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Research Article

Derivation and Validation of a Simplified Risk Prediction Model for Patients undergoing Major Abdominal Surgeries

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Abstract

Introduction: Pre-operative risk stratification is useful for resource allocation, for shared decision-making, and informed consent. Pre-operative risk prediction is not widely used due to the subjective nature of available models, the requirement of additional pre-operative investigations, or complex calculations.

Objective: We aimed to derive and internally validate a simple risk prediction model, which could address most possible aspects of patient assessment pre-operatively and help clinicians to predict postoperative morbidity or 30 days mortality with reasonable accuracy in patients undergoing Laparotomy.

Methodology: A prospective and retrospective observational study was carried out in a tertiary care hospital. Two hundred retrospective and 101 prospective patients of age more than 18 years, who had undergone Emergency or Elective laparotomy were included. In 1st stage, Patient data like demographics, comorbidities, physiological data, laboratory results, and surgical details were collected in a retrospective manner from 2016-2019. The outcome of the patient including details of post-operative 30 days mortality and morbidities was recorded. A simplified risk prediction model was derived using regression analysis and considering the odds ratio. A 10-point score so derived labeled as "Simplified Max Score (SMS)" was validated in a prospective manner (2019-2020).

Results: Serum Urea, Serum Albumin, Neutrophils to Lymphocytes ratio, METS, and the presence of CVA, CLD, and COPD were the most significant predictors per the retrospective cohort (n=200). On this basis, a Simplified Max Score (SMS) was derived. The derived formula had an AUROC of 0.801 for morbidity and 0.935 for mortality in the retrospective cohort. Results were validated in the prospective cohort (n=101) which showed acceptable reproducibility with AUROC of 0.99 for morbidity and 0.64 for mortality. SMS showed good predictability with AUROC of 0.804 for morbidity and 0.86 for 30 days post-operative mortality, when applied to an entire cohort of 301 patients. SMS also performed better than the American Society of Anesthesiologist's score.

Conclusion: The 10-point SMS score gives a simplified prediction of both postoperative morbidity and mortality after laparotomy.

Introduction

An estimated 250 million surgeries are performed worldwide each year, and this number is increasing rapidly [1]. As access to surgery is increasing, so is number of patients with post-operative morbidities and mortality. Data from European countries suggests that in-hospital mortality after surgery can be 3-4% [2] and morbidities can range from 3-17% [3,4]. Pre-operative risk

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stratification is useful for resource allocation, for decision making and for informed consent and prognostication. Three of the most commonly used risk stratification tools, the American Society of Anaesthesiologists' Physical Status Score (ASA-PSS) [5,6], Charlson Age-comorbidity index (CACI), and the Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) [7] have been evaluated in various validation studies. A number of derivatives of these three systems have also been validated like the Surgical Risk Scale [8], and Donati's Surgical Risk Score [9], both based on the ASA-PSS, but also include details of the proposed surgical procedure. There are hundreds of other models available for pre-operative risk prediction. Drawbacks associated with most of these are either their subjective nature or involved complex calculations. Many of these models may need of additional investigations and generally have disease specific [10] or outcome specific [11] risk prediction. Recent studies have also evaluated functional capacity as prediction measure of post-operative morbidity and mortality [12-14]. It has been found that, these are more beneficial for identifying patient with low cardiopulmonary risk.

Variety of biomarkers are available for pre-operative evaluation of patients. Many are used in most commonly known risk prediction models in some form or another. We wanted a simple system of risk prediction, based on routine assessment for patients undergoing laparotomies. Aim of the present study is to derive and also internally validate a simple risk prediction model, which could address all possible aspects of patient assessment pre-operatively and help clinicians to predict possibility of post-operative morbidity or 30 days mortality with reasonable accuracy.

