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Retrospective Cohort Study

Assessment of the American College of Surgeons surgical risk calculator of outcomes after hepatectomy for liver tumors: Results from a cohort of 950 patients

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A R T I C L E I N F O

Keywords:
Hepatectomy
Complications
Mortality
Liver failure
Bile leak
ACS-NSQIP calculator

A B S T R A C T

Background: The American College of Surgeons National Surgical Quality Improvement Program's (ACS-NSQIP) calculator has been endorsed to counsel patients regarding complications. The aim of this study was to assess its ability to predict outcomes after hepatectomy.

Methods: Outcomes generated by the ACS-NSQIP were recorded in a consecutive cohort of patients. By using established classifications of complications, post-hepatectomy insufficiency and bile leak, the calculator was tested by the comparison of expected versus observed rates of events. The performance of the calculator was tested by using c-statistic and Brier score.

Results: 950 patients who underwent hepatectomy between January 2014 and June 2019 were included. Predicted rates were significantly lower than actual rates: the mean ACS-NSQIP morbidity was 17.97% ± 8.4 vs. actual 37.01% ± 0.56 (P < 0.001); the mean ACS-NSQIP mortality was 0.91% ± 1.48 vs. actual 1.76% ± 0.11 (P < 0.001). Predicted length of stay (LOS) was significantly shorter: mean ACS-NSQIP was 5.81 ± 1.66 days vs. actual 10.91 ± 4.6 days (P < 0.001). Post-hepatectomy liver insufficiency and bile leak were recorded in 6.8% and 11.9% of patients, respectively. These events were not expressed by the calculator. ***C***-statistic and Brier scores showed low performance of the calculator.

Conclusion: The calculator underestimates the risks of complications, mortality and LOS after hepatectomy. Refinements of the ACS-NSQIP model that account for organ-specific risks should be considered.

1. Introduction

Hepatectomy is the treatment of choice for primary tumors, such as hepatocellular carcinoma (HCC), as well as for secondary tumors including colorectal liver metastases (CLM) [1,2]. Despite the increased safety of hepatectomy in past years, the rate of mortality and morbidity remains significant [3]. In order to provide informed consent, patients must be counseled accurately on perioperative risks and the likelihood of complications after hepatectomy. For this purpose, several different methods have been proposed to refine the selection process for hepatectomy candidates, with the aim to be able to identify patients that require increased acute postoperative care on an individual basis, or even exclude those patients with a significantly greater risk of complications. However, there is no definitive agreement on their values and applicability.

The American College of Surgeons National Surgical Quality Improvement Program's (ACS-NSQIP) calculator was developed to counsel patients on their 30-day postoperative risk after many different surgical interventions [4]. Using the values of different preoperative variables, the ACS-NSQIP calculator gives back the risk of 9 different events, including the overall morbidity, mortality and length of stay (LOS). Interestingly, the calculator compares the estimated risks with the average of all patients treated with the same intervention [5]. This calculator has been endorsed by the surgeons' community to drive surgical decision making and informed consent. However, it does not include organ-specific risks which in the case of hepatobiliary surgery are usually taken into account to accurately measure the risk of a specific major intervention.

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The aim of this study was to assess the ACS-NSQIP calculator's ability to predict complications, mortality and length of stay (LOS) in patients undergoing hepatectomy for liver tumors.

2. Methods

2.1. Study design and data collection

This is an observational retrospective study conducted in a tertiary-referral university hospital on prospectively collected data. The study examined a historical cohort of consecutive patients that underwent hepatectomy at our institution. Written informed consent was obtained from each patient included in the study. The study protocol was in accordance with the ethical guidelines established in the 1975 Declaration of Helsinki. It was also compliant to the procedures of the local ethical committee of the institution. Results were reported according to Strengthening the Reporting of Cohort Studies in Surgery (STROCSS guidelines) [6]. The protocol was also submitted to the international clinical trial registry (clinicaltrials.gov – registration number NCT03793933).

2.2. Study endpoint

The overall endpoint was to test the reproducibility of the ACS-NSQIP calculator [7–9]. For this purpose, the postoperative outcomes generated by the ACS-NSQIP calculator were compared with the postoperative outcomes observed in our patient cohort.

