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# Sample entropy predicts lifesaving interventions in trauma patients with normal vital signs☆

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A B S T R A C T

*Introduction:* Heart rate complexity, commonly described as a "new vital sign," has shown promise in predicting injury severity, but its use in clinical practice is not yet widely adopted. We previously demonstrated the ability of this noninvasive technology to predict lifesaving interventions (LSIs) in trauma patients. This study was conducted to prospectively evaluate the utility of real-time, automated, noninvasive, instantaneous sample entropy (SampEn) analysis to predict the need for an LSI in a trauma alert population presenting with normal vital signs.
*Methods:* Prospective enrollment of patients who met criteria for trauma team activation and presented with normal vital signs was conducted at a level I trauma center. High-fidelity electrocardiogram recording was used to calculate SampEn and SD of the normal-to-normal R-R interval (SDNN) continuously in real time for 2 hours with a portable, handheld device. Patients who received an LSI were compared to patients without any intervention (non-LSI). Multivariable analysis was performed to control for differences between the groups. Treating clinicians were blinded to results.
*Results:* Of 129 patients enrolled, 38 (29%) received 136 LSIs within 24 hours of hospital arrival. Initial systolic blood pressure was similar in both groups. Lifesaving intervention patients had a lower Glasgow Coma Scale. The mean SampEn on presentation was 0.7 (0.4-1.2) in the LSI group compared to 1.5 (1.1-2.0) in the non-LSI group ($P < .0001$). The area under the curve with initial SampEn alone was 0.73 (95% confidence interval [CI], 0.64-0.81) and increased to 0.93 (95% CI, 0.89-0.98) after adding sedation to the model. Sample entropy of less than 0.8 yields sensitivity, specificity, negative predictive value, and positive predictive value of 58%, 86%, 82%, and 65%, respectively, with an overall accuracy of 76% for predicting an LSI. SD of the normal-to-normal R-R interval had no predictive value.
*Conclusions:* In trauma patients with normal presenting vital signs, decreased SampEn is an independent predictor of the need for LSI. Real-time SampEn analysis may be a useful adjunct to standard vital signs monitoring. Adoption of real-time, instantaneous SampEn monitoring for trauma patients, especially in resource-constrained environments, should be considered.

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## 1. Introduction

Traditional vital sings often fail to reflect the true severity of injury in trauma patients until compensatory mechanisms have been exhausted [1-5]. In fact, heart rate (HR) may even decrease in response to severe trauma, which carries a risk of undertriage and, consequently, increased mortality [4]. Heart rate variability (HRV) analysis, commonly described as a "new vital sign," has shown promise in predicting injury severity, but its use in clinical practice, despite availability of real-time data [4,6-8], has not been widely adopted.

The primary goal of trauma triage is to identify high-risk patients who would benefit from aggressive, resource-unlimited medical care (appropriate triage) while limiting exclusion of those who could benefit from such care (undertriage) [8]. Specificity of screening criteria for trauma team activation is often sacrificed for an increased sensitivity. Furthermore, current triage systems are supported by little evidence and commonly reflect expert opinion [9,10]. These triage limitations are particularly apparent in combat casualty care, in which an additional need to minimize the operational risk for responding medics has led to the concept of "remote triage" [3,11]. The application of remote triage may also play a role in civilian prehospital trauma triage during mass casualty and tactical interactions. For remote triage to be useful, data need

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to be automated and provide valuable information for rapid clinical decision making. Heart rate variability analysis could possibly serve that purpose, as it has shown promise in the reported literature as a potential objective triage tool [2-4,6-8,11-14]. Some studies, using an alternative approach for quantifying cardiac variability based on the amount of irregularity or fractal dimension by curve length, have indicated a superior diagnostic performance to predict poor outcome [3-5]. As biologic systems are inherently complex, a decreased irregularity or loss of complexity measured by sample entropy (SampEn) has been suggested to reflect early changes to occult and nonoccult physiologic stress [3,4,15], perhaps making SampEn a more powerful predictor of impending physiologic compromise.

In a previous investigation, we examined the diagnostic utility of real-time SampEn analysis for predicting the need of lifesaving interventions (LSIs) in trauma patients upon hospital arrival [16], many of whom had grossly abnormal vital signs. In the present prospective study, we restricted the study population to only patients with normal vital signs upon presentation as well as narrowed the definition of LSI to avoid risking overfitting the diagnostic usefulness of SampEn. We hypothesized that SampEn is decreased in trauma patients with normal presenting vital signs who undergo LSIs.

## 2. Methods

Patients who met criteria for trauma team activation (6 AM-9 PM, convenience sample) were prospectively enrolled in our study between April 2012 and January 2014. Research staff responded to trauma activations to determine if a new patient was eligible for enrollment. Trauma team activation at our institution is a 2-tiered system based upon mechanism of injury and physiology. Tier 1 activation mobilizes the most resources and includes patients with Glasgow Coma Scale (GCS) less than 8, hypotension of any cause, any penetrating torso injuries, and traumatic arrest, among other criteria. Tier 2 activation includes patients with GCS 9 to 13, any airway support, any patient with a tourniquet applied, suspected pelvic fracture, multiple long bone fractures, and multisystem trauma (eg, chest and long bone injuries), among other criteria. In addition, trauma team activation can be called at the discretion of the prehospital providers if specific criteria are not met. Patients were enrolled who met either tier 1 or tier 2 activation criteria. Patients with a presenting HR greater than 110 beats per minute or systolic blood pressure (SBP) less than 110 mm Hg were excluded. Additional exclusion criteria included age younger than 18 years and transfer from an outside institution. This study was approved by the Massachusetts General Hospital Institutional Review Board with waiver of informed consent.

