The Value of POSSUM and P-POSSUM as Surgical Audit Tool Predicting Morbidity and Mortality in Emergency Laparotomy: Retrospective Review in HUSM 2012-2015

By

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ABSTRAK (BAHASA MELAYU)

Pembedahan Laparotomi Kecemasan adalah prosedur pembedahan gastro-usus berisiko tinggi yang memerlukan penyiasatan dan rawatan segera. Ia mempunyai kadar komplikasi dan kematian yang tinggi di serata dunia. Secara dasarnya, faktor-faktor yang menyumbang kepada situasi ini berkait rapat dengan mekanisma biologi dan kualiti rawatan kesihatan yang disediakan.

Audit pembedahan boleh mengurangkan kadar komplikasi dan kematian ini. Analisis berdasarkan risiko terlaras digunakan secara meluas dalam audit pembedahan. Mengumpul analisis data terlaras risiko akan memberikan maklumat yang membolehkan pengenalpastian ciri-ciri di mana penambahbaikan yang perlu dibuat. Pelbagai model peramalan risiko telah diperkenalkan untuk digunakan dalam sesuatu audit. Di United Kingdom (UK), model peramalan risiko seperti "Physiology and Operative Severity Score for the enUmeration of Mortality" (POSSUM) dan "The Portsmouth Physiology and Operative Severity Score for the enUmeration of Mortality (P-POSSUM)" telah diguna pakai di dalam audit Pembedahan Laparotomi Kecemasan.

Model peramalan risiko POSSUM memerlukan parameter fisiologi dan pembedahan untuk meramalkan komplikasi dan risiko kematian selepas pembedahan. Perbandingan di antara ramalan risiko dengan komplikasi dan kematian sebenar disesuaikan mengikut risiko pesakit. Maka dengan itu, perbandingan risiko terlaras ini memberikan satu perbandingan yang adil. Terdapat banyak kajian telah mengesahkan POSSUM sebagai model ramalan risiko yang berkesan. Namun begitu, bilangan yang mengkaji model peramalan risiko POSSUM untuk pembedahan laparotomi kecemasan adalah sedikit. Objektif kajian ini adalah untuk mengkaji POSSUM dan P-POSSUM

sebagai wadah audit pembedahan meramalkan morbiditi dan kematian selepas pembedahan laparotomi kecemasan di sebuah pusat perubatan tertiari.

ABSTRACT

Emergency laparotomy is a surgical procedure of gastrointestinal tract which is potentially life threatening condition that requires prompt investigation and management. It is associated with high rates of morbidity and mortality worldwide. The factors that are responsible for poor outcome are the biological mechanism and quality of surgical care provided.

Surgical audit can improve the outcome of this high risk surgery. Risk-adjusted analysis is a widely used in surgical audit. Collecting a risk-adjusted data analysis will provide information that allows identification of area where improvement needed to be made. Various risk prediction model have been developed as surgical audit tool. In United Kingdom (UK), Physiology and Operative Severity Score for the enUmeration of Mortality (POSSUM) and The Portsmouth Physiology and Operative Severity Score for the enUmeration of Mortality (P-POSSUM) risk prediction models are utilized as surgical audit tool for continuous auditing of emergency laparotomy surgery.

POSSUM risk prediction models requires physiological and operative parameters to predict the likelihood of a surgical morbidity and mortality. It compares the expected outcome against the observed outcome of the surgery according to the patient risk stratification. Risk-adjusted analysis thus reflects a fair comparative surgical audit. Many studies have validated POSSUM as risk prediction models. However, there are only few POSSUM risk prediction models for emergency laparotomy. The objective of this study is to examine POSSUM and P-POSSUM as surgical audit tools predicting morbidity and mortality in emergency laparotomy in a single tertiary center which possibly valuable to be incorporated into local surgical audit practice.