Methodology

A retrospective and prospective observational study was carried out in a tertiary care hospital of North India. 200 retrospective and 101 prospective patients of age more than 18 years, who had undergone Emergency or Elective laparotomy were included in the study. In 1st stage, data was collected in a retrospective manner using available document of patients from 2016-2018. Details including gender, age, any associated comorbid diseases, general physical examination, biochemical investigations, biophysical assessment and systemic examination were recorded. Data also included details of investigations requested, treatment given, and surgical intervention. Outcome of patient included, post-operative 30 days mortality and morbidities as defined by Clavien-Dindo classification (CDC). Severe morbidity was defined as CDC >/=3. A regression analysis was done on retrospective data, to identify most significantly associated factors as predictors of morbidity and 30 days mortality. Predictive formula was derived based on identified variable. In 2nd stage, validation of developed score was done in a prospective manner, which involved collection of patient's data as before, but prospectively in view of our developed score. Finally, a simplified risk prediction model was formulated using predictors derived. This simplified score was validated on entire cohort.

Statistical Analysis

The presentation of the Categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data were presented as the means ± SD and as median with 25th and 75th percentiles (interquartile range). The data normality was checked by using Kolmogorov-Smirnov test. The cases in which the data was not normal, we used non parametric tests. The following statistical tests were applied for the results:

1. The association of the variables which were quantitative and not normally distributed in nature were analyzed using Mann-Whitney Test (for two groups) and independent t test was used for association of normally distributed data between two groups.
2. The association of the variables which were qualitative in nature were analyzed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used.
3. Multivariate forward logistic regression was used to find out significant risk factors of mortality and morbidity.
4. Receiver operating characteristic curve was used to find out cut off point of parameters for predicting morbidity and mortality.
5. Sensitivity, specificity, positive predictive value and negative predictive value of model was calculated.

The data analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver. 21.0.

For statistical significance, p value of less than 0.05 was considered statistically significant.

Results

Out of total 301 patients, 200 were retrospectively collected data for derivation and 101 prospective subjects for internal validation of risk prediction score.

Derivational Phase

Retrospective data from 200 patient was collected and analysed. Descriptive data of retrospective cohort is given in table 1.

Regression analysis

Details of clinical examination, investigations done, treatment given, surgical intervention, and outcome of retrospective patients were collected. Factors most significantly

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Table 1: Descriptive data of derivational cohort (200 patients). American Society of Anaesthesiologists (ASA), metabolic equivalents (MET), Gastrointestinal (GI), chronic obstructive pulmonary disease (COPD)

		Total (200)	Morbidity (47)	Mortality (24)
Age		57.62 ± 14.1	58.68 ± 16.28	59.17 ± 13.26
Male: Female		122:78	34:13:00	18:06
ASA	</=3	160	22	7
	>3	40	25	17
MET	<4	45	28	18
	>/=4	155	19	6
Organs	Colorectal	54	17	9
	Hepato-biliary	54	7	5
	Multi visceral	3	1	0
	Pancreas	16	2	2
	Renal	3	1	1
	Retro peritoneum	5	1	1
	Small bowel	35	10	3
	Spleen	3	0	0
	Upper GI	27	8	3
Co-morbidities (%)	Malignancy	74 (45%)	17 (18.68%)	7 (7.69%)
	Hypertension	80 (40%)	23 (28.75%)	13 (16.25%)
	Diabetes	39 (19.50%)	10 (25.64%)	7 (17.95%)
	COPD/Asthma	34 (17%)	17 (50%)	11 (32.35%)
	Chemo-radiotherapy	28 (14%)	6 (21.43%)	2 (7.14%)
	Coronary artery disease	23 (11.50%)	9 (39.13%)	4 (17.39%)
	Hypothyroid	15 (7.50%)	2 (13.33%)	1 (6.67%)
	Chronic liver disease	15 (7.50%)	8 (53.33%)	7 (46.67%)
	Chronic kidney disease	8 (4%)	7 (87.5%)	7 (87.50%)
	Cerebral vascular accident	7 (3.50%)	5 (71.43%)	5 (71.43%)
	Inflammatory bowel disease	1 (0.50%)	0.00%	0.00%