2.3. Study eligibility criteria

Patients were eligible if they met the following inclusion criteria: 1) full clinical, radiologic, pathologic, and surgical perioperative data; 2) regular postoperative follow-up. Exclusion criteria were the following: 1) bile duct interventions; 2) patients who underwent thermo-ablations; 3) unavailability of clinical, radiological, pathologic, surgical as well as postoperative follow-up data.

2.4. Definitions

The nomenclature and extent of hepatic resection were recorded according with the Brisbane classification [10]. Hepatic resections were considered major when three adjacent segments were removed. Minor hepatectomies were also detailed by using the recent classification proposed by the CLISCO group [11]. Briefly, minor hepatic resections were divided in three categories according with the different expected postoperative outcomes: limited resection, defined as those resection without exposure of major intrahepatic vessels; complex limited resection, defined as limited resection with exposure of major intrahepatic vessels; complex core hepatectomies, defined as resection of segment 1 combined with resection of segments 7,8 and/or 4 superior. Complications were defined and graded based on the Clavien-Dindo classification [12]. Liver failure was defined and graded based on the definition of the International Study Group of Liver Surgery [13]. Bile leak was defined and graded based on our previously reported protocol [14]. Finally, postoperative mortality was recorded at 30-day after surgery.

2.5. Predictors of postoperative complications

We considered the variables deemed to potentially impact postoperative morbidity and predict the postoperative course, including: sex, age, presence of co-morbidities according with the ACS-NSQIP calculator and also graded using the age-adjusted Charlson Comorbidities Index (CCI) [15], the American Society of Anesthesiologists (ASA) score, the Model for End-stage Liver Disease (MELD) [16], the combination of serum values of bilirubin and cholinesterases (BIL-CHE score) [17], and the extent of hepatectomy. Of note, only the variables determined preoperatively were considered.

2.6. ACS-NSQIP calculator

The ACS-NSQIP surgical risk calculator's website (http://www.risk-calculator.facs.org/) was used to calculate the estimated risks for each patient. Then, any type of complications including the risks of mortality, serious complications, reoperation, and LOS were recorded in our database. To be consistent with the ACS-NSQIP program, serious complications were classified according with those events listed in the ACS-NSQIP website [4].

2.7. Statistical analysis

The categorical variables were reported as a number and percentage, while continuous variables were reported as the median and range or as mean and standard deviation. Only patients with complete data were considered. The categorical actual outcomes data and percentage incidence from the prospective database were compared to the continuous output of the ACS-NSQIP surgical risk calculator by using logistic regression. This was done to test the correlation between observed outcomes and the chance of outcomes. Subgroup analysis was also performed to test the ability of the ACS-NSQIP calculator in three specific categories of patients: patients with primary versus secondary liver tumors; patients with or without chronic liver diseases; patients undergoing major versus minor hepatectomy according with the Brisbane classification. For this purpose, we compared the differences in means between the predicted outcomes versus observed outcomes [18]. The performance of the surgical risk calculator was assessed using calibration and discrimination measures. The calibration was tested with the Hosmer-Lemeshow test, while the discrimination was tested with the c-statistic method, which is based on the receiver operating characteristic (ROC) curve analysis [19,20]. Finally, the accuracy of probabilistic predictions was tested by using the Brier score, which is defined as the average squared difference between patient's predicted and observed outcomes [21]. Results were considered significant if $p < 0.05$. All statistical computations were performed using the software IBM-SPSS.

3. Results

3.1. Patients

Among 1034 consecutive patients who underwent hepatectomy at the Division of Hepatobiliary and General Surgery of Humanitas University, Humanitas Clinical and Research Center (Milan, Italy) from January 2014 to June 2019, 84 were excluded because not meeting inclusion criteria or because of missing data. The final analysis was, then, conducted on 950 patients (Fig. 1). Table 1 details the patients' demographic and preoperative data. The study included 693 (73%) men and 2577 (27%) women, with a median age of 67 years (range 30–87). None of the included patients received hepatectomy in emergency nor during sepsis nor with decompensated liver function. The median value of the ASA score was 2 (range 1–4). The underlying liver function is summarized by the values of MELD and of BIL-CHE scores as reported in Table 1. Of note, the ACS-NSQIP surgical risk calculator does not include any specific test for the evaluation of the functional liver reserve. Table 1 details also the comorbidities of the included patients. The median value of the Charlson comorbidity index was 5 (range 0–12) indicating an average population otherwise fit for major surgery.

