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• *CLINICAL RESEARCH* •

Risk-adjustment in hepatobiliarypancreatic surgery

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Abstract

AIM: The present study evaluates the performance of the POSSUM, the American Society of Anesthetists (ASA), APACHE and Childs classification in predicting mortality and morbidity in hepatopancreaticobiliary (HPB) surgery. We describe especially the limitations and advantages of risk in stratifying the patients.

METHODS: We investigated 177 randomly chosen patients undergoing elective complex HPB surgery in a single institution with a total of 71 pre-operative and intra-operative risk factors. Primary endpoint was in-hospital mortality and morbidity. Ordered logistic regression analysis was used to identify individual predictors of operative morbidity and mortality.

RESULTS: The operative mortality in the series was 3.95%. This compared well with the p-POSSUM and APACHE predicted mortality of 4.31% and 4.29% respectively. Post-operative complications amounted to 45% with 24 (13.6%) patients having a major adverse event. On multivariate analysis the pre-operative POSSUM physiological score (OR = 1.18, P = 0.009) was superior in predicting complications compared to the ASA (P = 0.108), APACHE (P = 0.117) or Childs classification (P = 0.136). In addition, serum sodium, creatinine, international normalized ratio (INR), pulse rate, and intra-operative blood loss were independent risk factors. A combination of the POSSUM variables and INR offered the optimal combination of risk factors for risk prognostication in HPB surgery.

CONCLUSION: Morbidity for elective HPB surgery can be accurately predicted and applied in everyday surgical practice as an adjunct in the process of informed consent and for effective allocation of resources for intensive and high-dependency care facilities.

Key words: Hepatobiliarypancreatic surgery; Risk adjustment; Operative mortality; Operative morbidity; Regression models

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INTRODUCTION

Observed healthcare outcomes (mortality, length of hospital stay, quality of life) are increasingly relied upon for evaluating the quality of medical care. Expected outcomes represent predictions about what ought to happen to a particular patient, or group of patients, given pre-defined standards of care. Predictions are based on relevant prognostic factors including patient's age, disease severity and co-morbidity. Operative mortality and morbidity are objective measures of outcome that can be readily used for monitoring performance within a center or between centers. However, for this measure to be truly objective it must be adjusted for the patient-related risk factors (case-mix).

The Portsmouth Physiological and Operative Severity Score for enumeration of mortality and morbidity[1] (p-POSSUM) was developed as a modification of the original POSSUM equation which was described by Copeland *et al*[2], and has been widely applied to adjust for case-mix in general surgery. These scoring systems used a 12-factor, four-grade, physiological score and a 6-factor, four-grade, operative severity score, compensating for the type of procedure. Although the POSSUM scoring systems have been applied in patients undergoing general[3], colorectal[4] and vascular[5] surgery, recent reports have pointed out the limitations of applying the POSSUM scoring for example at the extremes of age in colorectal surgery[6] and in emergency vascular surgery[7].

Other types of risk scoring systems have been devised. The American Society of Anesthetists (ASA) grading system is a subjective pre-operative co-morbid index, which has been shown to be a good predictor of post-operative survival[8]. Specific to cirrhotic patients, the Child-Pugh grading system has been shown to be an adequate predictor of short-term and long-term survival[9]. Other systems such as APACHE II scoring system have also been used[10].

Hepatobiliarypancreatic surgical procedures are complex with difficult post-operative management. Many procedures of heterogeneous complexities are being carried out in the referral centers and in order to compare centers these factors may have to be taken into account. It requires a multi-disciplinary approach to patient management with a high dependence on the intensive care facilities. It is being concentrated akin to cardiac and neurosurgery in large centers with a good throughput. Risk adjustment of patients undergoing complex procedure is imminently needed for a qualified informed consent and allocation of meager high-cost resources. The aim of the present study was to compare the POSSUM equation with other risk scoring systems along with other peri-operative variables in order to identify factors, which may affect the outcome of patients undergoing hepatobiliarypancreatic surgery.

