

**COMPARISON OF P-POSSUM AND Cr-POSSUM SCORES IN  
PATIENTS UNDERGOING COLORECTAL CANCER RESECTION IN  
HOSPITAL TAIPING.**

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## ii. ABSTRAK IN BAHASA MALAYSIA

### **Pengenalan :**

P-POSSUM dan Cr-POSSUM merupakan sistem skor (markah) yang seringkali digunakan dalam menjangka kadar kematian selepas pembedahan di kalangan pesakit pembedahan.

### **Objektif :**

Objektif kajian ini adalah untuk menguji ketepatan P-POSSUM dan Cr-POSSUM dalam menjangka kadar kematian selepas pembedahan di kalangan pesakit barah kolorektal di Hospital Taiping.

### **Kaedah:**

Kajian merupakan jenis retrospektif melibatkan pesakit selepas menjalani pembedahan barah kolorektal. Pesakit yang menjalani pembedahan CRC dari jangkamasa April 2013-2015 di Hospital Taiping akan dimasukkan dalam subjek kajian retrospektif ini. Para pesakit yang skor P-Possium dan Cr-POSSUM tidak dapat dikira tidak akan dimasukkan dalam kajian berikut. Physiologic score (skor physiology) dan operative severity score untuk kedua-dua P-possium dan Cr-possium akan dikira berpandukan rekod perubatan. Kematian (mortality) dalam hospital dan kematian dalam 30-hari selepas pembedahan akan direkodkan. Data akan dianalisa menggunakan 'linear method' analysis oleh Wijesinghe et al, di mana dalam analysis sebegini, pesakit akan digolongkan dalam kumpulan berdasarkan jangkaan risiko kematian. Jangkaan jumlah kematian seterusnya akan dikira bagi setiap kumpulan berisiko dengan cara mendarabkan bilangan pesakit dalam setiap kumpulan dengan purata risiko kematian dalam kumpulan tersebut. Kadar kematian sebenar kepada kadar jangkaan kematian akan dikira untuk setiap analisis. X2 test oleh Lemeshaw dan Hosmer akan digunakan

untuk menilai sebarang perbezaan diantara jangkaan kematian dengan kadar mortality dan morbidity yang sebenar. Kebolehan diskriminasi, merupakan kebolehan model untuk memberi kebarangkalian kematian yang lebih tinggi kepada pesakit yang mati, yang diukur menggunakan ROC curves, yang dianalisis untuk kedua-dua skor.  $P < 0.5$  akan diambil kira sebagai “statistically significant”.

**Keputusan:**

87 orang pesakit dimasukkan dalam kajian. Bilangan kematian yang dijangkakan menggunakan linear analysis Cr-POSSUM dianalisis. Nisbah kadar kematian sebenar/ jangkaan kematian untuk semua kumpulan berisiko ialah 1.5, yang menunjukkan bahawa Cr-POSSUM menjangkakan kadar kematian yang lebih rendah sebanyak 50%. Bagaimanapun, tiada perbezaan yang ‘statistically significant’ antara kadar kematian sebenar dengan kadar kematian yang dijangkakan ( $X^2 = 2.33$ ;  $P = 0.51$ ). Sistem P-POSSUM dilihat menjangkakan kematian dengan baik, dengan kadar nisbah keseluruhan kematian sebenar kepada jangkaan kematian sebanyak 1. Tiada perbezaan ketara antara jangkaan kematian berbanding kematian sebenar ( $X^2 = 1.5$ ;  $P = 0.91$ ). Discriminatory power P-possum dan Cr-possum dalam menjangkakan kadar kematian dianalisa menggunakan ROC curves. Area under the receiver operating characteristic curve (AUC) bagi Cr-POSSUM ialah 0.831 (95% confidence interval (CI) , 0.681-0.981). Bagi P-POSSUM, AUC ialah 0.857 (95% CI, 0.762-0.951), menunjukkan satisfactory discriminatory power.