Upon arrival to the resuscitation bay, research staff monitored the patient with an ICON Noninvasive Cardiac Monitor (Osypka Medical, La Jolla, CA) that has been modified and programmed to calculate and display SampEn and SD of the normal-to-normal R-R interval (SDNN) in real time. Apart from instantaneous SampEn and SDNN that were recorded on a minute-by-minute basis, the monitor also provided continuous measurements of HR, stroke volume, and cardiac output. Sample entropy was calculated through electrocardiographic recordings of 200 consecutive beats in a continuous sliding-window fashion, as previously described [7,16]. Sample entropy is a measure of the likelihood of finding similar patterns in the signal. A lower value implies increased regularity and, likewise, decreased complexity of the signal, thereby limiting the effects of stationarity. For SampEn calculations, the dimension parameter $m$ was 2, and the filter parameter $r$ was 20% of the SD [17,18]. Traditional HRV was determined using standard time-domain analysis, specifically SDNN [14,16,19,20]. Clinical management of the patient occurred at the discretion of the treating physician who was blinded to the ongoing study results.

A standardized data collection sheet was used for all patients. In addition to demographics, other collected data included initial vital signs, injury burden, and laboratory parameters. Comorbidities on admission were noted, such as diabetes mellitus, coronary artery disease, atrial fibrillation, cerebrovascular disease, and use of antiarrythmic medications and sedative medications (benzodiazepines, propofol, fentanyl, morphine, and hydromorphone). The primary outcome was a LSI within 24 hours of arrival to the emergency department (ED). Lifesaving interventions were defined as the following: blood transfusion, cardioversion, tube thoracostomy, cardiopulmonary resuscitation, intubation, cricothyrotomy, thoracotomy, angiography with or without embolization, needle decompression, laparotomy, use of vasoactive medications, hyperosmolar fluid therapy, and other emergent surgical intervention [21]. With respect to blood transfusion, each case was reviewed and excluded if the indication for the transfusion could not be clearly defined and directly attributable to an anatomical injury. In this way, delayed blood transfusions for management of a pelvic fracture after angioembolization would be included, while excluding blood transfusions given empirically in the setting of a nonoperatively managed liver laceration with normal vital signs and stable hemoglobin. Other exceptions that would not constitute an LSI were defined a priori as orthopedic surgery for fractures without apparent or potential for hemodynamic instability (eg, radius fracture) and the use of vasoactive medications for indications other than hemodynamic instability (eg, to augment perfusion of suspected spinal cord injury without hemodynamic instability). *Hospital admission* was defined as a secondary outcome. The occurrence and analysis of an LSI were binary (present or not present, regardless of whether the patient received >1 LSI). A patient was considered to have received sedation if an anxiolytic, sedative/hypnotic, opioid agonist, or dopaminergic antagonist was administered before beginning of the electrocardiographic recording. This was also analyzed in a binary fashion, regardless of dosing.

Continuous data were described using mean with SD or median with interquartiles, whichever more appropriate, and compared using the Student $t$ tests or Wilcoxon rank sum tests, whereas categorical data were summarized using proportions and compared using $\chi^2$ tests. Sample entropy, HR, and SDNN were compared between outcome groups at 1, 5, 10, 60, and 120 minutes. Multiple logistic regression models were constructed to identify independent predictors of LSIs and hospital admission. Two diagnostic approaches were used for the purposes of analysis. First, only the first-minute data that were derived from the monitor were considered, to resemble its use for remote telemetry and triage. Second, additional data that would be available during a primary survey (eg, GCS) were also considered in a separate model. To assess diagnostic performance of the models, receiver operating characteristic (ROC) curves were constructed, and area under curve (AUC) was used to summarize model performance. Cutoff points of SampEn at the first minute were selected to allow determination of sensitivity, specificity, negative predictive value, and positive predictive value. All statistical analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC).

## 3. Results

One hundred twenty-nine patients were enrolled during the study period; the mean age was 44 ± 17 years and 78% were male. Injury was caused by a blunt mechanism in 112 patients (87%), commonly after a fall (n = 46, 36%), motor vehicle accident (n = 42, 33%), and/or pedestrian struck (n = 12, 9%). Of approximately 3600 trauma activations during the study period, 1722 patients were screened (based upon daily manpower availability of this convenience sample) for enrollment. Upon presentation, the mean HR was 89 ± 20 beats per minute; respiratory rate, 19 ± 4 breaths/min; SBP, 143 ± 25; and initial GCS score, 15 [15-29]; the motor component of GCS was 6 [6-29]. Initial laboratory values indicated mean hemoglobin level of 13.8 ± 1.7 g/dL and a lactate level of 2.9 ± 1.9 mmol/L. Blood gas analysis was performed in 64 patients (50%), which demonstrated a mean pH of 7.35 ± 0.13 units, $pO_2$ of 120 (80-174) mm Hg, $pCO_2$ of 45 ± 14 mm Hg, and base deficit of 2 ± 4.0 mEq/L. There were no difference in blood gas or lactate values between groups. Forty-four patients (34%) were discharged home

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