MATERIALS AND METHODS

Data and variables

A team of surgeons, anesthetists and intensivists met to decide the risk factors and scoring systems, which may be valuable predictors for post-operative outcome in hepatopancreaticobiliary (HPB) surgery. Dedicated proformas comprised of (1) demographic details, (2) pre-operative assessment and clinical staging, (3) surgical treatment, (4) postoperative course and complications and (5) data points for various scoring systems [POSSUM, APACHE, ASA, Child-Pugh] and other possible factors for HPB surgery (these currently available and widely used risk stratification models were used as starting point, other factors such as temperature, transfusion requirement were chosen based on literature review as factors affecting outcome in HPB surgery), (6) anesthetic data included intra-operative routinely collected data on a central computerized system, which included pulse, blood pressure, oxygen saturation, core temperature, blood gas measurements, blood loss and intra-operative fluid management, (7) outcomes as defined below. Data were recorded on a Microsoft Access 2000 database (Microsoft Corporation, USA). The patient records underwent an extensive process of data editing to check for missing or out-range values and inconsistencies between data fields. Following rectification of these records, error-free data were entered into a master file. Primary outcome was in-hospital operative mortality, defined as death during the same hospital admission as the operation, regardless of cause and post-operative morbidity classified as minor (delays discharge), intermediate (requiring non-invasive intervention), major (life-threatening or requiring invasive intervention). In-hospital mortality was validated from case records, hospital mortuary registers and the hospital Patient Administration System. The patient and procedural risk factors included (1) age; (2) gender; (3) POSSUM pre-operative physiological score and operative severity score[2] ; (4) surgical procedure categorized according to the OPCS4 system, (5) APACHE variables, (6) cancer staging according to TNM classification of HPB malignancies where applicable; (7) Child-Pugh classification, (8) ASA grade, (9) other peri-operative variables such as clotting profile, type of previous surgery, intra-operative parameters as defined above.

Patient selection

Patients undergoing major elective hepatobiliarypancreatic surgery at King's College Hospital were included in the study. Prospective data on 77 consecutive patients were collected for the year March 2000-February 2001. Retrospective data (n = 100) were collected from case notes for the period 1991-1999. Patients were selected randomly from a central prospective database using a computer-generated random number sample. Case notes were then retrieved and other data in surgical and anesthetic computerized data were further added.

Statistical analysis

Unifactorial ordered logistic regression was used to identify risk factors related to in-hospital adverse events[11]. Morbidity and mortality were combined as a single ordinal variable comprising three possible outcomes: (1) no morbidity or mortality, (2) mild to intermediate morbidity, (3) major morbidity or mortality. Continuous variables such as POSSUM and APACHE were categorized into quartiles, representing groups increasing operative risk. Any variable whose univariate test had a P-value of <0.25 was considered as a candidate for the multivariate analysis. In order to maximize the information extracted from the predictor variables, we used a median imputation technique for substituting any incomplete data[12]. Multifactorial ordered logistic regression analysis was used to adjust for multiple risk factors and their interactions, entered into the model in a stepwise fashion. Internal validation was performed by comparing observed and predicted complication rates across the various subgroups of international normalized ratio (INR) values using the Hosmer-Lemeshow χ^2 test[13].

Software

The following statistical software packages were utilized: "Intercooled STATA 6.0 for Windows" (STATA Corporation, USA), "Statistical Package for the Social Sciences" version 11 for Windows (SPSS, Chicago, IL, USA).

RESULTS

A summary of the diagnosis and type of operative procedures are shown in Tables 1 and 2 respectively. The patient demographic characteristics and in-hospital operative mortality and morbidity are shown in Tables 3 and 4. The overall observed in-hospital operative mortality was 3.95% and morbidity was 45.2%.

