ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
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Study Identification

Unique Protocol ID:	201-26104-132-108296
Brief Title:	Comparative Analysis of APACHE II and P-POSSUM
Official Title:	Comparative Analysis of APACHE II and P-POSSUM Scoring Systems in Predicting Postoperative Mortality in Patients Undergoing Emergency Laparotomy
Secondary IDs:	

Study Status

Record Verification:	May 2016
Overall Status:	Completed
Study Start:	December 2013 []
Primary Completion:	November 2014 [Actual]
Study Completion:	December 2014 [Actual]

Sponsor/Collaborators

Sponsor:	Tata Main Hospital
Responsible Party:	Principal Investigator Investigator: Dr.Deb Sanjay Nag [dnag] Official Title: Associate Specialist Affiliation: Tata Main Hospital
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 30/11/2013 Board Name: Institutional Ethics Committee Board Affiliation: Tata Main Hospital Phone: +91-7763807402 Email: drmamtadatta@gmail.com Address:
Data Monitoring:	Yes
FDA Regulated Intervention:	No

Study Description

Brief Summary:	To compare APACHE II and P-POSSUM scoring system in emergency laparotomy.
Detailed Description:	To compare APACHE II and P-POSSUM scoring system in predicting postoperative mortality in patients undergoing emergency laparotomy.

Conditions

Conditions:	External Causes of Morbidity and Mortality
Keywords:	

Study Design

Study Type:	Observational
Observational Study Model:	Cohort
Time Perspective:	Retrospective
Biospecimen Retention:	None Retained
Biospecimen Description:	

Enrollment:	159 [Actual]
Number of Groups/Cohorts:	1

Groups and Interventions

Outcome Measures

[See Results Section.]

Eligibility

Study Population:	All patients undergoing emergency laparotomy at Tata Main Hospital form 01st December 2013 to 30th November 2014 will be included in the study. All patients will be scored with APACHE II and P-POSSUM scoring systems on the day of surgery.The patients will be followed up till discharge, death or 30 days postoperatively.
Sampling Method:	Non-Probability Sample
Minimum Age:	
Maximum Age:	
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria: • All patients above 18 years of age undergoing emergency laparotomy at Tata Main Hospital form 01st December 2013 to 30th November 2014 will be included in the study. Exclusion Criteria: • Patients willingly seeking referral to a different hospital

Contacts/Locations

Central Contact Person:	Pratap Rudra Mahanty, MD Telephone: 917763807074 Email: drprmahanty@tatasteel.com
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Locations: **India**
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IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	All who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, India who met the inclusion criteria were included in the study

Reporting Groups

	Description
All Patients Who Underwent Emergency Exploratory Laparotomy	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria were scored using the P-POSSUM Score APACHE-II

Overall Study

	All Patients Who Underwent Emergency Exploratory Laparotomy
Started	159

	All Patients Who Underwent Emergency Exploratory Laparotomy
Completed	157
Not Completed	2
Lost to Follow-up	2

Baseline Characteristics

Reporting Groups

	Description
Emergency Laparotomy	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria were scored using the APACHE-2 Score & P-POSSUM Score

Baseline Measures

		Emergency Laparotomy
Overall Number of Participants		157
Age, Customized [1] Measure Type: Number Unit of measure: participants	Number Analyzed	157 participants
18- 20 years		11
21-40 years		45
41-60 years		60
61-80 years		38
> 80years		3
		[1] Measure Description: All patients above 18 years age were included in the study
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	157 participants
	Female	58 36.94%
	Male	99 63.06%

		Emergency Laparotomy
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	157 participants
India		157