**Kesimpulan:**

Keputusan kajian menunjukkan kedua-dua P-possum dan Cr-Possum merupakan sistem skor yang berguna dan berfungsi dengan baik dalam menjangkakan kematian selepas pembedahan pesakit kolorektal. Kedua-dua sistem berfungsi sama baik dan skor

khas (Cr-possum) tidak menunjukkan kelebihan berbanding P-possum dalam menjangkakan kematian selepas pembedahan.

### **iii. ABSTRACT IN ENGLISH**

#### **Introduction :**

P-POSSUM and Cr-POSSUM are two common scoring systems used in predicting post-operative mortality in surgical patients.

#### **Objectives :**

The objective of this study was to assess the accuracy of P-POSSUM and Cr-POSSUM systems in predicting post-operative mortality in patients with colorectal cancer in Hospital Taiping.

#### **Methods :**

It was retrospective cohort study of patients after resection of colorectal cancer (CRC). Patients who underwent CRC resection from April 2013 to April 2015 at Hospital Taiping will be retrospectively included in the study. Those patients for whom P-POSSUM and Cr-POSSUM scores could not be calculated because of lack of data will be excluded. Physiologic scores and operative severity scores for both P-POSSUM and Cr-POSSUM will be calculated for each patients based on their medical records. In-Hospital mortality and death within 30 days after colorectal surgery were recorded. Data will be analyze using the linear method of analysis described by Wijesinghe et al; where, in this type of analysis, patients are stratified into groups based on the predicted risk of death. Expected number of deaths is then calculated for each risk group by multiplying the number of patients in a given group with average risk of death in that group. The ratio of observed to expected deaths (O/E ratio) will be calculated for each analysis. The  $X^2$  test of Lemeshaw and Hosmer will be used to assess any differences between predicted and observed morbidity and mortality rates. Discrimination ability,



that is, the ability of the model to assign higher probabilities of death to those patients who died, was measured using receiver operating characteristic curves, which were analyzed for both scores.  $P < 0.05$  will be considered statistically significant.

### **Results :**

Eighty seven patients included in study. The number of deaths predicted by Cr-POSSUM with linear analysis when all patients were analyzed. The Observed / Expected (O/E) ratio for all risk group was 1.5, indicating that the Cr-POSSUM system under predicted mortality in this study by 50%. However, there was no significant difference between the observed and predicted values ( $X^2 = 2.33$ ;  $P = 0.51$ ). On the other hand, P-POSSUM system seemed predicting mortality well in this study, with an overall O:E ratio of 1. There were no significant difference between the predicted and observed values ( $X^2 = 1.5$ ;  $P = 0.91$ ). Discriminatory power of P-POSSUM and Cr-POSSUM scores in predicting death as an outcome measure was analyzed using receiver operating characteristic (ROC) curves. Area under the receiver operating characteristic curve (AUC) for Cr-POSSUM was 0.831 (95% confidence interval (CI) , 0.681-0.981). For P-POSSUM, the AUC was 0.857 (95% CI, 0.762-0.951), indicating satisfactory discriminatory power.

### **Conclusions :**

In conclusion, the results of present study demonstrate that both P-POSSUM and Cr-POSSUM are a useful scoring system that performs well in prediction of mortality after surgery in colorectal patients. Both scoring system performed equally good and specialized scoring systems (Cr-POSSUM) show no superiority over P-POSSUM in predicting mortality after surgery.

## A. INTRODUCTION

### i. Literature review

Perioperative care plays major role in determining the success of surgeries, and perioperative mortality is one of the main concern for patients and family members. How to evaluate the risk of surgery based on patient's preoperative health status and general condition remain as major challenge faced by clinician in daily practice.

