Study Protocol

Project title:

Physicians' Understanding of the Glasgow Coma Score and Effects of a Scoring Aid - A Simulator-based Randomized Clinical Trial

Background:

Since its introduction in 1974(1), the Glasgow Coma Scale (GCS) is commonly used worldwide to describe the level of consciousness(2) and to predict outcomes(3,4,5,6,7) of a wide variety of critically ill patients. Despite its frequent and worldwide use, only few attempts have been made to explore interventions aimed at enhancing scoring reliability. Yet, investigations used specific clinical scenarios presented only in written form, encompassing different GCS ranges(8) instead of centering on a specific GCS with clinical implications. A GCS of 8 or less in trauma patients defines severe traumatic brain injury requiring specific treatment algorithms including advanced airway management(9).

Aims:

The aim of this study was to examine the effect of utilizing a scoring aid on the accuracy and duration of the GCS assessment within a highly standardized clinical scenario, and to evaluate the physicians' knowledge of the GCS regarding its assessment, interpretation, and clinical application.

Design:

Investigator-initiated randomized trial performed at the simulator center at the University Hospital of Basel, a Swiss academic medical center.

Methods:

Physicians will be confronted with an adult trauma case presenting with a GCS of 8 (comprising best eye response of 1, best verbal response of 2, and best motor response of 5) and will be randomized to receiving or not receiving a scoring aid. Video/audio recordings of the assessments and questionnaires completed by the participants will be analyzed by two investigators.
Participants will include intensivists, emergency physicians, internists, and neurologists.

Intervention: GCS assessment with and without a scoring aid outlining all integral components for best eye, verbal and motor response and their scoring based on the patient's clinical presentation.

Main Outcomes: The primary outcome will be the accuracy of GCS assessments with or without scoring aid. Two operational definitions will be employed to determine accurate GCS assessments as the primary outcome. The correct assessment of the GCS as 8, and allowing for a deviation of +-1 as a common occurrence as described by literature(10). The key secondary outcome will be the duration of assessment with and without the scoring aid, and physicians' knowledge regarding assessment, interpretation, and clinical applications of the GCS.

Relevance: First, the study will investigate the quality and reliability of the GCS assessment of physicians in a clinical scenario with the focus on a specific GCS holding significant clinical implications for trauma management, such as a GCS of

8(9). Second, the randomized trial will elucidate whether using a scoring aid will increase the quality and reliability of the GCS assessment in clinical practice.
By using a high-fidelity simulation generated by a proficiently trained nurse a highly standardized setting will be assured.

Role of the applicant in the project: Prof. Raoul Sutter is the principal investigator of this study.

Detailed methodology

Consent

A consent will be received from the volunteering physicians for the anonymized analyses of the video- and audio recordings of their performances.

Setting and study design

This investigator-initiated randomized clinical simulator-based trial will be performed at the simulation center of the ICUs at the University Hospital Basel, a Swiss academic tertiary care center and will be started in 2019.
The participants will be assigned by random numbering by the principal investigator (Raoul Sutter) to either the intervention group receiving a scoring aid (i.e., GCS scoring card) or the control group.
Training will be provided to resident physicians specializing in intensive care medicine, emergency medicine, internal medicine, and neurology, with the aim of enhancing their clinical management skills in simulated emergency scenarios. Prior to attending, none of the physicians will received any prior training of GCS assessment. To minimize knowledge transfer among participants, a strict prohibition

on sharing information will have to be agreed upon by all physicians. Debriefing sessions will conducted individually after each scenario/training. The participants will be aware of the concurrent participation of others but will not be informed about any details about the identities of their peers.

All participants will be asked to complete questionnaires prior and after the simulation. The first questionnaire will include questions about age, medical knowledge, medical specialization, prior experience with simulator-based training, clinical experience, hours worked prior to simulation and their stress level (quantified as 0 for not stressed and 10 for experiencing maximal stress). The second questionnaire will include questions about their stress level during the simulation, the GCS assessed during simulation, confidence of accurate assessment (rated from 0 [not confident at all] to 10 [very confident]), if they use the GCS in daily clinical practice, if a GCS scoring card was felt to be missing, which of the GCS from 3 to 15 (multiple answers) would be difficult to assess without a scoring aid, which of the three GCS components (i.e., eye, verbal, motor response) is the most difficult to assess, which is the highest GCS an intubated patient can present, and if a patients with a GCS <9 must be intubated. Finally, the participants will be asked to rate expected probability of a discordant GCS assessment by other physicians for the identical simulated scenarios using a probability score ranging from 0% denoting [not existing] to 100% indicating the [highest probability].

The participants will be assigned randomly to either the experimental group receiving a scoring aid (i.e., GCS scoring card) or the control group.

Simulator setup and simulated scenario

Detailed information regarding the equipment of the high-fidelity simulator center was described in our prior studies(11,12). In contrast to our prior studies, the clinical

scenario was not simulated by a programmable high-fidelity mannequin but by a pre-trained ICU nurse with profound knowledge of both clinical ICU management and simulator-based studies. Prior to the study initiation, the nurse was instructed and rigorously trained to consistently present a GCS of 8. The training will be led by two senior physicians (Kai Tisljar & Raoul Sutter) being board certified in intensive care medicine and internal medicine (K.T.), and in intensive care medicine and neurology (R.S.), respectively.

The participants will be informed by either K.T. or R.S. that an adult "patient" (referring to the trained nurse) was involved in a car accident, and they will be asked to assess the GCS. Subsequently, the participants will be provided with the GCS scoring card if assigned to the intervention group.

Data assessment

The participants' performances will be video and audio recorded using frame-in-frame technology. Data to assess the primary and secondary end points will be coded by two independent observers based on the audio- and video-recordings assessed during the simulator training sessions. All actions and utterances will be coded second-by-second and interpreted by two experts (Paulina Kliem & R.S). Duration of GCS assessment will be defined as the time from first contact with the “patient” to stating a score for the first time.

Interrater variability regarding video/audio analyses

Cohen kappa (**κ**) will be used to estimate interrater agreement/disagreement regarding categorical variables for the first analyses. In cases with an interrater disagreement, the video recordings will be jointly reviewed and discussed until 100% consensus will be reached.

Outcomes

The primary outcome will be the accuracy of GCS assessments with or without scoring aid. Two operational definitions will be employed to determine accurate GCS assessments as the primary outcome. The correct assessment of the GCS as 8, and allowing for a deviation of +-1 as a common occurrence as described by literature(10). The key secondary outcome will be the duration of assessment with and without the scoring aid, and physicians' knowledge regarding assessment, interpretation, and clinical applications of the GCS.

Sample size calculation

Based on a prior study assessing the GCS evaluation with and without a scoring aid of a variety of written scenarios presenting a variety of different levels of consciousness(8) we estimate the sample size required for our study at 90 participants (significance level of 5% with a power of 90%).

Statistics

Participants will be categorized as receiving a scoring aid or not. Discrete variables will be presented as counts with corresponding percentages, continuous variables will be reported as medians with interquartile ranges (IQR). For all univariable comparisons and analyses regarding primary and secondary outcomes the Chi-square test will be applied for categorical data, the Mann-Whitney test for continuous variables.

Statistical significance will be determined with a threshold of ≤0.05. The statistical analysis will be conducted using STATA®16.1 software (Stata Corp., College Station, TX, USA).

References

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