1 INTRODUCTION

1.1 LITERATURE REVIEW

The POSSUM scoring system proposed by Copeland *et al.* in 1991 (44) is a risk-adjusted analysis for surgical audit. It was developed due to the need of a scoring system that could be used across general surgical spectrum. Copeland analyzed 48 physiological factors & 14 operative factors in 1440 patients that underwent emergency and elective surgery in Walton Hospital, Liverpool. Using multivariate analysis techniques, 12 physiological and 6 operative important factors were identified and afterward risk prediction model was developed from the study. Each of physiological parameter and operative parameter were graded and scored exponentially as 1,2,4 and 8 with highest given to the most deranged value. The combined physiological and operative score analyses with logistic regression, generating a predictor equation. The risk equation changed the scores into a predicted mortality and morbidity (44).

While POSSUM has been shown to be a good predictor of morbidity and mortality in general, vascular, colorectal and many other specialty surgery, Prytherch *et al.* (43) showed the tendency of POSSUM scoring system to over predict mortality in low risk patient. P-POSSUM (Portsmouth – POSSUM) scoring system was developed by Whiteley & Prytherch in 1998 using a better predictor equation for mortality (43). Subsequently, there were more studies validated POSSUM and P-POSSUM scoring system on a more diverse case mix and different population. There was also development in terms of adjustment of the scoring system that suits certain type of surgery such as CR-POSSUM for Colorectal Cancer Surgery, V-POSSUM for Vascular Surgery and many others.

The main analysis output of POSSUM risk prediction model was the concept of O:E ratio (Observed to Expected). Copeland (37) proposed O:E ratio as a risk-adjusted

quality measure for comparative surgical audit. Following scoring of physiological and operative parameter, the expected morbidity and mortality were calculated using the predictor equation. The expected mortality and morbidity were compared against the calculated observed morbidity and mortality. An O:E ratio of 1.0 indicates average performance; greater than 1.0 indicates worse performance than expected and less than 1.0 indicates better performance than expected.

The risk adjusted analysis provides a fair comparative audit. As highlighted by Copeland *et al*. (37), it can be used to compare the outcome between individual surgeons or between centers. It also allows monitoring of surgical outcome that may change with time. POSSUM risk prediction model is practical to use since the data set needed for the calculation of adjusted risk are obtainable from patient's medical record. The calculation for the expected morbidity and mortality is easily done by simply entering physiological and operative parameter into available online calculator.

1.2 RATIONALE FOR THE STUDY

This study aims to improve the surgical outcome in emergency laparotomy by evaluating a practical risk prediction model for morbidity and mortality which suits local population. A good risk prediction model can be beneficial in several ways. A standardized outcome measurement may play significant role in effort to improve quality outcome. It provides evidence for service improvement and quality assurance of surgery. It can be used as a guide for allocation of resources subsequently improves their practice.

Crude mortality and morbidity value can be misleading in measuring outcome of surgery. It makes no distinction between differences in case mix and fitness of patients. Thus, there is need for risk adjusted analysis of outcome in order to have a fair comparative surgical audit

In Malaysia, a reliable and holistic system that measure morbidity and mortality are not in place. Morbidity outcome at this moment is compartmentalized according to specific parameter for each surgical specialties which known as National Indicator Approach (NIA) set by the Ministry of Health, Malaysia. Thus, by examining the value of POSSUM scoring for mortality and P-POSSUM scoring for morbidity respectively for emergency laparotomy cases, it may shows the usefulness of the risk prediction model as surgical audit tools in local setting.

2 - STUDY PROTOCOL

2.1 - DOCUMENT SUBMITTED FOR ETHICAL APPROVAL

STUDY PROTOCOL

THE VALUE OF POSSUM & P-POSSUM AS SURGICAL AUDIT TOOLS PREDICTING MORBIDITY & MORTALITY IN EMERGENCY LAPAROTOMY: RETROSPECTIVE REVIEW IN HUSM 2012-2015

Protocol number and date: USM/JEPeM/16040159

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Study site:

Hospital Universiti Sains Malaysia (HUSM)

Background and Significance

Introduction

By definition, emergency laparotomy is described as group of surgical procedure non-elective, non-trauma procedures on the gastro-intestinal tract which is potentially life threatening condition that requires prompt investigation and management (3).

