Assessment of Acute Stress and Main Sources of Concern among Trauma Patients in Triage Categories 3-5 in the Emergency Department: A Prospective Observational Study

Short title:

Stress in Trauma Patients in Triage Categories 3-5

Document version: 1.0
Date: 03 / 07 / 2026
Institution: General County Hospital Požega
Principal Investigator: Assistant Professor Gabriela Katharina Pomper, MD, PhD
Department / Clinic: Department of Surgery

1. Study title

STUDY PROTOCOL

Assessment of Acute Stress and Main Sources of Concern among Trauma Patients in Triage Categories 3-5 in the Emergency Department: A Prospective Observational Study

2. Short title

Stress in Trauma Patients in Triage Categories 3-5

3. Study type

Prospective, observational, non-interventional study.

4. Study setting

The study will be conducted in the Emergency Department / emergency surgical admission unit / trauma outpatient clinic and on the surgical wards of the hospital.

5. Participants

The study will include adult trauma patients presenting to the Emergency Department because of an acute traumatic injury and classified as triage category 3, 4, or 5 according to the current triage system.

6. Introduction and scientific background

Traumatic injuries are among the common reasons for presentation to the Emergency Department. In addition to the physical injury, patients often experience substantial psychological burden. Sources of stress may include pain, fear regarding the severity of the injury, the possibility of surgery, uncertainty about further treatment, fear of permanent consequences, and concerns about family, children, work, and the financial situation.

In clinically stable trauma patients, particularly those in triage categories 3-5, psychological stress is often not assessed systematically. However, this group of patients often has sufficient time and capacity to complete a brief questionnaire, and their experiences may provide important information for improving communication, information provision, and support in the Emergency Department.

This study aims to assess the level of acute stress in trauma patients in triage categories 3-5 and to identify the most important sources of concern immediately after injury. In hospitalized patients, changes in stress level and dominant stressors will additionally be assessed 24 hours after hospital admission.

7. Study objectives

7.1. Primary objective

To assess the overall level of acute stress in trauma patients in triage categories 3-5 in the Emergency Department.

7.2. Secondary objectives

1. To identify the most common sources of stress in trauma patients immediately after injury.
2. To compare stress levels among triage categories 3, 4, and 5.
3. To examine the association between pain intensity and overall stress level.
4. To examine the association between the type of injury and the dominant sources of stress.

5. In hospitalized patients, to assess the change in stress level 24 hours after admission.

8. Hypotheses

1. Patients in triage category 3 will have higher stress levels than patients in triage categories 4 and 5.

2. Greater pain intensity will be associated with a higher overall stress level.

3. The most common sources of stress will be pain, uncertainty about treatment, fear of permanent consequences, and concerns about family or work.

4. In hospitalized patients, the dominant stressors 24 hours after admission will shift from the acute injury toward hospitalization, surgery, recovery, family, and work.

9. Study design

The study is prospective, observational, and non-interventional. Patients will be assessed at one or two time points:

T0 - Emergency Department

The questionnaire is completed after the initial medical assessment, when the patient is clinically stable and able to provide informed consent.

T1 - 24 hours after admission

The T1 questionnaire is completed only by patients who are hospitalized. The questionnaire is completed approximately 24 hours after the injury or hospital admission.

10. Inclusion criteria

Patients may be included in the study if they meet all of the following criteria:
1. Age 18 years or older.
2. Presentation to the Emergency Department because of an acute traumatic injury.
3. Triage category 3, 4, or 5.

4. Clinical stability after the initial assessment.

5. Ability to understand the study information and the questionnaire.

6. Ability to provide written informed consent.

11. Exclusion criteria

Patients will be excluded from participation if one or more of the following criteria are present:

1. 1. Triage category 1 or 2 (an acutely life-threatening condition or an immediate need for emergency medical or surgical intervention; hemodynamic or respiratory instability).
2. 2. Severe impairment of consciousness, disorientation, or inability to cooperate.
3. 3. Inability to provide informed consent; cognitive impairment or a language barrier preventing comprehension of the questions.
4. 4. Severe alcohol or drug intoxication preventing valid completion of the questionnaire.
5. 5. A situation in which completion of the questionnaire is inappropriate for medical, ethical, or organizational reasons.

12. Study procedures

1. The patient presents to the Emergency Department because of a traumatic injury.
2. Standard triage and initial medical assessment are performed.
3. The investigator checks the inclusion and exclusion criteria.
4. If the patient is eligible to participate, written and/or verbal information about the study is provided.
5. After informed consent is obtained, the patient completes the T0 questionnaire.
6. The investigator completes the clinical section of the CRF.
7. If the patient is hospitalized, the T1 questionnaire is completed approximately 24 hours later.
8. Data are entered into a pseudonymized database.