Table 2 details the operative data. Most of the patients (89.1%) underwent minor hepatectomy in according with our well-established surgical approach in performing parenchymal-sparing hepatectomy [22,23]. However, the reported use of the thoraco-abdominal approach, the median length of operations as well as of the Pringle' maneuver indicate that the included cases were complex, which reflect our current clinical activity. Indeed, only one half of those minor hepatectomies

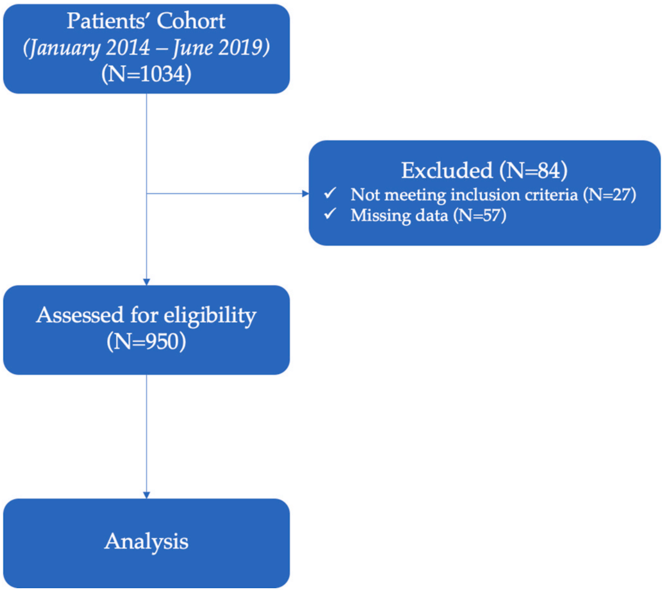

Fig. 1. Flow diagram. The figure shows the patients' cohort, which included 1034 patients prospectively collected between January 2015 and June 2019. Among 1034, 84 patients were excluded because not meeting inclusion criteria or because of missing data. The final analysis was conducted on 950 patients.

Table 1
Patients' demographics and preoperative data. The table shows the demographics and preoperative baseline data of the 950 patients included in the study.

Variable	Data
Age	
Median; range	67; 30-87
Sex	
Men/women	693 (73%)/257 (27%)
Pathology	
Primary liver tumors	352 (37.1%)
Secondary liver tumors	568 (59.8%)
Benign liver conditions	30 (3.1%)
BMI	
Median; range	26.8; 19.1–33.4
ASA	
Median; range	2; 1-4
MELD	
Median; range	7; 6-19
BIL-CHE	
Median; range	0; 0-3
Chronic liver disease/Cirrhosis	201 (21.1%)
Hypertension	437 (46%)
Diabetes	133 (14%)
Congestive heart failure	25 (2.6%)
Smokers	190 (20%)
COPD	38 (4%)
Dialysis	0
Use of steroids	19 (2%)
Dyspnea	0
Acute renal failure	0
Functional status – independent	950 (100%)
Emergency case	0
Ventilator dependent	0
Sepsis	0
Disseminated cancer	0
Ascites	0
Charlson comorbidity index	
Median; range	5; 0-12

Abbreviations: BMI, Body Mass Index; ASA, American Society of Anesthesiologists; MELD, Model for End-stage Liver Disease; BIL-CHE, combination of Bilirubin and Cholinesterases levels; COPD, Chronic Obstructive Pulmonary Disease.

Table 2
Operative data. The table shows the details of the surgical procedures performed in the cohort of 950 patients included in the study.