associated with post-operative morbidity and mortality as per Clavien-Dindo classification were analysed using Univariate regression. On performing multivariate regression for morbidity, neutrophil/lymphocyte ratio, Urea (mg/dL) and albumin (gm/dL) were significant independent risk factors of morbidity after adjusting for confounding factors. With the increase in albumin (gm/dL), risk of morbidity significantly decreases with odds ratio of 0.358(0.215 to 0.594). With the increase in neutrophil/lymphocyte ratio, Urea (mg/dL), risk of morbidity significantly increases with odds ratio of 1.056(1.003 to 1.111), 1.025(1.004 to 1.046) respectively. On performing multivariate regression for mortality analysis, neutrophil/lymphocyte ratio, Urea(mg/dL), MET: <4, cerebrovascular accident, COPD/Asthma, chronic liver disease were significant independent risk factors of mortality after adjusting for confounding factors. With the increase in neutrophil/lymphocyte ratio and Urea (mg/dL), risk of mortality significantly increases with adjusted odds ratio of 1.094(1.01 to 1.184), 1.029(1.005 to 1.053) respectively. Patients with MET: <4, cerebrovascular accident, COPD/Asthma, chronic liver disease had significantly high risk of mortality with adjusted odds ratio of 4.918(1.249 to 19.358), 28.905(2.747 to 304.137), 6.499(1.775 to 23.799), 15.205(3.055 to 75.684) respectively. These data have been compiled in table 2.

Receiver operating characteristic curve (ROC) figure 1, suggest, derived parameters had significant discriminatory power to predict morbidity. Discriminatory power of Urea (mg/dL) (AUC 0.677; 95% CI: 0.608 to 0.741), neutrophil/lymphocyte ratio (AUC 0.685; 95% CI: 0.616 to 0.749) and albumin (gm/dL) (AUC 0.75; 95% CI: 0.684 to 0.809) was acceptable. Among all the parameters, Albumin (gm/dL) was the best predictor of morbidity at cut off point of ≤3.1 with 75.00% chances of correctly predicting morbidity. Neutrophil/lymphocyte ratio had sensitivity of 65.96% followed by albumin (gm/dL) (61.70%), Urea (mg/dL) (53.19%). In prediction of morbidity, Urea (mg/dL) had lowest sensitivity of 53.19%. On the other hand, Urea (mg/dL) had specificity of 83.01% followed by albumin (gm/dL) (79.74%), neutrophil/

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Table 2: Univariate and Multivariate analysis on derivational cohort for morbidity and mortality prediction. American Society of Anaesthesiologists (ASA), metabolic equivalents (MET), chronic obstructive pulmonary disease (COPD), chronic liver disease (CLD), cerebrovascular accident (CVA), chronic kidney disease (CKD), glutamic-oxaloacetic transaminase (SGOT), international normalised ration (INR), hepatitis C virus (HCV)

Regression analysis of multiple factors affecting morbidity		-		**Regression analysis of multiple factors affecting mortality**			
Univariate analysis	**p-Value**	**Multivariate analysis**	**p-Value**	**Univariate analysis**	**p-Value**	**Multivariate analysis**	**p-Value**
ASA>/= 3	<0.0001			ASA>/= 3	<0.0001		
MET<4	<0.0001			MET<4	<0.0001	MET<4	0.023
Emergency surgery	<0.0001			Emergency surgery	<0.0001		
High estimated blood loss	0.002			Cerebrovascular accident	0.0003	Cerebrovascular accident	0.005
Cerebrovascular accident	0.009			COPD/Asthma	<0.0001	COPD/Asthma	0.005
COPD/Asthma	<0.0001			CLD	<0.0001	CLD	0.001
CLD	0.005			CKD	<0.0001		
CKD	0.0002			High pulse rate	<0.0001		
High pulse rate	<0.0001			Low Systolic Blood Pressure	0.009		
Low Systolic Blood Pressure	0.005			Low Diastolic Blood Pressure	0.021		
Low Diastolic Blood Pressure	0.006			High Respiratory rate	<0.0001		
High Respiratory rate	<0.0001			Low Packed cell volume	0.0006		
Low Haemoglobin	0.004			High Neutrophils	0.0002		
Low Packed cell volume	0.0003			Low Lymphocytes	0.0002		
High Neutrophils	0.0006			High Neutrophils to Lymphocytes ratio (>4.24)	<0.0001	High Neutrophils to Lymphocytes ratio	0.027
Low Lymphocytes	0.0003			High Urea (>30.7)	<0.0001	High Urea	0.019
High Neutrophils to Lymphocytes ratio (>4.24)	<0.0001	High Neutrophils to Lymphocytes ratio	0.037	High Creatinine	<0.0001		
High Urea (>32.1)	0.0002	High Urea	0.017	Hypernatremia	0.008		
High Creatinine	0.0006			High direct bilirubin	0.046		
High SGOT	0.049			High SGOT	0.003		
High INR	0.002			High INR	0.001		
Low Total protein	<0.0001			Low Total protein	<0.0001		
Low Albumin (<3.1)	<0.0001	Low Albumin	<0.0001	Low Albumin	<0.0001		
Albumin: Globulin ratio	0.0001			Albumin: Globulin ratio	0.0009		
				HCV	0.039		