In view of this, The Physiological and Operative Severity Score for the enumeration of Mortality and Morbidity (POSSUM) were developed by Copeland et al in 1991. A scoring system which employed 12 factor, 4 grades physiologic score (PS) and a 6 factor, 4 grade operative score (OS). POSSUM system has been widely applied to predict mortality in adult inpatient surgeries (Copeland, Jones *et al.* 1991). However, POSSUM grading has the problem of over predicting mortality rate; moreover, exponential analysis was used in POSSUM, which is not a standard statistical technique to calculate the predicted mortality (Leung, McArdle *et al.* 2011).

To tackle the problem of over predicting of mortality rate in POSSUM, Whiteley *et al* developed Portsmouth POSSUM (P-POSSUM) in 1996. This new scoring system continued to use the risk factors and grades of POSSUM, but revised its regression equation constant and weight to predict inpatient mortality. P-POSSUM system subsequently found to be more accurate predictability then POSSUM. And unlike POSSUM scoring system, P-POSSUM system uses linear analysis technique, a simple and standard method of analysis which is applicable to individual patient (Whiteley, Prytherch *et al.* 1996). Though P-POSSUM is more accurate, it also has some limitations. The predicted mortality in elderly patients and in emergency surgery was less than the actual mortality, whereas the predicted mortality in low-risk groups and in

elective surgery was higher than the actual mortality. Hence, P-POSSUM has certain limitations when surgical risk is very high or very low.

Subsequently, in 2004, Tekkis *et al* suggested Colorectal POSSUM (Cr-POSSUM) for patients who have undergone colorectal surgery. Cr-POSSUM incorporated the preoperative and intraoperative risk factors from the POSSUM model into a new grading system and established a new regression equation to predict inpatient mortality. Like P-POSSUM, Cr-POSSUM continued to use the linear analysis method, but reduced the use of some of the preoperative and intraoperative risk factors. Cr-POSSUM predict mortality in colorectal patient satisfactorily (Tekkis, Prytherch *et al.* 2004) .

There is currently no specific method to predict perioperative mortality for colorectal carcinoma patients, hence, POSSUM, P-POSSUM and Cr-POSSUM are commonly adapted to predict the post-operative mortality of colorectal carcinoma patients. But since these 3 above mentioned scoring systems are originally designed for broad applications, they only able to predict the actual mortality rate up to a certain extent only. Their ability to predict mortality rate for specific patient population remain doubtful.

For information, all these 3 systems are all based on the study of patients in the UK. However, researchers have indicated that these systems may be applicable for patients in others country as well. Bennett-Guer-rero *et al* has compared English and American patients and observed a higher than the actual mortality rate in American patients by using POSSUM scoring system (Bennett-Guerrero, Hyam *et al.* 2003).

At the same time, few studies have been performed in China to evaluate the efficacy of POSSUM grading system in predicting mortality rate of colorectal

carcinoma patients. For example, Law *et al* studied 400 laparoscopic colorectal surgery patients in Hong Kong, concluded that the 3 POSSUM grading systems are over predicting the inpatient mortality rate. Another study with a smaller number of sample from mainland China indicated that the mortality rate predicted by POSSUM shows higher than actual mortality rate, but the difference had no statistical significant (Ren, Upadhyay *et al.* 2009).

ii. Rationale of study

Taiping Hospital is one of the high volume center in northern region of Perak state, consist of 600 beds. As a district hospital, Taiping Hospital encounter average of 50-60 colorectal cancer patients per year, quite a significant number of patients hence is being selected in this study. Aiming to :

- Use an objective and standardized scoring system to measure the in-hospital mortality rate and number of deaths within 30 days after surgery.
- To assess the validity and applicability of P-POSSUM and Cr-POSSUM scoring system in Taiping Hospital setting.
- To utilize the measured mortality rate to predict colorectal patient's outcome, improve services and outcome of colorectal surgery patients.
- To facilitate comparison of quality of health care with other centers.

## A. STUDY PROTOCOL

- i. Document submitted for ethical approval

### **Introduction**

Surgical audit is not a new phenomenon. As early as 1750 BC, King Hammurabi of Babylon issued order for the punishment of negligent physicians, particularly surgeons (Copeland, Jones et al. 1991).