Incomplete data for the 177 cases with 77 variables were 2% and were mainly for clotting profiles such as APTT

Table 1 Diagnosis

Organ	Number of patients (% of total)	Number of deaths (% mortality)
Hepatic	89 (50.3)	1 (1.1)
Liver primary	14 (7.9)	0
Colorectal secondaries	47 (26.6)	1 (2.1)
Other secondaries	5 (2.8)	0
Carcinoid tumors	10 (5.6)	0
Benign liver lesions	13 (7.3)	0
Biliary	63 (35.6)	4 (6.3)
Cholangiocarcinoma	24 (13.6)	4 (16.6)
Iatrogenic biliary strictures	24 (13.6)	0
Benign biliary strictures	15 (8.5)	0
Pancreatic	25 (14.1)	2 (8)
Pancreatic malignancy	18 (10.2)	2 (11)
Pancreatitis	7 (3.9)	0
Total	177 (100)	7 (3.95)

Table 2 Type of procedure and in-hospital mortality

Procedure	Number of patients (% of total)	Number of deaths (% mortality)
Right hepatectomy	29 (16.4)	1 (3.4)
Left hepatectomy	15 (8.5)	0
Extended right hepatectomy	16 (9)	2 (12.5)
Extended left hepatectomy	5 (2.8)	1 (20)
Segmental liver resection	28 (15.8)	0
Hepaticojejunostomy	47 (26.6)	0
Pancreaticoduodenectomy	22 (12.4)	3 (13.6)
Total pancreatectomy	2 (1.1)	0
Distal pancreatectomy	2 (1.1)	0
Others	11 (6.2)	0
Total	177 (100)	7 (3.95)

Table 4 Types of morbidity

System	Minor/intermediate[1]	Severe[1]
Respiratory	25 (14.1)	10 (5.6)
Gastrointestinal	23 (13.0)	12 (6.7)
Hematological	20 (11.3)	6 (3.4)
Wound	15 (8.5)	3 (1.7)
Intra-abdominal sepsis	15 (8.5)	2 (1.1)
Cardiac	9 (5.1)	3 (1.7)
Renal	8 (4.5)	3 (1.7)
Venous	2 (1.1)	2 (1.1)
Others	19 (10.7)	2 (1.1)
Total	56 (31.6)[1]	24 (13.6)[1]

[1]A given patient may have complications of varying grade in one or more systems.

and fibrinogen (0.5%), intra-operative hemodynamic and fluid balance parameters (1%) in the retrospective data set. Unadjusted odds ratios were calculated for each scoring system or factor's reference category as shown in Table 5. The POSSUM physiological score, the acute physiologic score of APACHE II, and ASA grade showed a significant association with postoperative morbidity particularly at the highest quartile. For example, patients with an APACHE score of 6-13 would be 2.9 times more likely to have a major adverse post-operative event in comparison with patients with an APACHE score of 0-1. The INR and intra-operative blood loss were the other discriminant risk factors of operative morbidity and mortality. Additional factors mentioned in Methods were tested but were found to be insignificant predictors of adverse outcomes in HPB surgery (results not shown). Adjusting for the type of other confounding variables, pancreaticoduodenectomy (Whipple's procedure) had the highest risk of operative morbidity (OR 2.27, 95%CI: 1.07-9.97) in comparison with the right hepatectomy, which was treated as the reference category.

The adjusted (multivariate ordered logistic regression) odds ratios and 95% CI for the POSSUM, INR, blood loss and type of operation are shown in Table 6.

Of the POSSUM physiologic score, the important factors were the serum sodium, creatinine and pulse rate.

Observed *vs* predicted probabilities of complications of all types or major complications are shown in Figure 1. There was no significant difference between observed and predicted operative morbidity rates across INR values ranging between 0.8 and 1.25. (Hosmer-Lemeshow χ^2 test = 7.762, degrees of freedom = 8, P = 0.457.) Similarly Figure 2 shows prediction curves for major and all complications based on the pre-operative POSSUM physiological score. Figures 3 and 4 show the probabilities of all complications and major complications respectively, based on the POSSUM physiological score and increasing values of INR.