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lymphocyte ratio (72.55%). In prediction of morbidity, Neutrophil/lymphocyte ratio had lowest specificity of 72.55%. Highest positive predictive value was found in Urea (mg/dL) (49.00%) and highest negative predictive value was found in neutrophil/lymphocyte ratio (87.40%).

Formula found fitting

Predicted (Morbidity) = 1 / (1 + exp (-(1.11065+0.05425xNeutrophil/lymphocyte ratio+0.02471xUrea (mg/dL)- 1.02844xAlbumin (gm/dL)))) Area under curve: - 0.801

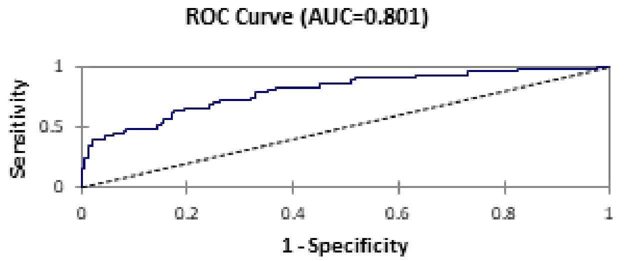

Figure 1: Multivariate forward logistic regression to find out significant risk factors of severe morbidity. Receiver operating characteristic curve (ROC), Area under curve (AUC)

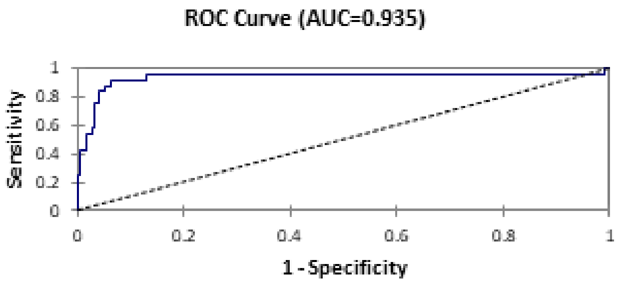

Figure 2: Multivariate logistic regression to find out significant risk factors of mortality. Receiver operating characteristic curve (ROC), Area under curve (AUC)

Receiver operating characteristic curve (ROC) figure 2, suggest, derived parameters had significant discriminatory power to predict mortality. Discriminatory power of Urea (mg/dL) (AUC 0.677; 95% CI: 0.608 to 0.741), neutrophil/lymphocyte ratio (AUC 0.685; 95% CI: 0.616 to 0.749) and albumin (gm) (AUC 0.75; 95% CI: 0.684 to 0.809) was acceptable. Among all the parameters, Albumin (gm) was the best predictor of morbidity at cut off point of ≤3.1 with 75.00% chances of correctly predicting morbidity. Neutrophil/lymphocyte ratio had sensitivity of 65.96% followed by albumin (gm) (61.70%), Urea (mg/dL) (53.19%). In prediction of morbidity, Urea (mg/dL) had lowest sensitivity of 53.19%. On the other hand, Urea (mg/dL) had specificity of 83.01% followed by albumin (gm) (79.74%), neutrophil/lymphocyte ratio (72.55%). In prediction of morbidity, Neutrophil/lymphocyte ratio had lowest specificity of 72.55%. Highest positive predictive value was found in Urea (mg/dL) (49.00%) and highest negative predictive value was found in neutrophil/lymphocyte ratio (87.40%).

