# Comparative Analysis of APACHE II and P-POSSUM



ClinicalTrials.gov Identifier: NCT02471612

Recruitment Status : Completed
First Posted : June 15, 2015
Results First Posted : June 27, 2016
Last Update Posted : June 27, 2016

**Sponsor:**
Tata Main Hospital

**Information provided by (Responsible Party):**
Dr.Deb Sanjay Nag, Tata Main Hospital



| | |
|---|---|
| **Study Type** | Observational |
| **Study Design** | Observational Model: Cohort; Time Perspective: Retrospective |
| **Condition** | External Causes of Morbidity and Mortality |
| **Enrollment** | 159 |

## Participant Flow

Go to

| | |
|---|---|
| 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 |
| Pre-assignment Details | |

| | |
|---|---|
| Arm/Group Title | All Patients Who Underwent Emergency Exploratory Laparotomy |
| Arm/Group Description | 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 |
| Period Title: **Overall Study** | |
| Started | 159 |
| Completed | 157 |
| Not Completed | 2 |
| Reason Not Completed | |
| Lost to Follow-up | 2 |

## Baseline Characteristics

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|---|---|---|---|
| Arm/Group Title | | Emergency Laparotomy | |
| Arm/Group Description | | 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 | |
| Overall Number of Baseline Participants | | 157 | |
| Baseline Analysis Population Description | | [Not Specified] | |
| Age, Customized [1]<br>Measure Type: Number<br>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<br>Measure Type: Count of Participants<br>Unit of measure: Participants | | | |
| | Number Analyzed | 157 participants | |
| | Female | 58 | 36.9% |
| | Male | 99 | 63.1% |
| Region of Enrollment<br>Measure Type: Number<br>Unit of measure: Participants | | | |
| India | Number Analyzed | 157 participants | |
| | | 157 | |

## Outcome Measures

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1. Primary Outcome

| | |
|---|---|
| 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 |
| 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 |

Outcome Measure Data

| 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). |

| Arm/Group Title | AUC Using APACHE II | AUC Using P-POSSUM |
|---|---|---|
| Arm/Group Description: | 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. | 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. |
| Overall Number of Participants Analyzed | 157 | 157 |
| Measure Type: Number 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

| | | |
|---|---|---|
| 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 |
| | 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

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

Outcome Measure Data

| Analysis Population Description |
|---|
| [Not Specified] |

| Arm/Group Title | Length of Stay |
|---|---|
| ▼ Arm/Group Description: | 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) |
| Overall Number of Participants Analyzed | 157 |
| Mean (Standard Deviation) Unit of Measure: Days | |
| Surviving Patients | 9.36 (8.04) |
| Patients who Died | 14.91 (15.43) |

3. Secondary Outcome

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

▼ Outcome Measure Data

| ▼ Analysis Population Description |
|---|
| [Not Specified] |

| Arm/Group Title | Surviving Patients | Patients Who Died |
|---|---|---|
| ▼ Arm/Group Description: | 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 | 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 |
| Overall Number of Participants Analyzed | 134 | 23 |
| Measure Type: Number Unit of Measure: participants | | |
| | 40 | 23 |

4. Secondary Outcome

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

▼ Outcome Measure Data

| ▼ Analysis Population Description |
|---|
| [Not Specified] |

| Arm/Group Title | Surviving Patients | Patients Who Died |
|---|---|---|
| ▼ Arm/Group Description: | 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.. | 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.. |
| Overall Number of Participants Analyzed | 134 | 23 |
| Measure Type: Number Unit of Measure: participants | | |
| | 25 | 23 |

5. Secondary Outcome

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

▼ Outcome Measure Data

| ▼ Analysis Population Description |
|---|
| [Not Specified] |

| Arm/Group Title | Patients Who Survived | Patients Who Died |
|---|---|---|
| ▼ Arm/Group Description: | 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) | 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) |
| Overall Number of Participants Analyzed | 134 | 23 |
| Measure Type: Number Unit of Measure: participants | | |
| | 1 | 7 |

6. Secondary Outcome

| | |
|---|---|
| Title | Number of Participants With Acute Kidney Injury (AKI) |
| ▼ Description | Acute Kidney Injury (AKI) was diagnosed based on the Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group (2012) guidelines<br>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<br>3. Urine volume <0.5 ml/kg/h for 6 hours |
| Time Frame | 30 days |

▼ Outcome Measure Data

| ▼ Analysis Population Description |
|---|
| [Not Specified] |

| Arm/Group Title | Patients Who Survived | Patients Who Died |
|---|---|---|
| ▼ Arm/Group Description: | 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 | 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 |
| Overall Number of Participants Analyzed | 134 | 23 |
| Measure Type: Number Unit of Measure: participants | | |
| | 14 | 18 |

7. Secondary Outcome

| | |
|---|---|
| Title | Patients Needing Re-exploration |
| ▼ 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 |

▼ Outcome Measure Data

| ▼ Analysis Population Description |
|---|
| [Not Specified] |

| Arm/Group Title | Patients Who Survived | Patients Who Died |
|---|---|---|
| ▼ Arm/Group Description: | 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. | 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. |
| Overall Number of Participants Analyzed | 134 | 23 |
| Measure Type: Number Unit of Measure: participants | | |

| | | |
|---|---|---|
| | 2 | 2 |

## Adverse Events

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|---|---|
| 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] |

| Arm/Group Title | APACHE-2 Scoring | P-POSSUM |
|---|---|---|
| Arm/Group Description | 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. | 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 | --/-- | --/-- |

### Serious Adverse Events

| | APACHE-2 Scoring | P-POSSUM |
|---|---|---|
| | Affected / at Risk (%) | Affected / at Risk (%) |
| Total | 0/157 (0.00%) | 0/157 (0.00%) |

### Other (Not Including Serious) Adverse Events

| | |
|---|---|
| Frequency Threshold for Reporting Other Adverse Events | 0% |

| | APACHE-2 Scoring | P-POSSUM |
|---|---|---|
| | Affected / at Risk (%) | Affected / at Risk (%) |
| Total | 0/157 (0.00%) | 0/157 (0.00%) |

## Limitations and Caveats

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

## More Information

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### Certain Agreements

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

### Results Point of Contact

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Responsible Party: Dr.Deb Sanjay Nag, Tata Main Hospital
ClinicalTrials.gov Identifier: NCT02471612 History of Changes

| | |
|---|---|
| Other Study ID Numbers: | 201-26104-132-108296 |
| First Submitted: | June 9, 2015 |
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