Until today, quality of health care is still the main concern of health care centres. One of the commonest methods employed to assess and compare quality of health care among hospitals is to measure the operative mortality rate. However, several limitations exist during comparison of mortality and morbidity rates and may be misleading because they generally do not consider the age, general condition, physiologic condition of the patient at the time of surgery, and the severity of the surgery.

Hence, in order to make objective comparison possible, various scoring systems have been introduced in past few decades. One of the earliest and well known scoring systems for predicting outcome in surgery was the Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM). POSSUM is a scoring system which employed 12 factor, 4 grades physiologic score (PS) and a 6 factor, 4 grade operative score (OS). It has been widely applied to predict mortality in adult surgical inpatients. However, POSSUM grading has the problem of over predicting mortality rate; moreover, exponential analysis was used in POSSUM, which is not a standard statistical technique to calculate the predicted mortality (Copeland, Jones et al. 1991).

In view of this, several modifications have been suggested since the introduction of original POSSUM system, aiming to suit certain surgical subspecialties. For example - Portsmouth POSSUM (P-POSSUM) system and Colorectal-POSSUM (Cr-POSSUM). P-POSSUM system was designed aiming to overcome the problem of over predicting mortality in low risk patient when using the original POSSUM scoring, this new scoring system continued to use the risk factors and grades of POSSUM, but revised its regression equation constant and weight to predict inpatient mortality and it managed to increase its accuracy in predicting mortality in general surgery compare to the original POSSUM.

On the other hand, Tekkis *et al* suggested Colorectal POSSUM (Cr-POSSUM) in 2004 for this specific surgical subspecialty. It is particularly important to oncologic colorectal surgery as patient with colorectal cancer are often at increased risk of developing post-operative complications owing to underlying colorectal cancer such as malnutrition, anemia, and immunocompromised status(Tekkis, Prytherch *et al.* 2004).

Unlike POSSUM scoring system, P-POSSUM system and Cr-POSSUM system uses linear analysis technique, a simple and standard method of analysis which is applicable to individual patient.

The objective of this study was to assess the accuracy and applicability of P-POSSUM and Cr- POSSUM systems in predicting 30 days post-operative mortality in patients with colorectal cancer resection in Hospital Taiping; to improve the outcome of colorectal patients; to improve services and to facilitate comparison of quality of health care with other center.

### **Important and Rationale of study**

Using an objective and standardized scoring system to measure the in-hospital mortality rate and number of deaths within 30 days after surgery.

To assess the validity and applicability of P-POSSUM and Cr-POSSUM scoring system in Taiping Hospital setting.

To utilize the measured mortality rate to predict colorectal patient's outcome, improve services and outcome of colorectal surgery patients.

To facilitate comparison of quality of health care with other center.

### **Objective**

The objective of this study was to assess the accuracy of P-POSSUM and Cr- POSSUM systems in predicting post-operative mortality in patients with colorectal cancer in Hospital Taiping.

### **Specific objective**

1. To assess the accuracy of P-POSSUM scoring systems in predicting post-operative mortality in colorectal cancers patient.
2. To assess the accuracy of CR-POSSUM scoring systems in predicting post-operative mortality in colorectal cancers patient.
3. To compare the accuracy of P-POSSUM and CR-POSSUM scoring systems in predicting post-operative mortality in patients with colorectal cancer.

## Literatures Review

Perioperative care plays major role in determining the success of any surgery, and perioperative mortality is one of the main issues of concern for patients and family members. How to evaluate the risk of surgery based on patient's preoperative health status and general condition becoming major challenge faced by clinician in daily practice.