Formula found fitting

Predicted(Mortality)=1/(1+exp(-(-5.52559+0.08953xNeutrophil/lymphocyte-ratio+0.02822xUrea (mg/dL)+1.59285xMET-<4+3.36401xCerebrovascular-accident-Yes+1.87163xCOPD/Asthma

yes+2.72163xChronic liver disease-Yes)))

Area under the curve: -0.935

Table 3: Sensitivity, specificity of model for predicting mortality and morbidity. Confidence interval (CI)

Variables	Predicted morbidity	Predicted mortality
Sensitivity (95% CI)	100% (59.04% to 100.00%)	28.57% (3.67% to 70.96%)
Specificity (95% CI)	97.87% (92.52% to 99.74%)	98.94% (94.21% to 99.97%)
AUC (95% CI)	0.99(0.94 to 1.00)	0.64(0.54 to 0.73)
Positive Predictive Value (95% CI)	77.78% (39.99% to 97.19%)	66.67% (9.43% to 99.16%)
Negative Predictive Value (95% CI)	100% (96.07% to 100.00%)	94.9% (88.49% to 98.32%)
Diagnostic accuracy	98.02%	94.06%

Table 4: Simplified risk prediction model for predicting mortality and morbidity- Simplified Max Score {SMS}.

Variables Score	0	1	2	3
Serum Urea (mg/dl)	</= 31.0	> 31.0	-	-
Neutrophils to Lymphocytes (N/L) ratio	</= 4.24	> 4.24	-	-
Serum Albumin (g/dl)	>/= 3.1	<3.1	-	-
MET	> 4	< 4	-	-
COPD	-	+	-	-
CLD	-	-	+	-
CVA	-	-	-	+

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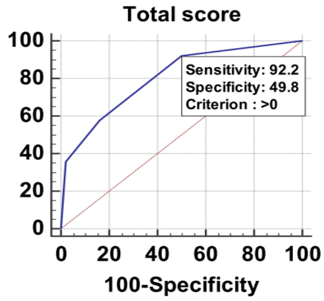

Figure 3: Receiver operating characteristic curve to find out cut off point of Simplified Max Score for predicting morbidity.

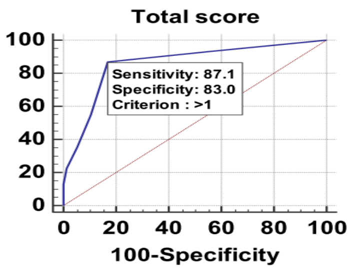

Figure 4: Receiver operating characteristic curve to find out cut off point of Simplified Max Score for predicting mortality.

Table 5: Receiver operating characteristic curve of SMS and ASA, for predicting 30 days post-operative mortality and severe morbidities

Model	AUROC for 30- days mortality	Standard error	AUROC for Severe morbidities	Standard error
SMS	0.86	0.0366	0.804	0.0296
ASA	0.811	0.0485	0.528	0.0417

Validation of derived model on prospective data

Prospective cohort consisting of 101 patients were analysed for validity analysis. Table 3 shows that the patients who had morbidity, 100.00% of patients were predicted by the model. If model has predicted morbidity, then there was 77.78% probability of morbidity and if model has not predicted morbidity, then 100.00% chances of no morbidity. Among patients who did not have morbidity, 97.87% of patients were not predicted as morbidity by the model. The above table shows that the patients who had mortality, 28.57% of patients were predicted by the model. If model has predicted mortality, then there was 66.67% probability of mortality and if model has not predicted mortality, then 94.9% chances of no mortality. Among patients who did not died, 98.94% of patients were not predicted as mortality by the model.

