESS: Extra surgical site

Other authors, using propensity score analysis, evaluated different criteria. De Mestral et al. (20) compared operative outcomes of early and delayed cholecystectomy for acute cholecystitis with a population-based propensity score analysis. Early cholecystectomy was associated with a lower risk of major bile duct injury, or death. Total hospital length of stay was shorter with early cholecystectomy. Shi et al. (21) concluded that the hospital treatment cost differed significantly between high-volume hospitals/surgeons and low/medium-volume hospitals/surgeons (2,073.70 vs. 2,350.91/2,056.73 vs. 2,553.76, P < 0.001). In our study, we did not assess these two variables that were not available.

Comparatively, four randomized clinical trials (RCT) have compared LC to OC. In their study including gangrenous cholecystitis, Kiviluoto et al. (22) found less post-operative complications (p= 0.0048) and a shorter post-operative stay (p= 0.006) in favor of LC; on the other hand, the conversion rate was 16%. Two other RCT (23, 24) showed that hospital stay was shorter in LC. Dauleh et al. (25) found that fewer patients had early fever in LC than in OC (15% vs 55%). These data showed that studies with different designs - propensity score matching analysis on one hand and RCT on the other - helped researchers to conclude in the same way for the same outcome measures. Moreover, observational studies using propensity score matching analysis are less expensive than RCT.

Furtheremore, Damiani et al. (26) concluded with a meta-analysis that post-operative pulmonary function, according to the Tiffenau index, was better preserved after LC than after OC. This meta-analysis included five RCT and eight cohort studies. Three other meta-analysis (27, 28, 29), focused on patients with liver cirrhosis. Laurence et al. (27) concluded that LC was associated with shorter operative time, reduced complication rates and reduced length of hospital stay. Cheng et al. (28) included 19 non-randomized studies (n=1082) in their meta-analysis and showed a significantly lower intra-hospital mortality and less total operative time in the LC compared to the OC group.

De Goede et al.(29) concluded that patients with Child –Turcotte-Pugh grade A or B liver cirrhosis who underwent LC for symptomatic cholecystolithiasis had fewer overall postoperative complications, a shorter hospital stay and resumed a normal diet more quickly than those who underwent OC.

Our study has some limitations. First, administrative databases provide limited clinical data, inherent to the risk of miscoding, under coding or over coding. Second, administrative databases are not focused on a specific question such as patient, intervention, comparison and outcome measures. Third, propensity score analysis could be biased if important true confounders are not systematically recorded in the administrative database. Fourth, Non Randomized Studies, observational studies with propensity score analysis were heterogeneous in terms of sample size.

CONCLUSION

LC should be considered as first-line therapy to treat cholelithiasis surgically even if it becomes necessary to convert to OC because of intra operative findings. LC decreases the rate of Extra Surgical Site morbidity (p= 0,010), median duration of intervention, median postoperative stay and median overall hospital stay (p= 0, 0001) compared to OC.

Our study, as others (11, 12), showed that administrative data bases can be useful to assess quality of care. Outcomes research based on administrative databases should be viewed as complementary and not inferior to prospective RCT in surgery (3). Furthermore, Lonjon et al. (30) reported a review which concluded that prospective non randomized studies with suitable and careful Propensity Score analysis can be relied upon as evidence when randomized clinical trials are not possible. In fact, evidence-based surgery is widely based on evidence from non-randomized studies.

Aurhor contributions

Dr Dziri had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Dziri, Ben Osman, Samaali, Fingerhut. Acquisition of data: Ben Osman, Bedoui, Chaker, Bouasker, Nouira. Analysis and interpretation of data: Dziri, Ben Osman, Samaali. Drafting of the manuscript: Dziri, Samaali, Nouira, Fingerhut. Critical revision of the manuscript for important intellectual content: Fingerhut, Dziri, Statistical analysis: Dziri. Study supervision: Dziri, Ben Osman.

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