13. Variables
The following data will be collected:
- **age**
- **sex**
- **employment status**
- **whether the patient has children or persons for whom they provide care**
- **time of injury**
- **time of arrival at the Emergency Department**
- **triage category**
- **mechanism of injury**
- **injury location**
- **type of injury**
- **pain intensity**
- **treatment plan**
- **need for surgery**
- **need for hospitalization**
- **overall stress level at T0**
- **individual stressors at T0**

- overall stress level at T1 in hospitalized patients
- individual stressors at T1
- level of information received and understanding of the treatment plan

14. Measurement instruments

The study uses a hybrid questionnaire that includes:
1. Global assessment of stress on a numerical scale from 0 to 10.
2. Specific trauma-related stressors rated on a numerical scale from 0 to 10.
3. Selection of the main sources of stress.
4. Open-ended questions regarding the patient's greatest concern.

15. Risks to participants

The study is non-interventional and does not affect the patient's medical treatment.

A possible minimal risk is emotional discomfort when answering questions about stress, fear, or concerns. The patient may skip any individual question or withdraw from participation at any time without any consequences for their treatment.

16. Benefits to participants

Participation does not provide a direct medical benefit to the individual patient. The study results may contribute to a better understanding of the psychological needs of trauma patients and improve communication, information provision, and support in the Emergency Department.

17. Data protection

Data will be collected in pseudonymized form. Each participant will be assigned a study code. Identifying information will not be entered into the analytical database.

Only members of the research team will have access to the data. Data will be stored in accordance with applicable personal data protection regulations.

18. Planned sample size

The planned sample size is approximately 150 participants. As this is a prospective observational pilot study, the sample size is based on the expected number of trauma patients in triage categories 3-5 during the recruitment period and on the feasibility of conducting the study.

19. Statistical analysis

Descriptive statistics will be used to summarize the baseline characteristics of the participants.

Continuous variables will be presented as mean and standard deviation or as median and interquartile range, depending on the data distribution.

Categorical variables will be presented as number and percentage.

Stress levels will be compared among triage categories 3, 4, and 5 using appropriate statistical tests. The association between pain intensity and stress level will be analyzed using correlation analysis. In hospitalized patients, T0 and T1 values will be compared using paired statistical tests.

The level of statistical significance will be set at $p < 0.05$.

STATISTICAL ANALYSIS PLAN

1. Primary outcome

The primary outcome is the overall stress level in trauma patients in triage categories 3-5 in the Emergency Department, measured on a numerical scale from 0 to 10 at time point T0.

2. Secondary outcomes

Secondary outcomes include:
1. Level of individual stressors at T0.
2. Difference in overall stress among triage categories 3, 4, and 5.
3. Association between pain intensity and overall stress.
4. Difference in stress according to type and location of injury.
5. Change in overall stress between T0 and T1 in hospitalized patients.
6. Change in dominant sources of stress between T0 and T1.
7. Association between the level of information received by the patient and overall stress.
3. Descriptive statistics

Continuous variables will be presented as mean and standard deviation if normally distributed, or as median and interquartile range if not normally distributed.

Categorical variables will be presented as number and percentage.

4. Comparison of triage categories

Overall stress level will be compared among patients in triage categories 3, 4, and 5. If the data are normally distributed, ANOVA will be used.
If the data are not normally distributed, the Kruskal-Wallis test will be used.
If a statistically significant difference is identified, an appropriate post-hoc analysis will be performed.
5. Analysis of the association between pain and stress

The association between pain intensity and overall stress will be analyzed using Pearson or Spearman correlation, depending on the data distribution.

6. T0-T1 analysis

In hospitalized patients, the following values will be compared between T0 and T1:
• overall stress
• pain
• stress related to surgery
• stress related to hospitalization
• family-related stress
• work-related and financial stress

• information received and understanding of the treatment plan
For paired continuous data, a paired t-test or Wilcoxon signed-rank test will be used. For categorical changes, McNemar's test or an appropriate frequency analysis will be used.

7. Analysis of main stressors

The main stressors will be presented as frequencies and percentages. The frequency of individual stressors will be compared among triage categories and between T0 and T1.

8. Multivariable analysis

If the sample size is sufficient, linear regression analysis will be performed with overall stress as the dependent variable.

Potential predictors include age, sex, triage category, pain intensity, type of injury, hospitalization, need for surgery, level of information received, family-related concern, and work-related or financial concern.

9. Missing data

Missing data will be described descriptively. Participants with missing values for individual variables will be excluded only from analyses requiring those variables.

10. Statistical significance

The level of statistical significance will be set at $p < 0.05$.