Variable	Data
Type of hepatectomy*	
Minor (<3 adjacent segments)	846 (89.1%)
Major (≥3 adjacent segments)	104 (10.9%)
Limited resections (without exposure of major vessels)	374 (50.3%)
Complex limited (with exposure of major vessels)	385 (40.5%)
Complex core limited (S1 with S8, S7 and S4s)	87 (9.1%)
Type of surgery	
Open surgery	827 (87.1%)
Laparoscopic surgery	123 (12.9%)
Thoraco-abdominal approach	351 (36.9%)
Associated procedures (bowel resections)	101 (10.6%)
Length of operation (min)	
Median; range	431; 151-801
Blood loss (ml)	
Median; range	0; 50–1500
Patients transfused with red blood packed cells	161 (16.9)
Number of red blood packed cells transfusions	
Median; range	1; 0-4
Use of Pringle's maneuver	
Number of clamping: median; range	2; 1–9
Length of clamping (min): median; range	68; 15–276

Data are expressed ad number and percentage or as median and range. *Classified according with the Brisbane and with the CLISCO classifications.

were limited resections, while the second half was complex limited or complex core hepatectomies [11].

3.2. Results of the ACS-NSQIP calculator

Table 3 reports the rates of complications predicted by the ACS-NSQIP surgical risk calculator and those actually observed in our patients. Each type of complication incorporated by the ACS-NSQIP calculator has been listed and analyzed. As shown, none of the events were correctly predicted. The calculator performance was unsatisfactory: half of the events were underestimated, and the other half were overestimated. In particular, the predicted rates of complications and mortality were significantly lower than actual rates: the mean ACS-NSQIP morbidity was 17.97% ± 8.4 versus the mean actual morbidity that was 37.01% ± 0.56 ($P < 0.001$); the mean ACS-NSQIP mortality was 0.91% ± 1.48 versus the mean actual mortality that was 1.76% ± 0.11 ($P < 0.001$). The predicted LOS was also significantly shorter: the mean ACS-NSQIP LOS was 5.81 ± 1.66 days versus the mean actual LOS that was 10.91 ± 4.6 days ($P < 0.001$). Most of the Brier scores of each predicted outcome were far from zero indicating poor performance of

Table 3
Overall complications data. The table shows the predicted and observed rates of event listed according with the ACS-NSQIP website. It is reported the p-value of the differences of these rates as well as the Brier scores.

Event	Predicted (%)	Actual (%)	p-value	Brier score
Serious complication	15.98	11.77	<0.001	0.722
Any complication	17.97	37.01	<0.001	0.688
Pneumonia	2.06	4.74	0.001	0.966
Cardiac event	1.80	2.67	0.001	0.011
Site infection	11.04	3.01	<0.001	0.222
Urinary tract infection	1.88	0.89	<0.001	0.013
Venous thromboembolism	2.71	0.91	0.001	0.967
Renal failure	1.19	1.03	0.037	0.010
Readmission	9.81	0.41	<0.001	0.934
Reoperation	2.08	3.71	0.006	0.011
Mortality	0.91	1.76	<0.001	0.112
Length of stay (days)	5.81	10.91	<0.001	0.431

The values are expressed as mean. Each type of event has been listed in the serious or any complication category according with the ACS-NSQIP website. A Brier score of 0 indicates perfect prediction, while a Brier score of 1 indicates poor prediction.

the calculator (Table 3).

3.3. Subgroup analysis

We also tested the ACS-NSQIP calculator by comparing the predicted and the observed rates of morbidity and mortality of patients with primary or secondary liver tumors, of patients with underlying chronic liver disease or normal liver, and of patients who underwent major or minor hepatectomy. As shown, the ACS-NSQIP calculator was inaccurate with an overall tendency of underestimation (Table 4).

3.4. Postoperative events not caught from the ACS-NSQIP calculator

We sought to investigate which factors were driving the observed increase in postoperative complications in our patients. In this sense, specific complications related to hepatectomy were analyzed, and post-hepatectomy liver insufficiency and bile leak were recorded in 6.8% and 11.9% of patients, respectively.

3.5. Validation of the ACS-NSQIP calculator

The performance of the ACS-NSQIP surgical risk calculator was assessed using calibration and discrimination measures. The calibration was analyzed using the Hosmer-Lemeshow test, which revealed a low p value ($p = 0.018$) indicating lack of fit between the ACS-NSQIP calculator and the actual rates of events. The discrimination was tested using the ROC curve analysis. The values of c-statistics of the ACS-NSQIP calculator for complications and mortality were 0.61 (95CI% = 0.51–0.63; $p < 0.001$) and 0.75 (95CI% = 0.68–0.81; $p < 0.001$) respectively, indicating low discrimination of these events (Fig. 2).