Worldwide Epidemiology of Emergency Laparotomy

It is associated with high rate of morbidity and mortality worldwide. The 30-day mortality rate in a study conducted in UK is 14.9% (21). Whereas a study conducted in Europe found that emergency surgery has a five times greater risk of mortality than elective surgery (8, 20).

Malaysia's Epidemiology of Emergency Laparotomy

In Malaysia, there is lack of published national data on outcome of emergency laparotomy. However, a review of data from National Perioperative Mortality Review by Kandasamy *et al.* (35), from 1996 to 1997, the crude mortality rate was 967 deaths per 100000 procedures. In a prospective study at Queen Elizabeth Hospital, Kota Kinabalu by Chieng *et al.* (26), the study found out that the proportion of morbidity and mortality in exploratory laparotomy patient were 49.2% and 9.0% respectively.

Discrepancy Between Elective and Emergency Surgery

It is important to highlight that there is discrepancy of morbidity and mortality outcome between elective surgery and emergency in general. In Malaysia, Inbasegaran *et al.* (40) reported that the ratio of emergency surgical mortality to elective surgical mortality was as high as 7:1 .

In a multicenter study by Smith *et al.* (12) conducted in Michigan, US, they found that from 2005 to 2010, the annual morbidity and mortality rates have remained relatively unchanged among patients undergoing emergency surgery. It was concluded that there is a need to refocus on improving surgical morbidity and mortality in emergency surgery cases.

Variation of Outcome in Exploratory Laparotomy

There is also wide variation in terms of outcome between different surgical center that underwent laparotomy. Symons *et al.* (14) reported that risk adjusted mortality ranged between 9.2 and 18.2 % from different health care centers. On the other hand, Saunders *et al.* (21) reported that 30-day mortality varied between 3.6 and 28.9%.

Various Risk Prediction Model

There are various risk prediction model has been developed throughout the years. In UK, the three commonly used risk stratification systems are the American Society of Anesthesiologists Physical Status (ASA-PS) score, the Charlson Age-Comorbidity Index and the Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) (24).

Whereas in US, American College of Surgeon (ACS) developed a logistic regression model for 30-day mortality after emergency laparotomy from National Surgical Quality Improvement Program (NSQIP). It is a locally validated program and database (15).

Various Outcome Measure

There are also various definitions and reporting systems on how to measure morbidity and mortality. However, there is no consensus yet worldwide on the best system to measure outcome. In terms of morbidity assessment, there are various ways used to classify, either based on disease or organ specific complication. Morbidity can be measured using tools like Clavien Dindo Classification, ACS-NSQIP and Post Operative Morbidity Survey. Others have tried to classify according to resource utilisation measures such as length of hospital stay or surrogate outcome measure such as opiod consumption and blood transfusion. The recent trend is to measure outcome through patient centered approach like Patient Reported Outcome Measures (PROM) (24). Mortality however is a clinically important objective outcome, which is not subject to interobserver variability (10).

POSSUM as Comparative Risk Adjusted Surgical Audit Tools

POSSUM

The POSSUM (Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity) has been proposed by Copeland *et al.* (44) as a risk adjusted surgical audit tool. It was developed in respond to the need of a simple scoring system that could be used across general surgical spectrum.

Copeland initially assessed 48 physiological factors and 14 operative factors in 1440 patient who underwent emergency and elective surgery. Using multivariate analysis techniques, 12 physiological and 6 operative important factors were identified. Risk prediction model was then developed from the study (44).

Each of physiological parameter were graded and scored exponentially as 1, 2, 4, and 8 with highest given to the most deranged value. Similarly, operative parameters were graded according to severity.

Subsequently, the combined physiological and operative scores were subjected to logistic regression analysis, generating a risk equation that changed the scores into a predicted percentage mortality and morbidity.

The logistic regression equation for mortality and morbidity are as follows:

Table 1: Logistic Regression Equation for Morbidity and Mortality Prediction

Morbidity ln R/1 = -5.91 + (0.16 x physiological score) + (0.19 x operative score)
Mortality ln R/1 = -7.04 + (0.13 x physiological score) + (0.16 x operative score

Alternatively, the calculation for the logistic regression can be done by using online website calculator. The scores are entered, automatically calculated the predicted percentage mortality and morbidity using above equation. Example of online calculator is *www.vasgbi.com/riskscores.php* (22).