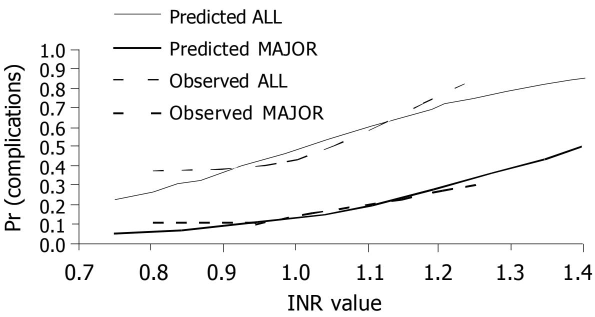

Figure 1 Observed *vs* predicted values of complications (all types or major only) with respect to INR values.

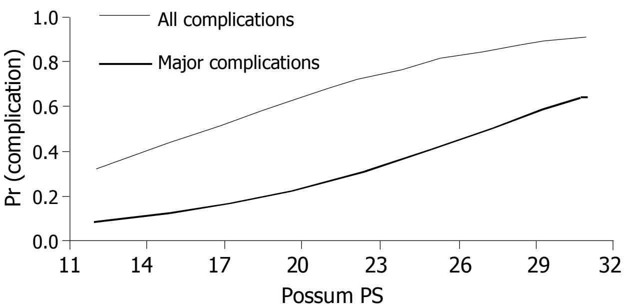

Figure 2 Prediction of possible complications (all types and major only) on the basis of POSSUM physiologic score in patients undergoing major elective HPB surgery.

Table 3 Patient characteristics and associated mortality and morbidity

Demographics	Number (% of total)
Age (median, range)	54.6 (19, 80)
Female patients	96 (54.2)
Length of stay (median, range)	
Hospital	15 (2-113)
ITU	0 (0–20)
HDU	0 (0–10)
Mortality (in-hospital)	7 (3.95)
Morbidity	
No morbidity	97 (54.8)
Minor/intermediate	56 (31.6)
Major	24 (13.6)

DISCUSSION

Quality of care is multidimensional, it may be viewed from the patient's, the doctor's or healthcare provider's perspective and be assessed in terms of structure, process and outcomes

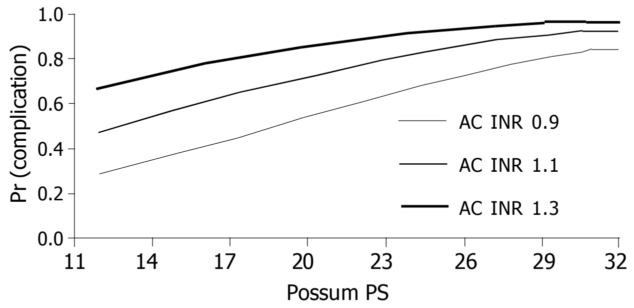

Figure 3 Prediction of all possible complications on the basis of POSSUM physiologic score and increasing values of INR in patients undergoing major elective HPB surgery.

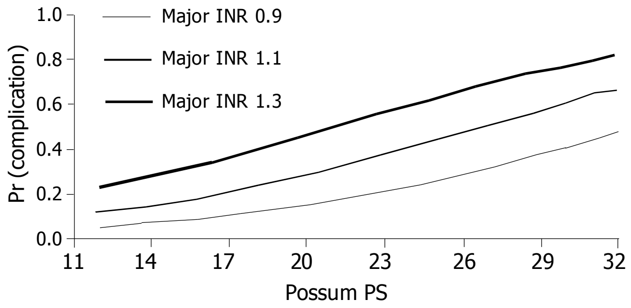

Figure 4 Prediction of possible major complications on the basis of POSSUM physiologic score and increasing values of INR in patients undergoing major elective HPB surgery.

of a healthcare delivery system[14,15]. The purpose of the present study was to identify and evaluate possible risk factors and scoring systems for HPB surgery.