4. Discussion

This study demonstrates that the ACS-NSQIP calculator underestimates the actual risks of hepatectomy for liver tumors giving an optimistic estimation. In particular, the actual rates of morbidity, mortality and LOS were approximately two-fold in comparison with the predicted rates.

These findings are significant both statistically and clinically and deserve attention for several reasons. First, the data from the surgical outcomes are increasingly included into the reports of some national governmental agencies that provide these pieces of information to those patients awaiting surgery [24]. Thus, the publication of surgical outcomes may be used to make hospital rankings, which finally may become one of the determinant factors in addressing patients to a specific institution [25]. Second, the same information about quality of surgical intervention are becoming linked also to provider reimbursement [24]. In North America, the Centers for Medicare and Medicaid Service specifically recommend the use of the ACS-NSQIP calculator for the elaboration of the payback amount [26]. Third, despite of the fact that the quality of any surgical intervention does not rely only on morbidity and mortality, while relies also on many others quality items, such as the verification of indications, the multidisciplinarity, and the postoperative follow-up, it is becoming a research priority the analysis of reliability of such calculator tool since it has been suggested as the benchmark in reporting quality of surgery.

The use of an optimistic prediction tool on surgical outcomes may have dramatic consequences. If used during counseling before surgery, the patient's and relatives' expectations might remain unsatisfied giving the overall idea of having received a suboptimal treatment. One of the consequences might be an increased recall of medico-legal liability, which conversely should be limited exactly by using some functioning calculators.

In the last years, a number of modifications have been recommended with the aim to improve the calculator performance [27–34]. Pitt et al. [27] reported that in the ACS-NSQIP the number of liver procedures were few in comparison with other more generic procedures. Madhavan et al. [28] reported that the calculator would benefit by the addition of more procedure-specific patients' characteristics and liver disease-specific parameters. However, the ACS-NSQIP program has grown significantly in terms of data without including organ-specific data.

The relatively low performance of the ACS-NSQIP calculator depends on several factors. Even though the calculator contains more than 1500 individual Current Procedural Terminology (CPT) codes, the variability of a given specific procedure is limited. For liver surgery there are only 4 CPT codes. Recently, according to the morbidity, mortality, and liver failure risks a more comprehensive classification of those hepatectomies usually classified as minor based on the amount of liver parenchyma removed has been released [11]. In the present series, those hepatectomies considered as complex represented up to 49.67%. That peculiar complexity cannot be modulated in the current ACS-NSQIP system. Yet, only a single CPT code per patient can be entered. Therefore, in cases in which surgery includes more procedures, the risk calculator can only estimate the risk of each procedure separately and is incapable of estimating a specific risk of the associated procedures. This is not inconsequential in liver surgery, where associated procedures are not rare. Furthermore, the incorporation of several preoperative acute onset events and the absence of organ-specific risks represent two other drawbacks. In general, liver surgery is not conducted in urgent/emergent situations. Thus, many of the preoperative variables included in the calculator, such as acute renal failure, dyspnea, sepsis, emergent case, and disseminated cancer should be weighted accordingly. On the contrary, their absence may lead to too optimistic, and at the end unreliable outcome estimations. This is related to the use of aggregated data that represent an aggregation bias [35].

As said, the absence of organ-specific risks is another explanation for the low performance of the ACS-NSQIP calculator in case of hepatectomy. In example, the ACS-NSQIP calculator does not include the size of liver tumor(s), the number of liver tumor(s), and the volume of the future liver remnant. These data should not be omitted in the risk estimation, in particular in series with high tumor burden and complex surgery such the one herein presented (Table 2). Zaydfudim VM et al. [29] analyzed a retrospective series of 522 patients reporting that the ACS-NSQIP calculator would benefit by the incorporation of metrics of chronic liver diseases such as the MELD score. In line with this result, in our subgroup analysis we found that the presence of chronic liver disease, the extent of resection, and the diagnosis of primary liver tumor were associated with different probability of complications indicating that at least these three factors should be implemented in the ACS-NSQIP

Table 4
Complication data by subgroup analysis. The table shows the predicted and the observed rates of morbidity and mortality of patients in the three different categories explored: 1) patients with primary versus secondary liver tumors; 2) patients with underlying chronic liver disease versus normal liver; 3) patients who underwent major versus minor hepatectomy.