The physiological and operative parameter scoring for POSSUM risk prediction model are as follows:

Table 2: Physiological Score

Score	**1**	**2**	**4**	**8**
Age	≤ 60	61 -70	≥ 71	
Cardiac History	Nil	On drug therapy	Oedema/ Warfarin	Raised JVP
Chest X-ray	Normal		Bordeline Cardiomegaly	Cardiomegaly
Respiratory History	Normal	Dyspnoea on exertion	Limiting dyspnoea (one flight stair)	Dyspnoea at rest
Chest X-ray		Mild COPD	Moderate COPD	Fibrosis/ Consolidation
Systolic BP	110 – 130	131 - 170	≥ 171	≤ 89
Pulse Rate	50 – 80	81 – 100 or 40 – 49	101 – 120	≤ 39 or ≥ 121
GCS	15	14 - 12	11 - 9	≤ 8
BUN	≤ 7.5	7.6 – 10.0	10.1 – 15	≥ 15.1
Hb	13.0 – 16.0	11.5 – 12.9 or 16.1 – 17.0	10.0 – 11.4 or 17.1 – 18.0	≤ 9.9 or ≥ 18.1
TWC	4.0 – 10.0	10.1 – 20.0 or 3.1 – 3.9	≥20.1 or ≤ 3.0	
Sodium	≥ 136	131 – 135	126 – 130	≤ 125
Potassium	3.5 – 5.0	3.2 – 3.4 or 5.1 – 5.3	2.9 – 3.1 or 5.4 – 5.9	≤ 2.8 or ≥ 6.0
ECG	Normal		MI > 6 months AF rate ≤ 90	MI < 6 months AF rate ≥ 90

Table 3: Operative Score

Score	1	2	4	8
Complexity	Minor	Moderate	Major	Major +
Number of Operations in 30 days	1		2	≥ 2
Blood loss (mL)	≤ 100	101 – 500	501 – 999	≥ 1000
Peritoneal soiling	None	Serous	Local Pus	Free bowel content, pus or blood
Malignancy	None	Primary only	Node metastases	Distal metastases
Timing of operation	Elective		Emergency >2h of resuscitation possible. Operation within 24h.	Emergency < 2h Immediate surgery needed.

P-POSSUM

Though POSSUM has been shown to be a good predictor of morbidity and mortality in general, vascular and colorectal surgery, studies have shown the tendency of POSSUM scoring system to over predict mortality in fit patient undergoing for minor surgery (41). P-POSSUM (Portsmouth – POSSUM) was developed by Whiteley & Prytherch (41) that studied on 10,000 patients at St Mary's Hospital, Porthsmouth. It still uses the same physiological and operative parameter and scoring but obtained a better predictor equation for mortality.

Table 4: Logistic Regression Equation for Mortality Prediction in P-POSSUM

Morbidity ln R/1 = -9.065 + (0.1692 x physiological score) + (0.155 x operative score

However, compared to POSSUM scoring system, P-POSSUM did not measure morbidity. Hence, with that consideration, this proposed study will use the POSSUM predictor equation for morbidity and P-POSSUM predictor equation for mortality.

The Concept of O/E Ratio in POSSUM and P-POSSUM Risk Prediction Model

Copeland (2002) proposed O/E ratio (observed to expected) as risk adjusted quality measure for comparative surgical audit. Following scoring of physiological and operative scoring, the expected morbidity and mortality is calculated using the predictor equation. The actual morbidity and morbidity or as it is called observed morbidity and mortality, will be compared against the calculated expected morbidity and mortality. An O/E ratio of 1.00 indicates average performance; greater than 1.00 indicates worse performance than expected; less than 1.00 indicates better performance than expected.