Combined modelling

To further ease the use of derived model, we explored various combined models. The use of predictors was based on already calculated odds ratio in regression analysis. Seven factors including 3 quantitative variables (S. Urea, S. Albumin, Neutrophils to Lymphocytes ratio) along with METS and 3 co-morbidities (CVA, CLD, COPD) were found to be significantly associated with post-operative morbidity and 30 days mortality. Derived simplified risk prediction model is presented in table 4.

As seen in figure 3, discriminatory power of Simplified Max Score (AUC 0.804; 95% CI: 0.754 to 0.847) was excellent for prediction of morbidity. Simplified Max score (SMS) was the significant predictor of morbidity at cut off point of >0 with 80.40% chances of correctly predicting morbidity when applied to combined 301 patients.

Table 6: Receiver operating characteristic curve of various studies with various models used, for predicting 30 days post-operative mortality and morbidities. The Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM), Portsmouth-POSSUM (P-POSSUM), National Surgical Quality Improvement Program (NSQIP), American Society of Anaesthesiologists (ASA), Estimation of Physiologic Ability and Surgical Stress (E-PASS), Modified E-PASS (mE-PASS), Combined Assessment of Risk Encountered in Surgery (CARES), simplified max score (SMS)

Authors	Model Used	Outcome	Morbidity %	AUROC reported	Mortality %	AUROC reported
Brook (22)	POSSUM	30 days mortality	NR	NR	8.4	0.92
	P-POSSUM					0.92
	Surgical risk scale					0.89
DasGupta (30)	Edmonton frail score	30 days mortality and post op morbidity	25%	0.69	0.80%	NR
Davenport (74)	NSQIP	30 days mortality and post op morbidity	6.70%	0.709	1.50%	0.958
	ASA			0.72		0.889
	ASA+NSQIP			0.782		0.96
Donati (9)	Surical risk score	30 days mortality	NR	NR	1.90%	0.888
	POSSUM					0.915
	P-POSSUM					0.912

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	ASA					0.81
Haga (75)	E-PASS	30 days mortality	NR	NR	NR	0.82
	mE-PASS					0.81
	P-POSSUM					0.74
	Surgical risk score					0.73
Kuzu (29)	Subjective Global Assessment	30 days mortality	28.47%	0.669	4.34%	0.687
	Nutritional risk index			0.659		0.797
	Maastricht index			0.671		0.743
Wong (66)	P-POSSUM	30 days mortality	NR	NR	1.40%	0.89
	Surgical risk scale					0.85
	Surgical Outcome Risk Tool					0.9
Chan et al (50)	CARES	30 days mortality	NR	NR	0.60%	0.934
Our Study	SMS model	30 days mortality and post op morbidity	21.93%	0.804	10.30%	0.86

Discriminatory power of Simplified Max Score (AUC 0.86; 95% CI: 0.816 to 0.897) was also excellent for prediction of 30- days post-operative mortality. Simplified max score (SMS) was the significant predictor of mortality at cut off point of >1 with 86.00% chances of correctly predicting mortality.

Comparison to ASA (American Society of Anaesthesiologists)

ASA is the most widely available pre-operative tool, used in world for prognostication of patients pre-operatively. We compared our simplified max score SMS model with ASA and found that SMS shows superior performance in predicting both morbidity and 30 days mortality as shown in table 5, below comparing area under receiver operating curve AUROC for both models. SMS in addition to being superior is also reproducible as it only uses objective data.

Discussion

We developed and internally validated a Simplified Max Score (SMS) for prediction of 30 days mortality and morbidity in patients who underwent laparotomy for both emergency and elective cases. Seven factors including 3 quantitative variables (S. Urea, S. Albumin, Neutrophils to Lymphocytes ratio) along with METS and 3 co-morbidities (CVA, CLD, COPD) were found to be significantly associated with post-operative morbidity and 30 days mortality.