In view of this, The Physiological and Operative Severity Score for the enumeration of Mortality and Morbidity (POSSUM) were developed by Copeland *et al* in 1991. A scoring system which employed 12 factor, 4 grades physiologic score (PS) and a 6 factor, 4 grade operative score (OS). POSSUM system has been widely applied to predict mortality in adult inpatient surgeries. However, POSSUM grading has the problem of over predicting mortality rate; moreover, exponential analysis was used in POSSUM, which is not a standard statistical technique to calculate the predicted mortality (Copeland, Jones *et al.* 1991).

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and in elective surgery was higher than the actual mortality. Hence, P-POSSUM has certain limitations when surgical risk is very high or very low.

Subsequently, in 2004, Tekkis *et al* suggested Colorectal POSSUM (Cr-POSSUM) for patients who have undergone colorectal surgery. Cr-POSSUM incorporated the preoperative and intraoperative risk factors from the POSSUM model into a new grading system and established a new regression equation to predict inpatient mortality. Like P-POSSUM, Cr-POSSUM continued to use the linear analysis method, but reduced the use of some of the preoperative and intraoperative risk factors. Cr-POSSUM predict mortality in colorectal patient satisfactorily (Tekkis, Prytherch *et al.* 2004).

There is currently no specific method to predict perioperative mortality for colorectal carcinoma patients, hence, POSSUM, P-POSSUM and Cr-POSSUM are commonly adapted to predict the post-operative mortality of colorectal carcinoma patients. But since these 3 above mentioned scoring systems are originally designed for broad applications, they only able to predict the actual mortality rate up to a certain extent only. Their ability to predict mortality rate for specific patient population remain doubtful.

For information, all these 3 systems are all based on the study of patients in the UK. However, researchers have indicated that these systems may be applicable for patients in others country as well. Bennett-Guer-rero *et al* has compared English and American patients and observed a higher than the actual mortality rate in American patients by using POSSUM scoring system (Bennett-Guerrero, Hyam *et al.* 2003).

At the same time, few studies have been performed in China to evaluate the efficacy of POSSUM grading system in predicting mortality rate of colorectal

carcinoma patients. For example, Law *et al* (2006) studied 400 laparoscopic colorectal surgery patients in Hong Kong, concluded that the 3 POSSUM grading systems over predicting the inpatient mortality rate. Another study with a smaller number of sample from mainland China indicated that the mortality rate predicted by POSSUM shows higher than actual mortality rate, but the difference had no statistical significant .

## **METHODOLOGY**

### **Design**

Retrospective cohort study of patients after resection of colorectal cancer.

### **Setting**

General hospital – Hospital Besar Taiping

### Sampling size

Sample size calculation was based on Single proportion formula:

$$n = \left( \frac{Z\alpha}{\Delta} \right)^2 p (1 - p)$$

Based on previous informal audit in Hospital Taiping, the sensitivity and specificity of P-POSSUM and Cr-POSSUM scores were 70% and 73% respectively.

Thus;

$$Z\alpha = 1.96$$

$$\Delta = 10\%$$

$$\text{The number of samples with expected sensitivity} = \left( \frac{1.96}{0.10} \right)^2 0.70 (1-0.70) = 81$$

$$\text{Sample size} + 10\% \text{ drop out} = 90$$

$$\text{The number of samples with expected specificity} = \left( \frac{1.96}{0.10} \right)^2 0.73 (1-0.73) = 76$$

$$\text{Sample size} + 10\% \text{ drop out} = 84$$

Therefore, the total sample size that will be used in this study will be 90 samples.

### **Data collection and analysis**

All patients who underwent colorectal cancer resection from April 2013 to April 2015 at Hospital Taiping will be retrospectively included in the study. Those patients for whom P-POSSUM and Cr-POSSUM scores could not be calculated because of lack of data will be excluded.

All data will be assessed and collected by 1 assigned personnel to ensure the consistency of data collection. Folder will be traced and data collected from patient's folder. Those patients for whom P-POSSUM and Cr-POSSUM scores could not be calculated because of lack of data will be excluded, for instance :

- Patient who die within 30 days after operation but not in hospital or not being notified will be excluded.
- We use 30 days as cut off point because 30 days is standard health indicator applied for perioperative mortality rate.
- Only colorectal cancer resection performed by gazzetted surgeon will be included in this study.
- Pre op parameter (the parameters for pre op assessment by anesthesiologist) will be used for scoring purposes.