The advantage of this system is to provide a fair comparison between an individual surgeon or individual surgical center. The risk adjusted analysis provides a quality marker for outcome of surgery, assessing the performance of a particular surgeon or a particular surgical center (37). It is more practical to use as the data set needed for the calculation of adjusted risk is easily obtained from patient's medical record. The calculation for the expected morbidity and mortality is made easy by entering into any available online calculator.

There are numerous studies which have validated POSSUM and P-POSSUM risk prediction model across various surgical specialities with different case mix and locality. National Emergency Laparotomy Audit (3), a Royal College of Anaethetist lead audit, involving 178 hospital across UK, as part of Quality Improvement, funded by NHS, among others, recommends completion of P-POSSUM variables to ensure risk estimation is accurate. At this moment it is the most common risk prediction model used in UK (10).

Study Design and Methodology

This is a retrospective medical record review of patients underwent emergency laparotomy in HUSM from 2012 until 2015 in HUSM. The list of patients underwent emergency laparotomy in HUSM from 2012 till 2015 from HUSM will be obtained from record office.

Medical records will be reviewed by principal investigator. Patients that fulfill inclusion and exclusion criteria will be recruited in this study. All primary and secondary variables from the medical records will be entered into data collection form (Refer Appendix 1) in accordance with definition of variables. Expected mortality and morbidity will be calculated using online calculator, https://www.vasgbi.com/riskscores.php (22) . All data then anonymized and transferred into IBM SPSS Statistics v22 software for statistical analysis.

Study Population

All patient underwent exploratory laparotomy in HUSM from January 2012 until 2015

Sample Size

Sample size calculated using G*Power 3 for multiple linear regression analysis. For a confidence level of (α) 0.05, and power of study 95%, with correlation coefficient of 0.3 & number of predictors equal to one, the required sample size was 56. . However, in view of previous published studies sample size were >100, the sample size for this study were determined as 100 to be consider appropriate.

Primary Objective:

To examine the value of POSSUM & P-POSSUM Scoring in Predicting In-Hospital Morbidity and In-Hospital Mortality in Patient Underwent Emergency Laparotomy in HUSM

Secondary Objectives:

- To determine the profile of sample
- To determine the proportion of in-hospital morbidity and in-hospital mortality in sample
- To compare POSSUM number of predicted in-hospital morbidity with observed in-hospital morbidity
- To compare P-POSSUM number of predicted in-hospital mortality with observed in-hospital mortality

Study Duration: 9 months

Inclusion Criteria

All patients undergoing expedited/urgent/emergency abdominal surgery via a midline upper and/or lower abdominal incision irrespective of the cause.