Operative morality and morbidity are objective measures of healthcare, which can be easily measured[16]. Furthermore, major complications, which may be life threatening (major hemorrhage) or they may be requiring invasive treatment (percutaneous drainage of biliary tree or collection, or re-operation for intra-abdominal catastrophe). These have to be effectively managed in order to convert the near-misses to successes thereby maintaining low post-operative mortality. The management of major post-operative complications after major HPB surgery is multi-disciplinary requiring intensivists, interventional radiologists, endoscopists, hepatologists, anesthetists and dedicated ward and theatre staff not to mention high-cost technology. Thus, the major complications and mortality both have to be measured and risk adjusted in order to give a true picture of in-hospital and intra-hospital comparisons. Operative mortality and morbidity is expected to vary between hospitals. This variation is a function of differences in patient case-mix, random adverse events and differences in the process and structure of care[15]. Statistical analysis is intended to adjust for the case-mix as much as possible so that the remaining variation is more likely to be due to differences in the quality of care. The present study identifies the important factors associated with the adverse events in patients undergoing major HPB surgery.

Ordered logistic regression allowed us to order the types of complications in three groups of increasing severity of adverse outcome: no complications, minor/intermediate complications and major complications along with death[12]. Thus, the ordinal outcomes as mentioned above could be used to quantify the nature of complications and provide

Table 5 Analysis of the separate risk scoring systems by unifactorial ordered logistic regression using sampling quartiles for continuous variables

Risk score/factor	Group	Number of patients (% of total)	Minor/intermediate complications (%)	Major complications/ death (%)	Unadjusted odds ratio[1]	95%CI [1]
POSSUM	12-13	62 (35.0)	13 (21)	7 (11.3)	1	
Physiological	14-15	53 (29.9)	20 (37.7)	6 (11.3)	1.8	0.24, 3.77
Score[1,2]	16-17	31 (17.5)	13 (41.9)	3 (9.7)	1.9	0.81, 4.41
	18-31	31 (17.5)	10 (32.3)	8 (25.8)	3.12	1.32, 7.38
APACHEII	0-1	30 (16.9)	9 (30)	3 (10)	1	
Acute	2-3	66 (37.3)	20 (30.3)	6 (9.1)	0.97	0.41, 2.28
Physiological	4-5	49 (27.7)	14 (28.6)	7 (14.3)	1.18	0.48, 2.89
Score[1,3]	6-13	32 (18.1)	13 (40.6)	8 (25)	2.86	1.09, 7.5
ASA	1	47 (26.6)	12 (25.5)	3 (6.4)	1	
	2	77 (43.5)	27 (35.1)	8 (10.4)	1.73	0.15, 3.63
	3-4	31 (17.5)	17 (33.3)	12 (23.5)	3.16	1.41, 7.07
	Missing	2 (1.1)				
Child-Pugh	A	145 (81.9)	49 (33.8)	16 (11)	1	
	B	32 (18.1)	7 (21.9)	8 (25)	1.34	0.64, 2.94
	C	0				
INR	<0.9	45 (25.4)	13 (28.9)	4 (8.9)	1	
	0.9-1.1	119 (67.2)	36 (30.3)	16 (13.5)	1.32	0.67, 2.63
	>1.1	13 (7.3)	7 (53.9)	4 (30.7)	5.5	1.78, 17.5
Blood loss	<1	90 (50.9)	24 (26.7)	9 (10)	1	
	1-2	38 (21.5)	11 (29.0)	2 (5.3)	0.85	0.39, 1.85
-	>2	49 (27.7)	21 (43.0)	13 (26.0)	4.1	1.49, 11.13

[1]For illustration purposes all the scores (continuous variables) were grouped into meaningful quartiles. †Odds ratios and 95% confidence intervals (CI) calculated using unifactorial ordered logistic regression analysis. [2]Theoretical range of values for the physiological score of POSSUM is 12–96. [3]Theoretical range of values for the acute physiological score of APACHE II is 0-44.

