* Predictive Accuracy of ACS Risk Calculator in determining intra- and postoperative complications in Pakistani population

Naveed Aman Pasha

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# Abstract

Clear understanding of the risks and benefits of any surgical procedure is crucial for both surgeon and patient when committing to any surgical treatment. Surgeons are interested in the ability of the patient to survive the procedure without harm. Patients are interested primarily in the gravity of the surgery and secondarily in the expected length of hospital stay in order to manage their lives according to what best suits patient care. Unfortunately there exists no validated surgical risk calculator for the Pakistani population. The objective of this study is to ascertain the accuracy of the American College of Surgeons National Survey on Quality Improvement Project risk calculator in predicting intra- and postoperative adverse outcomes as well as postoperative length of stay.

# Introduction

Undertaking surgical procedures involves a decision making process shared between the surgeon and the patient. Clear understanding of the procedure, its risks and benefits is essential for patients to make an informed decision. Therefore, patients need to know not only what complications can take place but also the probability of those complications in order to weigh them against the benefits. Knowing the probability of complications becomes especially vital in emergency setting when patients are confronted with a sudden decision where both affirmation and negation have drastic consequences. Unfortunately, there exists no calculator for post-operative morbidity and mortality in the emergency setting for the entire South-East Asia Region.

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# Rationale

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# Objective

The primary objective of this study is assess the accuracy of the ACS NSQIP risk calculator in estimating the probability of post-operative mortality and morbidity in patients of the Pakistani population undergoing elective and emergent surgeries.

# Operational Definitions

These operational definitions have been adapted from the [ACS risk calculator website](https://riskcalculator.facs.org/RiskCalculator/PatientInfo.jsp)

1. Functional Status

* Independent: the patient does not require assistance from another person for any activities of daily living. This includes a person who is able to function independently with prosthetics, equipment or devices
* Partially dependent: the patient requires some assistance from another person for activities of daily
* Totally dependent: the patient requires total assistance for all activities of daily living

1. ASA classification

* ASA 1: Normal healthy patient
* ASA 2: Patient with mild systemic disease
* ASA 3: Patient with severe systemic disease
* ASA 4: Patient with severe systemic disease that is a constant threat to life
* ASA 5: Moribund patient who is no expected to survive without operation

1. Steroid Use

This includes any administration of steroids greater a single pulse dose or a short taper course less than 10 days.

1. Ascites

The presence of fluid accumulation in peritoneal cavity noted on physical examination, abdominal ultrasound or abdominal CT/MRI.

1. Systemic Sepsis

Any patient displaying signs and symptoms of:

* Systemic inflammatory response syndrome
* Sepsis
* Septic shock

1. Ventilator Requirement

This does not include patients requiring CPAP for sleep apnoea.

1. Disseminated Cancer

* The patient has a primary cancer that has metastasized to a major organ AND
  + active treatment for the cancer within one year of the surgery date. If the surgical procedure is the treatment for the metastatic cancer, answer “Yes”
  + the patient has elected not to receive treatment for the metastatic disease
  + the patient’s metastatic cancer has been deemed untreatable
* EXCEPT
  + Chronic lymphocytic leukemia,
  + Chronic myelogenous leukemia,
  + Lymphomas of stages I through III or multiple myeloma

1. Presence of Diabetes

* This will not include patients whose diabetes is controlled by diet alone.

1. Congestive Heart Failure

* Newly diagnosed CHF within previous 30 days
* Diagnosis of chronic CHF with signs or symptoms of CHF in the 30 days prior to proposed surgery

1. Current Smoker

* A current smoker will not include patients who consumed cigars, pipes or chewing tobacco.

1. Severe COPD

* Functional disability from COPD
* Hospitalisation in the past fro treatment of COPD
* Chronic bronchodilator therapy with oral or inhaled agents
* FEV1 of < 75% of predicted
* Does not include patients whose only pulmonary disease is asthma
* Does not include patients with diffuse interstitial fibrosis or sarcoidosis

1. Requirement for Dialysis

* Acute or chronic renal failure requiring peritoneal dialysis, hemodialysis, hemofiltration or ultrafiltration within 2 weeks of proposed surgery
* If a patient refuses dialysis but requires it, the answer will be “yes”

1. Acute Renal Failure

* Increased BUN on two measurements AND two creatinine results > 3mg/dL
* Surgeon or physician has documented Acute Renal Failure AND one of the following
  + Increased BUN on two measurements
  + Two Cr results > 3 mg/dL

1. Pneumonia

* Infection of the lungs, diagnosed using both radiologic (i.e., infiltrate, consolidation or opacity, cavitation) and clinical (e.g., fever, leukopenia/leukocytosis, culture results, patient symptoms) criteria.

1. Cardiac complication

* Cardiac arrest: The absence of cardiac rhythm or presence of a chaotic cardiac rhythm requiring the initiation of CPR, which includes chest compressions.
* Myocardial infarction: ECG changes, new elevation in troponin, or physician diagnosis.