In routine surgical practice pre-operative risk prediction is not done. Reason for this is, complex and subjective nature of available models. Some of the available models require additional pre-operative investigations which make them difficult to be universally applied. SMS is a practical model, which uses minimal and routinely done objective data for prediction of post-operative morbidities and 30 days mortality.

The SMS tool is an economical model, consisting of only 7 preoperative data, which are used to predict both 30 days mortality and severe morbidity risk, compared to 18 preoperative, intraoperative and postoperative variables for POSSUM and 22 preoperative patient risk factors for the ACS-NSQIP model [24,67]. Apart from most commonly studied and validated models like POSSUM, P-POSSUM and ACS-NSQIP, there are plenty of other validated model like APACHE II, SORT, SRS, E-PASS etc., but they all are either too subjective to be applied or based on intra-operative findings. In addition to, using minimal number of pre-operative data, prediction of morbidity and mortality using SMS model is good in our cohort of patient. Reason for this can be that, use of chronic illness factors (covered by major co-morbidities) with bio-chemical data (reflecting current health status), along with physiological indicators (in form of Metabolic Equivalent score (MET)), nearly cover all clinical perspective of pre-operative patient evaluation.

Various biochemical parameters evaluated are part of varied models with similar aim. SMS includes, serum urea, serum albumin and Neutrophils to Lymphocytes ratio only, as found significant on multi-regression for our cohort of the patients. Besides being objective in nature, these variables are among the most basic investigations done as part of pre-operative evaluation of any patient. For identifying cut off for various quantitative variables we used area under the curve separately for each variable. Various cut off has been reported for serum urea as an indicator of pre-operative hydration status [68]. Higher pre-operative values and inability to return to normal in post-operative setting is associated with morbidity and mortality among patients. Serum albumin is a useful indicator of pre-operative nutritional status of

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patient and its lower values are important predictor of worse post-operative prognosis [69]. Evaluation of Neutrophils to Lymphocyte ratio have shown that higher pre-operative values are associated with higher infectious complications and mortality [64,65,70].

We included both elective as well as emergency cases in our cohort as the physiological reserve of patient and associated exercise tolerance is important for deciding prognosis of patient undergoing non-cardiac surgeries. Various modalities like Time up and go (TUG) and Timed stair climb (TSC) have been evaluated and found significant previously [47,49]. Plethora of recent literature have evaluated and proved frailty as a significant factor predicting post-operative morbidity and mortality [30,31]. Calculation of frailty is cumbersome and frequently involve need of additional evaluations and also, it's a new domain for many practitioners. There are studies which found Metabolic equivalent (MET) to be association with frailty, which is an easily available data, based on exercise tolerance during preoperative history taking [55].

There is a defined co-relation between co-morbidities of patients and their post-operative morbidities and mortality. Among long list of co-morbidities, SMS model included CVA, CLD and COPD as most significant co-morbidities to be significantly associated with post-operative complications. Our set of data is unique in the sense that, it includes CVA (71), CLD (62), and COPD [72] according to strength of association, based of odds ratio derived during regression analysis. For keeping model simple and easily applicable, we did not grade or age adjust the comorbidities according to their respective severity as was proposed by Charlson et al [20]. Proper evaluation and management of each co-morbidity was done in pre-operative stage whenever possible.

For post-operative morbidity evaluation, we opted Clavien-Dindo classification (CDC) [73], which is widely accepted modality for reporting of post-operative complications in surgical patients. As in our set of cohorts, variety of surgical procedure including upper Gastrointestinal surgery, Hepato-pancreatico-biliary, peritoneal, retroperitoneal, splenic, small bowel and colorectal surgeries are included we defined post-operative CDC accordingly. Most common morbidity was in form of need of additional intravenous support in form of transfusion of packed red blood cell (PRBC) or fresh frozen plasma (FFP) and total parenteral nutrition (TPN). Some of the patient required additional cardiac medications in form of anti-hypertensive or rate control drugs or diuretics, all were classified to be included in CDC class 2. We defined severe morbidities as class 3a and 3b, for patients who needed secondary suturing, re-laparotomy, upper and lower gastrointestinal endoscopy, percutaneous drainage, pleural tapping or placement of intercostal drainage or angioembolisation etc. under local or general anaesthesia respectively. CDC 4a and 4b, were defined for patients with sepsis who required single organ or multi-organ support with vasopressors, ventilator, non-invasive ventilation, positive presser ventilations or dialysis due to any of the underlying complications respectively.