Patient had to be at least 18 years old

Exclusion Criteria

Appendicectomy of any type as the sole surgical procedure

Cholecystectomy of any type as the sole surgical procedure

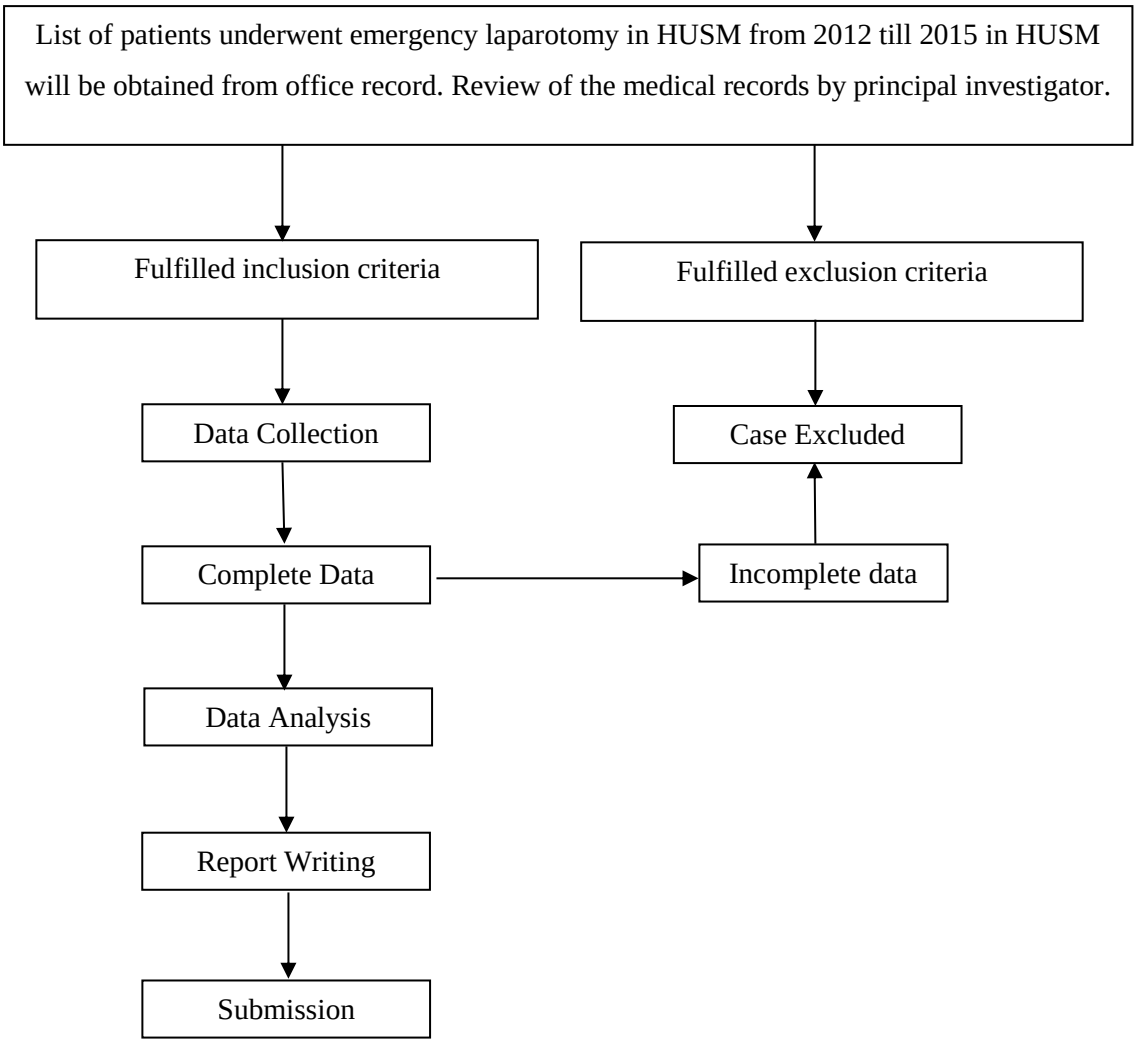
Gynaecological laparoscopy/laparotomy of any type unless the primary pathology is proven to be general surgical

Emergency laparotomy for vascular surgery

Surgery related to organ transplantation

Pancreatectomy of any type

Flow Chart


List of patients underwent emergency laparotomy in HUSM from 2012 till 2015 in HUSM will be obtained from office record. Review of the medical records by principal investigator.
Fulfilled inclusion criteria
Fulfilled exclusion criteria
Data Collection
Case Excluded
Complete Data
Incomplete data
Data Analysis
Report Writing
Submission

Definition of Variables

Medical records will be reviewed by Principal Investigator. All relevant data will be entered into data collection form. The variables are as followed:

Primary Variables

Physiological Score

Operative Score

Calculated POSSUM Expected Morbidity

Calculated P-POSSUM Expected Mortality

Observed Morbidity

Observed Mortality

Secondary Variables

Sociodemographic Data

Clinical Pathological Profile

Patient's Clinical Management Pathway

Primary Variable

Physiological Score

Physiological score will be taken from data preoperatively prior to emergency operation. The scoring will follow similarly as described by original author for POSSUM system Copeland *et al.* (44) (Refer Table 2)

Operative Score

Operative score will be taken from operative notes. The scoring will follow similarly as described by original author for POSSUM system Copeland *et al.* (44) (Refer Table 3)

POSSUM Expected Morbidity and Calculated P-POSSUM Expected Mortality

Combine score of both physiologic and operative score will be calculated using online calculator *https://www.vasgbi.com/riskscores.php* (22). The expected morbidity and mortality will be entered into data collection form.