Table 6 Multivariate ordered logistic regression analysis of risk factors for HPB surgery

Factor	Category	Estimate (b)	Adjusted OR	CI 95%
Physiological score-POSSUM	10^{-1} units increase		1.18	1.07, 1.31
INR[2]	10^{-2} units increase		1.47	1.12, 1.94
Blood loss	< 2 L		1	
	>2 L		4.1	1.49, 11.13
Procedure	Right hepatectomy		1	
	Pancreaticoduodenectomy		3.27	1.07, 9.97
Sub-factors of POSSUM[3]				
Serum sodium[1]	10^{-1} units increase		0.89	0.82, 0.97
Serum creatinine	10^{-1} units increase		1.01	1.00, 1.02
Pulse rate (bpm)	10^{-1} units increase		1.04	1.01, 1.06

[1]OR denotes that patients do worse with every unit decrease in sodium below the lower limit of normal range (130 mmol/L). [2]OR denotes that patients do worse with every 0.1 unit increase in INR above 1.1. [3]When the physiological score of the POSSUM variables are analyzed separately with multifactorial ordered logistic regression, the significant factors are sodium, creatinine and pulse rate which affect mortality and morbidity.

accurate and justifiable risk adjustment to take account of case-mix. Since the procedures in HPB surgery are mainly elective, the risk stratification is skewed towards fitter patients as compared to patients undergoing surgery for vascular or colorectal causes, where up to 40% of the workload may be emergency in nature; thus bringing in unfit patients. As can be seen from the physiologic scores for POSSUM, which ranged in this dataset from 12 to 31 as compared to a theoretical range of 12-96. Moreover more than 80% of patients had a pre-operative physiologic POSSUM score of less than 17. Similar scenario can be seen with the APACHE II acute physiologic score (80% below a score of 5) and ASA grading (around 80% ASA I or II). Also all the patients operated upon were either Child's A or B. Thus, we can observe a self-selection of fitter patients undergoing HPB surgery.

INR, intra-operative blood loss and type of procedure are other important risk factors, which may be important in predicting the outcome. Deranged INR in an elective situation represents established preoperative liver dysfunction.

Pancreaticoduodenectomy (PD) remains the single operation in the spectrum of major HPB operations, which has to be adjusted for whilst comparing outcomes from different units. Gastrointestinal and respiratory complications are higher in patients undergoing PD. This may artificially distort the outcomes of units performing higher or lower numbers of PD, making them appear worse or better respectively. Thus in these two aspects HPB surgery differs from other types of surgery. In addition, excessive intra-operative blood loss may make a particular patient remain in a high dependency unit for a longer duration than normal. However, this operator-dependent variable should be left out of the equation when comparing units, as it can be a surrogate marker for quality of surgery and the surgeon as a risk factor[17].

In addition, we have shown that it is possible to have demonstrable risk adjusted graphs (Figures 3 and 4), which can calculate risk predictions pre-operatively. This can make an informed consent a more objective procedure and justify the need for high dependency facilities in high risk patients for prolonged use.

The expected outcome for a population of patients can be calculated by summing the probabilities estimates of all patients in the population. Having calculated the expected outcome for a population of patients and adjusted for the patient-related risk factors, the observed to the expected outcomes can be compared. This can be done either as an O/E ratio[18] or as a mortality difference, i.e., the observed minus the expected outcomes (O-E difference)[19,20]. Such methodologies can be used as the basis of cross-sectional audits and for continuous or sequential monitoring of surgical performance within hospitals. Numerous studies have been done to develop audit tools for different specialities of surgery[21-30].

There are a number of limitations in this study. First, the sample size is small and it is a single hospital dataset. However, here we are attempting to identify the risk factors specific to HPB surgery. It needs to be validated across national datasets in order to develop a specific equation applicable to HPB surgery. Secondly, the number of pancreatic resections carried out as a proportion to the total number of operations is low and may affect the overall predictive power. If PD is incorporated as an independent risk factor, this shortcoming can be accounted for.

In conclusion the present study has demonstrated the uses and limitations of risk adjustment using the various scoring systems in HPB surgery. The availability of good quality data and validated models is fundamental for a continuous program of quality improvement. With adequate sample size the new risk scoring system can be devised and used for monitoring surgical outcomes between or within hospitals in order to meet the demands of professional and public scrutiny of outcomes in HPB surgery.

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