Physiologic scores and operative severity scores for both P-POSSUM and Cr-POSSUM will be calculated for each patients based on their medical records. In-Hospital mortality and death within 30 days after colorectal surgery were recorded.

Data will be analyzed using the linear method of analysis described by Wijesinghe *et al*; where, in this type of analysis, patients are stratified into groups based on the predicted risk of death. Expected number of deaths is then calculated for each risk group by multiplying the number of patients in a given group with average risk of death in that group.

The ratio of observed to expected deaths (O/E ratio) will be calculated for each analysis. The  $\chi^2$  test of Lemeshaw and Hosmer will be used to assess any differences between predicted and observed morbidity and mortality rates.

Discrimination ability, that is, the ability of the model to assign higher probabilities of death to those patients who died, was measured using receiver operating characteristic curves, which were analyzed for both scores.  $P < 0.05$  will be considered statistically significant.

### **Formula**

#### **FORMULA TO CALCULATE MORTALITY RISK FOR P-POSSUM SCORING SYSTEM.**

$\ln [R/(1-R)] = -9.065 + (0.1692 \times \text{Physiologic Score}) + (0.1150 \times \text{Operative Severity Score})$ , where  $R$  is the predicted risk of mortality.

#### **FORMULA TO CALCULATE MORTALITY RISK FOR Cr-POSSUM SCORING SYSTEM.**

$\text{Log}_e [R/1-R] = -9.167 + (0.33 \times \text{physiological score}) + (0.30 \times \text{operative score})$



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**Appendices**

Parameters for calculating P-POSSUM Score

ID : \_\_\_\_\_

Date of operation: \_\_\_\_\_

Diagnosis: \_\_\_\_\_

Operation: \_\_\_\_\_

<b>Parameter</b>	<b>Points</b>
<b>Physiologic score</b>	
Age (years)	
≤ 60	1
61-70	2
≥71	4
Cardiac signs and symptoms	
- No failure	1
-Diuretic, digoxin, antianginal, or antihypertensive therapy	2
-peripheral edema, warfarin therapy, borderline cardiomegaly on CXR	4
-elevated JVP, cardiomegaly on CXR	8
Respiratory findings	
-no dyspnea	1
-dyspnea on exertion; mild evidence of COPD on CXR	2
-Limiting dyspnea after walking upto 1 flight of stairs; moderate COPD on CXR	4
-dyspnea at rest; respiratory rate>30 breath/minute; fibrosis or consolidation on CXR	8
Systolic blood pressure, mmHg	
≤89	8
90-99	4
100-109	2
110-130	1
131-170	2
≥171	4
Pulse rate, per minute	
<39	8
40-49	2
50-80	1
81-100	2
101-120	4
>121	8
Glasgow Coma Scale Score	
15	1



12-14	2
9-11	4
≤8	8
<b>Hemoglobin, g/dL</b>	
≤9.9	8
10.0-11.4	4
11.5-12.9	2
13.0-16.0	1
16.1-17.0	2
17.1-18.0	4
≥18.1	8
<b>White blood cell count, No./μL</b>	
≤3000	4
3100-3999	2
4000-10000	1
10100-20000	2
≥20100	4
<b>Serum urea nitrogen, mg/dL</b>	
≤21	1
21.3-28.0	2
28.3-42.0	4
≥43.0	8
<b>Sodium, mEq/L</b>	
≤125	8
125-126	4
131-135	2
≥136	1
<b>Potassium, mEq/L</b>	
≤2.8	8
2.9-3.1	4
3.2-3.4	2
3.5-5.0	1
5.1-5.3	2
5.4-5.9	4
≥6.0	8
<b>Electrocardiographic findings</b>	
Normal	1
Atrial fibrillation with heart rate 60-90 beats/min	4
Any other abnormal rhythm	8
≥5 ectopic beats per minute	8
Q wave or ST-T wave changes	8
<b>Operative severity score</b>	
<b>Operative severity</b>	
Minor	1
Moderate	2
Very major	4
Complex major	8
<b>No. of procedures</b>	
1	1