Observed Morbidity

Morbidity can be defined as clinically significant non-fatal complication.

Definition of "In-hospital morbidity" is at least one case of complication that occurred while patient in the hospital.

Table 5: Definition of Specific Morbidity

Type of Morbidity	Definition
Wound Hemorrhage	Local hematoma requiring evacuation
Deep Hemorrhage	Post operative bleeding require re-exploration
Chest Infection	Production of purulent sputum with positive bacteriological culture, with or without chest radiography changes or pyrexia, or consolidation on chest x ray
Urinary Infection	The presence of > 10^5 bacteria/ml with the presence of white cells in the urine, in previously clear urine
Wound Dehiscence	Superficial or deep wound breakdown
Organ/Space Infection	The presence of an intra-abdominal collection confirmed clinically or radiologically
Respiratory failure	Respiratory difficulty requiring emergency ventilation
Septicaemia	Positive blood culture
DVT/PE	When suspected, confirmed radiologically by venography,or ventilation/perfusion scanning or diagnosed at post mortem
Impaired Renal Function	Arbitrarily defined as an increase in BUN of > 5 mmol/L from preoperative level
Hypotension	A fall in systolic blood pressure below 90mmHg for more than 2 h as determined by sphygmanometry or arterial pressure transducer measurement
Cardiac Failure	Symptom or signs of left ventricular or congestive cardiac failure which required an alteration from preoperative therapeutic measure
Anastomotic Leak	Discharge of bowel content via the drain, wound or abnormal orifice

Observed Mortality

Definition of "In-hospital mortality" is death that occurred while patient in the hospital, regardless of time from surgery for all cause of mortality. While various published study on POSSUM and P-POSSUM took 30-day mortality as the primary endpoint, this study took in-hospital mortality as the endpoint. A 30-day mortality data would require a good documentation and follow up post operatively or alternatively need to trace and interview by telephone. This study followed the original description of Whiteley *et al*. (43) that used in-hospital morbidity. It reduces loss to follow up bias. It is also chosen due to resource limitation of this study.

Secondary Variable

Sociodemographic Data

Patient's age, gender and ethnicity.

Clinical Pathological Profile

- Preoperative Diagnosis:

  Recorded documentation of diagnosis prior to surgery

- Operative Findings:

  Recorded documentation of operative findings in operative note

Patient's Clinical Management Pathway

Time of Clinical Decision to Surgical Operation:

Duration of time (minute) taken between the time patient decided by managing surgical team for operation to the starting operating time.

Length of Stay:

Duration of time (day) patient stay in hospital.

Preoperative CT Scan Availability:

Presence of CT Abdominal Scan in the same admission prior to surgery.

Pre-Op ICU stabilization:

Admission to ICU for the purpose of stabilization of patient prior to surgery.

Adjunct Perioperative Parenteral Nutrition:

Usage of perioperative parenteral nutrition. Either before of after surgery.

Post Op ICU Admission:

Admission to ICU post operatively for any reason throughout the stay in hospital of the same admission.

Study Duration and Timeline

Table 6: Timeline of Proposed Study

	June 2015 – March 2016	**April 2016 – June 2016**	**July 2016 – Nov 2016**	**Dec 2016 – Jan 2017**	**Feb 2017 – March 2017**
Literature Review & Proposal					
Submission for Appoval to Ethics Committee					
Data Collection					
Data Analysis					
Manuscript Write Up					

Study Visits and Procedures

Not Applicable

Statistical Analysis Plan

Descriptive Statistic

The sociodemographic, clinical pathological profile and clinical management pathway will be analysed by descriptive analysis. Continuous variables will be summarized by mean & standard deviation while categorical variables will be summarized in frequency table.

Table 7: Patient's Sociodemographics

Patients' Demographics	**No.**	**(%)**
Age group (years) 18 - 30 31 - 40 41 - 50 51 - 60 61 - 70 >70		
Gender Male Female		
Ethnicity Malay Chinese Indian Others		