1. Surgical site infection (SSI)

* Superficial Incisional SSI: infection that involves only skin or subcutaneous tissue of the incision. It also includes either: purulent drainage, positive culture, signs/symptoms of infection and the incision is deliberately opened by the surgeon or diagnosis by the attending physician
* Deep Incisional SSI: infection that appears to be related to the operation and involves deep soft tissues (for example, fascial and muscle layers) of the incision. It also includes either: purulent drainage, spontaneous dehiscence, deliberate opening by the surgeon, abscess involving the deep incision, or diagnosis by the attending physician
* Organ Space SSI: infection that involves any part of the anatomy (for example, organs or spaces), other than the incision, which was opened or manipulated during an operation. It also includes either: purulent drainage, positive culture, abscess, or diagnosis by the attending physician

1. Urinary tract infection

* Bladder infection, diagnosed using a combination of clinical symptoms and laboratory confirmation (e.g., urine culture, pyuria, positive dipstick) or initiation of appropriate antimicrobial therapy

1. Venous thromboembolism / blood clot

* The identification of a new thrombus within the venous system, described in studies as present in the superficial or deep venous systems but requires therapy. This diagnosis is confirmed by a duplex, venogram, CT scan or other imaging modality, AND the patient requires treatment with anticoagulation therapy and/or placement of a vena cava filter or clipping of the vena cava

1. Renal failure

* Progressive renal insufficiency: a rise in creatinine of >2 mg/dL from preoperative value, but with no requirement for dialysis
* Acute renal failure requiring dialysis: A patient who did not require dialysis preoperatively, worsening of renal dysfunction postoperatively requiring hemodialysis, peritoneal dialysis, hemofiltration, hemodiafiltration, or ultrafiltration

1. Ileus

* Prolonged Postoperative NPO or NGT Use: Prolonged NPO status or NGT use for suctioning or decompression, more than 3 days postoperatively (postoperative day 4 or later) OR reinsertion of NGT or reinstating NPO status any time postoperative day 4 or later within 30 days

1. Anastomotic Leak

* There was a leak of endoluminal contents through an anastomosis. This could include air, fluid, GI contents, or contrast material. The presence of an infection/abscess thought to be related to an anastomosis, even if the leak cannot be definitively identified as visualized during an operation, or by contrast extravasation, would still be considered an anastomotic leak if this is indicated by the surgeon including
  + Without a documented treatment intervention
  + Treated with NPO, Antibiotics, TPN or other non-interventional, non-operative means
  + Treated with percutaneous/radiological/endoscopic interventional means- i.e.,- percutaneous drainage with or without indwelling drain, endoscopic stent, etc.
  + Treated with re-operation

1. Return to Operating Room

* Return to the operating room for additional surgery that was not planned at the time of the initial surgery

1. Serious Complication

* Cardiac arrest
* Myocardial infarction
* Pneumonia
* Progressive renal insufficiency
* Acute renal failure
* Pulmonary embolism
* Deep venous thrombosis
* Return to the operating room
* Deep incisional SSI
* Organ space SSI
* Systemic
* Sepsis
* Unplanned intubation
* UTI
* Wound disruption as defined previously

# Methods

Approval for the study will be taken from the Ethical Review Committee of the Aga Khan University Hospital.

## Study Design

This will be a single centre descriptive longitudinal study.

## Study Setting

The study conducted at the Aga Khan University Hospital in the Departments of Surgery and Emergency Medicine. Surgeries will be performed in the operating rooms. Patients will be observed postoperatively in the General Ward, High Dependency Units or outpatient clinics (based on patient condition).

## Inclusion criteria

The study population will comprise of adult patients undergoing any of the following surgical procedures:

* Thyroidectomy (total or partial)
* Parathyroidectomy
* Diversion or resective colonic surgery
  + Right hemicolectomy
  + Left hemicolectomy
  + Total colectomy
  + Lower Anterior Resection
  + Abdomino-perineal resection
* Pancreatic Procedures
  + Whipple procedure
  + Distal Pancreatectomy

## Data Collection and Management

Pertinent patient variables that will be collected are:

* Age
* Gender
* BMI
* Functional Status
* Whether surgery is emergent
* ASA Class
* Steroid use for chronic condition
* Ascites within last 30 days prior to presentation
* Systematic sepsis within previous 48 hours
* Presence of congestive heart failure on presentation
* Presence of acute renal failure on presentation
* Presence of disseminated cancer
* Presence of diabetes (none, on oral hypoglycemics, on insulin)
* Presence of hypertension requiring medication
* Current Smoker for last one year
* Presence of severe COPD
* Dialysis Dependent
* Ventilator requirement 48 hours prior to planned surgery

These variables will be collected on a preformed performa. The data gathered by the performa will be entered into the [ACS risk calculator](https://riskcalculator.facs.org/). The risk of each of the following outcomes will be noted:

* Pneumonia
* Cardiac Complication
* Surgical Site Infection
* Urinary Tract Infection
* Renal Failure
* Ileus
* Anastomotic Leak
* Return to Operating Room
* Serious Complication

The patients will be followed for 90 days postoperatively for the occurrence of the same outcomes at 30 and 90 days postoperatively. These data will be stored online in the form of spreadsheet under password protection. Once data collection is complete, hard copies of the performas will be destroyed. Data will be anonymised in order to protect patient privacy.

## Duration of Study

One to two years after the approval of synopsis.

## Sample Size

– to be calculated –

## Duration of Study

Non-probability consecutive sampling.

## Data Analysis

The statistical analysis will be performed using the R statistical programming language and environment. Distributions of the predicted probabilities of mortality as well as each morbidity will be plotted. Receiver operating curves will be plotted for these distributions by comparing the estimated probabilities of each outcome with the actual observed outcomes and the area under the curve will be calculated. Data will be gathered prospectively.

# Expected Outcomes of the Study

Provision of surgical risk calculator in the emergency setting will be a tremendous asset to patients. The risk calculator will assist in weighing the risks and benefits of the emergency surgery by providing the probability of adverse outcomes. It will aid patients in justifying the cost of the surgical procedure. It will aid surgeons in tailoring selection of candidates for surgery in cases where benefits of surgery are equivocal.

# Dissemination of Results

Results are intended to be submitted for publication as free access so that the risk calculator may be freely available to surgeons across for application. Study results will be reported in accordance with the STROBE guidelines.