2	4
≥2	8
Total blood lost, mL	
≤100	1
101-500	2
501-999	4
≥1000	8
Peritoneal soiling	
None	1
Minor, serous fluid without pus	2
Local pus	4
Free bowel content, pus or blood	8
Presence of cancer	
None	1
Primary lesion only	2
Nodal metastases	4
Distant metastases	8
Mode of surgery	
Elective	
Emergency with resuscitation ≥2 h	
Surgery < 24 h after admission	
Immediate surgery	

Abbreviations = CXR, chest x ray; COPD, chronic obstructive pulmonary disease; P-POSSUM, Portsmouth Physiologic and Operative Severity Score for the enumeration of mortality and morbidity.

SI conversion factors: To convert hemoglobin to grams per litre, multiply by 10.0; white blood cell count to  $\times 10^9/L$ , multiply by 0.001; serum urea nitrogen to millimoles per litre, multiply by 0.357; and sodium and potassium to millimoles per litre, multiply by 1.0.

In  $[R/(1-R)] = -9.065 + (0.1692 \times \text{Physiologic Score}) + (0.1150 \times \text{Operative Severity Score})$ , where  $R$  is the predicted risk of mortality.

## Parameters for Calculating Cr-POSSUM Score

ID : \_\_\_\_\_

Date of operation: \_\_\_\_\_

Diagnosis: \_\_\_\_\_

Operation: \_\_\_\_\_

Parameter	Points
<b>Physiologic score</b>	
Age (years)	
≤ 60	1
61 – 70	3
71 – 80	4
> 80	8
Cardiac failure	
No failure	1
Moderate	2
Severe	3
Systolic blood pressure (mmHg)	
100 – 170	1
> 170 or 90 – 99	2
< 90	3
Pulse (/min)	
40 – 100	1
101 – 120	2
> 120 or < 40	3
Hemoglobin, g/dL	
13.0 – 16.0	1
10 .0 – 12.9 or 6.1 – 18.0	2
< 10 or > 18.0	3
Serum urea (mmol/L)	
<3.6	1
3.6 – 5.4	2
> 5.4	3
<b>Operative severity score</b>	
Operative severity	
Minor <sup>a</sup>	1
Intermediate <sup>b</sup>	3
Major <sup>c</sup>	4
Complex major <sup>d</sup>	8
Peritoneal soiling	
None or serous fluid	1
Local pus	2
Free bowel content, pus or blood	3
<b>Cancer stage<sup>e</sup></b>	
No cancer or Duke A or B	1
Duke C	2
Duke D	3

Mode of surgery	
Elective	1
Emergency	3
Immediate	8

<sup>b</sup>intermediate procedures include: laparotomy only, adhesiolysis, reversal of stoma, prolapse surgery, anal sphincter repair and proctectomy

<sup>c</sup>Major procedures include any laparotomy or bowel resection.

<sup>d</sup>Complex major include tumor resection (+/- stoma) with additional surgical procedure such as pelvic exenteration, cystectomy with ileal conduit, removal of reproductive organ etc.

<sup>e</sup>Duke system of cancer staging: A, lesion involved till muscularispropria; B, lesion invade into or beyond serosa layer but no nodes involvement; C, lesion extends beyond serosa and involved regional lymph node (C1) or apical lymph nodes (C2); D, extensive local spread or with distant metastases

\*Cr-POSSUM is  $\text{Log}_e [R/1-R] = -9.167 + (0.33 \times \text{physiological score}) + (0.30 \times \text{operative score})$

## ii. Ethical approval letter



Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM)  
Human Research Ethics Committee USM (HREC)

21<sup>st</sup> November 2016

*OK 21/11/16*  
Dr. Yew Chor Giap

Department of Surgery  
School of Medical Sciences  
Universiti Sains Malaysia  
16150 Kubang Kerian, Kelantan.