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Area Under the Receiver Operating Curve (ROC) as a Measure of the Accuracy of the APACHE II and P-POSSUM Scoring Systems to Predict Mortality
Measure Description	Participants will be followed for the duration of hospital stay (expected average of 30 days) and mortality was noted.All patients undergoing emergency laparotomy at Tata Main Hospital form 01st December 2013 to 30th November 2014 were included in the study. All patients were scored with APACHE II and P-POSSUM scoring systems on the day of surgery. Area under the curve (AUC) is used to measure the “size” of the prediction composed by the graphic display between the ‘sensitivity’ and the ‘1–specificity’ relationship. AUC can range from 0.5 to 1.0 and a result of 1.0 indicates a perfect discriminatory ability. An AUC value > 0.8 is considered good, a range between 0.60-0.80 is considered as moderate, and an AUC value < 0.60 is regarded as poor. For APACHE-II, a cut off score of >/=24 was determined; for P-POSSUM, a cut off score of >/= 63 was determined.
Time Frame	30 days

Analysis Population Description

All patients undergoing emergency laparotomy at Tata Main Hospital form December 2013 to November 2014 were scored with APACHE II & P-POSSUM scoring systems on the day of surgery. The patients were followed up till at least 30 days after discharge or death (during admission or within 30 days after discharge).

Reporting Groups

	Description
AUC Using APACHE II	All patients undergoing emergency laparotomy at Tata Main Hospital form 01st December 2013 to 30th November 2014 were included in the study. All patients were scored with APACHE II on the day of surgery.
AUC Using P-POSSUM	All patients undergoing emergency laparotomy at Tata Main Hospital form 01st December 2013 to 30th November 2014 were included in the study. All patients were scored with P-POSSUM on the day of surgery.

Measured Values

	AUC Using APACHE II	AUC Using P-POSSUM
Overall Number of Participants Analyzed	157	157

	AUC Using APACHE II	AUC Using P-POSSUM
Area Under the Receiver Operating Curve (ROC) as a Measure of the Accuracy of the APACHE II and P-POSSUM Scoring Systems to Predict Mortality Number (95% Confidence Interval) Unit of measure: probability of accurate prediction	0.965 (0.928 to 1.000)	0.989 (0.974 to 1.000)

Statistical Analysis 1 for Area Under the Receiver Operating Curve (ROC) as a Measure of the Accuracy of the APACHE II and P-POSSUM Scoring Systems to Predict Mortality

Statistical Analysis Overview	Comparison Group Selection	AUC Using APACHE II, AUC Using P-POSSUM
	Comments	Area under the curve (AUC) is used to measure the “size” of the prediction composed by the graphic display between the ‘sensitivity’ and the ‘1–specificity’ relationship. AUC can range from 0.5 to 1.0 and a result of 1.0 indicates a perfect discriminatory ability. An AUC value > 0.8 is considered good, a range between 0.60-0.80 is considered as moderate, and an AUC value < 0.60 is regarded as poor.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.665
	Comments	Comparing the sensitivity of APACHE-II and P-POSSUM
	Method	McNemar
	Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Length of Stay (LOS)
Measure Description	The mean duration of hospital stay or Length of Stay was recorded
Time Frame	30 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Length of Stay	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria were observed for their length of stay (LOS)

Measured Values

	Length of Stay
Overall Number of Participants Analyzed	157
Length of Stay (LOS) Mean (Standard Deviation) Unit of measure: Days	
Surviving Patients	9.36 (8.04)
Patients who Died	14.91 (15.43)

3. Secondary Outcome Measure:

Measure Title	Need for Postoperative Ventilator Support
Measure Description	Number of patients needing post-operative ventilatory support
Time Frame	30 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Surviving Patients	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and survived during the study period were observed if they needed ventilatory support postoperatively
Patients Who Died	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and died during the study period were observed if they needed ventilatory support postoperatively

Measured Values

	Surviving Patients	Patients Who Died
Overall Number of Participants Analyzed	134	23
Need for Postoperative Ventilator Support Measure Type: Number Unit of measure: participants	40	23

4. Secondary Outcome Measure:

Measure Title	Need for Post Operative Inotropic Support
Measure Description	Number of patients needing post-operative inotropic support
Time Frame	30 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Surviving Patients	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and survived during the study period were monitored for the need for inotropic support during their stay..
Patients Who Died	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and died during the study period were monitored for the need for inotropic support during their stay..