In development of SMS model, we used Univariate and multivariate regressions of various preoperative factors and odds ratio were derived for most significant factors. For checking reproducibility, derived score was applied to prospective data set and found to have acceptable validity. On basis of strength of association each significant factors were allotted simple scores and a simplified scoring model was drafted. This exercise was done for making model more user friendly without compromising its accuracy. This Simplified Max Score was then validated over entire cohort.

As data collected for evaluation of our patients were limited to most basics of pre-operative investigations, we compared SMS model with most widely used ASA model, available for our set of data in pre-operative assessment sheet (PAC).

ASA is the most widely available pre-operative tool, used in world for prognostication of patients pre-operatively. We compared our SMS model with ASA and found that SMS shows superior performance in predicting both morbidity and 30 days mortality, comparing AUROC for both models, as shown in table 5. SMS in addition to being superior is also reproducible as it only uses objective data.

Various other studies have used different models like POSSUM, P-POSSUM, SRS and others and calculated AUROC for mortality prediction. Outcome of studies and models are compared in table 6 below.

A study of this table suggests that with 0.86 AUROC our model compares well with other established models with 0.687 to 0.96 AUROC for mortality. Besides, our model uses simple 10-point score of routinely done preoperative investigations and assessments. For derivation of SMS model, we used retrospective data and all patients with missing data set were excluded from this study. Mortality in our cases is high as Max being a tertiary referral centre, all high-risk patients are treated here. Also, we have excluded cases such as Laparoscopic Cholecystectomy or hernia which have minimal mortality. Slight bias may also have been introduced by exclusion of missing data which could be due to better maintenance of the records in sicker patients. This could potentially, lead to interference in the results obtained. We tried to keep it to minimal by its validation on prospective data set as well.

Sample size for study, although calculated before starting of study is small as it is a single centre study done within a short time span. Much larger cohort and multi-institutional validation of model is required for generalised acceptance

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of our model. We included both elective and emergency surgeries in our cohort with the aim to avoid complexity in model. Physiological reserve of patients, which can be assessed with co-morbidities and relevant physiological data in form of MET is equally efficacious for proper evaluation of the patients in elective as well as emergency setting.

We believe, SMS is simple model that can be used, not only for mortality but also morbidity prediction in post-operative period by using easily available pre-operative variables. Ten-point format makes SMS a user friendly and easy score to apply with acceptable sensitivity and specificity. SMS can be beneficial at both institutional level and patient level as prediction of possible severe morbidities and mortality in operated patients. It helps surgeon in "shared decision making" [76], can help in preventing "failure to rescue events" [77], can act as useful guide for patient allocation to levels of clinical care.

Declaration

Authorship- The author declare that all authors have made substantial contributions in conception and design of the study, acquisition of data, analysis, and interpretation of data. The authors further confirm that- The manuscript, including related data, figures and tables has not been previously published and is not under consideration elsewhere. No data have been fabricated or manipulated to support your conclusions. This submission does not represent a part of single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. "salami-publishing"). The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal. No data, text, or theories by others are presented as if they were the author's own. Proper acknowledgements of other's work has been given (this includes material that is closely copied, summarized and/or paraphrased), quotation marks are used for verbatim copying of material. Permissions have been secured for material that is copyrighted.

Conflict of interest

The authors declare no conflict of interest.

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Ethical approval

Full ethical approval was obtained from institutional ethical committee Max Super specialty hospital, Vaishali, Ghaziabad, India. (Ref: TS/MSSH/VSH/CRL/IEC/GASTRO/20-06). Due to the retrospective nature of the study, Hospital approval was granted to obtain necessary data from medical records. Written informed consent was waived by the ethics committee because of the study was non-interventional and retrospective in nature.

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