Event	Difference in morbidity	p-value*	Difference in mortality	p-value*
Pathology				
Primary tumor	−0.724		−0.711	
Secondary tumor	−0.235	0.013	−0.312	0.021
Chronic liver disease				
Yes	−0.212		−0.234	
No	−0.262	0.781	−0.187	0.065
Extent of resection**				
Major	−0.441		−0.431	
Minor	−0.021	0.041	−0.121	0.003

The values are expressed as difference in means between predicted and observed probability of morbidity and mortality for the three main categories of patients. *The *p*-value shows the statistical significant differences between the differences in means. **Classified according with the Brisbane classification.

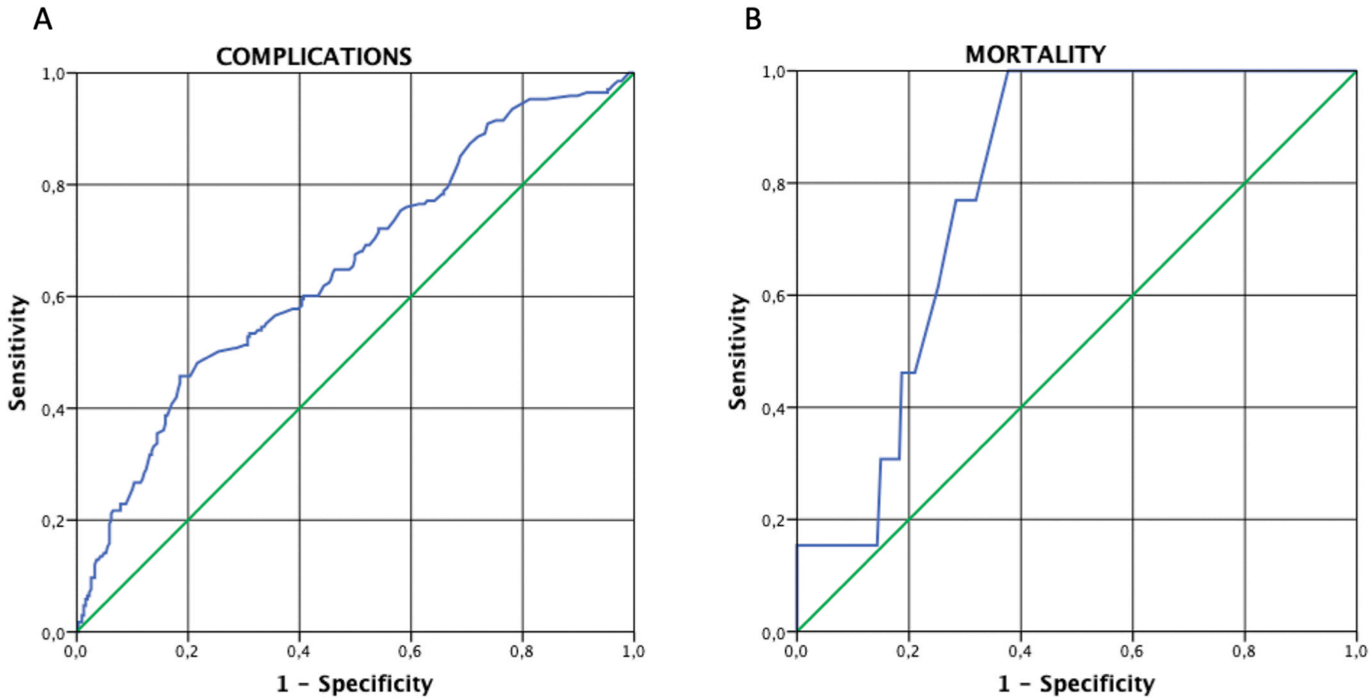

Fig. 2. ACS-NSQIP performance. The figure shows the receiver operating characteristic (ROC) curve that was used to measure the ACS-NSQIP performance. A) ROC curve analysis for complications: the area under the curve (AUC) was 0.61 (95CI% = 0.51–0.63; $p < 0.001$). B) ROC curve analysis for mortality: the AUC was 0.75 (95CI% = 0.68–0.81; $p < 0.001$).

calculator. Furthermore, among several different outcome determinants, liver insufficiency and bile leak are very important even when self-limited and graded as minor complications because they increase the length of stay and represent the two main source of mortality [36]. Since these two liver-specific events remained unaccounted by the ACS-NSQIP calculator, they represent a major limitation of the model.