Measured Values

	Surviving Patients	Patients Who Died
Overall Number of Participants Analyzed	134	23
Need for Post Operative Inotropic Support Measure Type: Number Unit of measure: participants	25	23

5. Secondary Outcome Measure:

Measure Title	Cardiac Morbidity (AMI or Arrhythmias Needing Treatment)
Measure Description	Number of patients noted to have Cardiac morbidity: Acute myocardial infarction (AMI) or arrhythmias needing treatment
Time Frame	30 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Patients Who Survived	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and survived during the study period were monitored for Cardiac morbidity (Acute Myocardial Infarction (AMI) or arrhythmias needing treatment)
Patients Who Died	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and died during the study period were monitored for Cardiac morbidity (Acute Myocardial Infarction (AMI) or arrhythmias needing treatment)

Measured Values

	Patients Who Survived	Patients Who Died
Overall Number of Participants Analyzed	134	23
Cardiac Morbidity (AMI or Arrhythmias Needing Treatment) Measure Type: Number Unit of measure: participants	1	7

6. Secondary Outcome Measure:

Measure Title	Number of Participants With Acute Kidney Injury (AKI)
Measure Description	Acute Kidney Injury (AKI) was diagnosed based on the Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group (2012) guidelines 1. Increase in Serum Creatinine (S. Cr) by ≥0.3 mg/dl (≥ 26.5 µmol/l) within 48 hours; OR 2. Increase in S. Cr to ≥1.5 times baseline, which is known or presumed to have occurred within prior 7 days; OR 3. Urine volume <0.5 ml/kg/h for 6 hours
Time Frame	30 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Patients Who Survived	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and survived during the study period were monitored for the Acute Kidney Injury
Patients Who Died	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and died during the study period were monitored for the Acute Kidney Injury

Measured Values

	Patients Who Survived	Patients Who Died
Overall Number of Participants Analyzed	134	23
Number of Participants With Acute Kidney Injury (AKI) Measure Type: Number Unit of measure: participants	14	18

7. Secondary Outcome Measure:

Measure Title	Patients Needing Re-exploration
Measure Description	Number of patients needing return to the operation theater for surgery for the same pathology or any other complication arising out of the initial surgery
Time Frame	30 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Patients Who Survived	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and survived during the study period were observed if they needed re-exploration during the post-operative period.
Patients Who Died	All patients who underwent emergency exploratory laparotomy from December 2013 to November 2014 at the Tata Main Hospital, Jamshedpur, and met the inclusion criteria and died during the study period were observed if they needed re-exploration during the post-operative period.

Measured Values

	Patients Who Survived	Patients Who Died
Overall Number of Participants Analyzed	134	23
Patients Needing Re-exploration Measure Type: Number Unit of measure: participants	2	2

Reported Adverse Events

Time Frame	The patients were followed up for the duration of admission and till at least 30 days after discharge or death (whichever was earlier).
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
APACHE-2 Scoring	All patients undergoing emergency laparotomy at Tata Main Hospital form 01st December 2013 to 30th November 2014 were included in the study. All patients were scored with APACHE II on the day of surgery.
P-POSSUM	All patients undergoing emergency laparotomy at Tata Main Hospital form 01st December 2013 to 30th November 2014 were included in the study. All patients were scored with P-POSSUM on the day of surgery

All-Cause Mortality

	APACHE-2 Scoring	P-POSSUM
	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	/	/

Serious Adverse Events

	APACHE-2 Scoring	P-POSSUM
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/157 (0%)	0/157 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	APACHE-2 Scoring	P-POSSUM
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/157 (0%)	0/157 (0%)

Limitations and Caveats

Observational study. So no specific adverse effect because of the study.

More Information

Certain Agreements:

All Principal Investigators ARE employed by the organization sponsoring the study.

Results Point of Contact:

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