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www.jepem.kk.usm.my

JEPeM Code : USM/JEPeM/16070233

Protocol Title : Comparison of P-POSSUM and Cr-POSSUM Scores in Patients Undergoing Colorectal Cancer Resection in Hospital Taiping.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/16070233**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **21<sup>st</sup> November 2016** until **20<sup>th</sup> November 2017**.

Study Site: General Hospital, Taiping, Perak.

The following researchers also involve in this study:

1. Dr. Wan Zainira Wan Zain
2. Dr. Umasangar Ramasamy

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

1. Data Collection Sheet – Parameters for Calculating P-POSSUM Score
2. Data Collection Sheet – Parameters for Calculating Cr-POSSUM Score

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2015: Continuing Review Application Form**. Subsequently this need to be done yearly as long as the research goes on.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2015: Study Protocol Amendment Submission Form**.
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2015: Study Protocol Amendment Submission Form**.
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2014: Adverse Events Report**.
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2015**.

6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2014: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: [www.jepem.kk.usm.my](http://www.jepem.kk.usm.my)

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

**"ENSURING A SUSTAINABLE TOMORROW"**

Very truly yours,



**PROF. DR. MOHD SHUKRI OTHMAN**  
Deputy Chairperson  
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM  
Universiti Sains Malaysia



**Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM)**  
Human Research Ethics Committee USM (HREC)

Date of meeting : 30<sup>th</sup> August 2016  
Venue : Meeting Room, Division of Research & Innovation,  
USM Kampus Kesihatan.  
Time : 9.00 a.m – 2.00 p.m  
Meeting No : 342

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Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

Member (Title and Name)	Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
<b>Deputy Chairperson :</b> Professor Dr. Mohd Shukri Othman	Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ <b>(Deputy Chairperson)</b>
<b>Secretary:</b> Mr. Mohd Bazlan Hafidz Mukrim	Research Officer	M	✓
<b>Members :</b>			
1. Dr. Azlan Husin	Lecturer, School of Medical Sciences	M	✓
2. Mr. Harry Mulder	Community Representative	M	✓
3. Dr. Haslina Taib	Lecturer, School of Dental Sciences	F	✓
4. Mr. Hj. Ismail Hassan	Community Representative	M	✓
5. Dr. Mohammad Farris Iman Leong Abdullah	Lecturer, Advanced Medical and Dental Institute (AMDI)	M	✓
6. Dr. Mujahid Bakar	Lecturer, School of Health Sciences	M	✓
7. Professor Dr. Nik Hazlina Nik Hussain	Lecturer, School of Medical Sciences	F	✓
8. Associate Professor Dr. Nor Azwany Yaacob	Lecturer, School of Medical Sciences	F	✓
9. Dr. Teguh Haryo Sasongko	Lecturer, Human Genome Centre	M	✓
10. Dr. Win Mar @ Salmah	Lecturer, School of Medical Sciences	F	✓
11. Mrs. Zawiah Abu Bakar	Community Representative	F	✓
12. Professor Dr. Zeehaida Mohamed	Lecturer, School of Medical Sciences	F	✓

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

**PROFESSOR DR. MOHD SHUKRI OTHMAN**  
Deputy Chairperson  
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM  
Universiti Sains Malaysia

**COMPARISON OF P-POSSUM AND Cr-POSSUM SCORES IN  
PATIENTS UNDERGOING COLORECTAL CANCER RESECTION IN  
HOSPITAL TAIPING.**

by

**DR YEW CHOR GIAP**

Dissertation Submitted In  
Partial Fulfillment Of The  
Requirements For The Degree Of  
Master Of Medicine  
(General Surgery)



2017



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