After using the calculator, we also noted that LOS did not significantly differ even adding several comorbidities. A possible reason for that could be the attitude of emphasizing the early discharge in clinical practice. Indeed, the ACS-NSQIP calculator predicted a 9-fold increased risk of readmission in our patients' cohort, which is definitely linked with the policy of an early discharge that is not applied in our center. Thus, the calculator seems unreliable for LOS prediction. Again, this is related to the use of aggregated data that represent an aggregation bias [35]. And considering that the reimbursements of surgery are usually calculated on prefixed LOS, the use of the ACS-NSQIP calculator may lead to legal controversy.

Other authors reported findings that are in line with ours. When used in real clinical settings, the calculator seems unreliable in colorectal surgery, sarcoma surgery, and pancreatic surgery [37–40]. Then, the ACS-NSQIP calculator lacks in generalizability [9]. However, while the ACS-NSQIP calculator did not provide an accurate risk estimation in patients undergoing hepatectomy, such calculator may be important as a general tool to guide clinicians in general hospitals.

Two more important aspects about calculators warrant further discussion. First, Lipkus et al. [41] report that up to 20% of a well-educated population may be unable to understand if 1%, 5% or 10% is a greater risk. Neuman et al. [42] and Schwarze et al. [43] show how statistical prediction tools give back a picture that may be extremely difficult for patients to reconcile with their specific situation. More efforts should be done to personalize the risk calculator. Indeed, a more comprehensive risk estimation method should include both general and specific risk factors. As herein shown, the ACS-NSQIP calculator is questionable for those elements inherent to the specific surgical interventions, which cannot remain uncounted. However, the ACS-NSQIP calculator has the merit to include factors representatives of patient frailties, which definitely should be accounted in any risk estimation method [44,45]. The weighting and balancing of interventions-related risks together with the targeted organ-related risks should be the next challenge.

This study has some limitations that need to be considered when interpreting the results. This is a retrospective monocentric study on 950 consecutive patients. Similar to other retrospective studies, this study may be subjected to information bias. The high homogeneity of patients in terms of indications, perioperative management, surgical technique, and follow-up may mean that we did not capture the whole spectrum of complications, which the ACS-NSQIP risk calculator, as a general tool, aims to catch. Another clear study limitation is the exclusion of patients who underwent bile duct interventions and thermo-ablations. However, a cohort of 950 consecutive patients should be adequate for the purpose of testing a previously published calculator [46–49]. Further expansion of this study including multi-institutional cohorts together with organ- and surgeon-specific factors may help to develop of a new predictive model.

In conclusions, in this current form the ACS-NSQIP risk calculator does not properly predict mortality, complications, and LOS. A review of the preoperative factors together with the incorporation of organ-specific risk variables greatly would improve it.

Ethical approval

Given the purely observational nature of the study and since no patient was contacted for the purpose of this study, informed written consent was waived according to local rules.

Sources of funding

Nothing to disclose.

Data statement

No additional data are available.

CRediT authorship contribution statement

Matteo Donadon: Study design, Formal analysis, Data analysis, Writing, Critical revision. **Jacopo Galvanin:** Data curation, Data collection. **Bruno Branciforte:** Data curation, Data collection. **Angela Palmisano:** Data curation, Data collection. **Fabio Procopio:** Formal analysis, Data analysis. **Matteo Cimino:** Formal analysis, Data analysis. **Daniele Del Fabbro:** Data curation, Data collection. **Guido Torzilli:** Study design, Writing, Critical revision.

Declaration of competing interest

Nothing to disclose, and the study was approved by the appropriate institution and/or national research ethics committee.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2020.10.003.

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