American Journal of Emergency Medicine xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

American Journal of Emergency Medicine

journal homepage: www.elsevier.com/locate/ajem

A brief assessment of capacity to consent instrument in acutely intoxicated emergency department patients

Marc L. Martel, MD [a,*], Lauren R. Klein, MD [a], James R. Miner, MD [a], Jon B. Cole, MD [a], Paul C. Nystrom, MD [a], Kayla M. Holm, BS [a], Michelle H. Biros, MS, MD [a,b]

[a] Department of Emergency Medicine, Hennepin County Medical Center, 701 Park Avenue, Minneapolis, MN 55415, United States
[b] Department of Emergency Medicine, University of Minnesota, 717 Delaware Street SE, Suite 508, Minneapolis, MN, 55414, United States

ARTICLE INFO

Article history:
Received 22 April 2017
Received in revised form 19 June 2017
Accepted 21 June 2017
Available online xxxx

Keywords:
Mental competency
Alcoholic intoxication
Research
Emergency service
Hospital
Informed consent

ABSTRACT

Objective: The aim of this study was to determine to what extent acute alcohol intoxication effects capacity to assent, consent, or refuse research participation.
Methods: This was a prospective, observation study performed at our inner city, county hospital with >100,000 annual emergency department visits. Non-pregnant, English speaking patients older than 18 with evidence of acute alcohol intoxication were considered eligible. After medical screening, a trained research associate presented the study version of the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) tool. The primary outcome was the number of patients able to correctly respond to all 10 questions.
Results: Of 642 screened patients, 415 patients were enrolled and completed the tool. The mean alcohol concentration was 227 mg/dL (range 25–500 mg/dL). Sixteen patients (3.9%) answered all 10 questions correctly; by definition of the UBACC, these patients were deemed to possess capacity to consent. Mean alcohol concentrations in the capacity group were lower than in those lacking capacity; 182 mg/dL (SD 6.7) versus 229 mg/dL, (SD 7.9). Of the 287 patients who were interviewed upon sobriety at discharge, 182 patients (63.4%) did not recall completing the questionnaire.
Conclusions: While intoxicated emergency department patients are able to complete the questionnaire, the majority do not possess capacity to provide informed consent to research. A minority of participants remember involvement once they have achieved sobriety, exception from informed consent protocols are needed to perform emergency research in this population.

1. Introduction

When individuals provide informed consent to participate in research, the presumption is that they possess the capacity to consent. In order to determine capacity, a patient must first exhibit the ability to 1) understand the details necessary to make a decision, 2) appreciate the meaning of the decision they are being asked to make, 3) comprehend the risks, benefits and alternatives, and finally 4) make and express their decision [1]. It is important for patients to possess capacity, not only to consent to medical treatment, but more so to consent to inclusion in research where there are inherent risks above and beyond accepted treatment modalities.

Many objective tools have been proposed to access capacity and have been validated in various patient populations. Among these are the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) tool. Originally developed as a practical method to screen and document decisional capacity, it has been used in potentially vulnerable patients with schizophrenia, schizoaffective disorder, traumatic brain injury, dementia and cognitively impaired individuals to determine the capacity to provide informed consent for clinical care and research [2-7]. There are 10 questions in the UBACC that are comprised of four items assessing understanding, five items for appreciation, and one assessing reasoning. Capacity, as defined by UBACC, is the ability to answer all 10 screening questions correctly.

Recently, an intriguing pilot study using the UBACC found that acutely intoxicated Emergency Department (ED) patients, irrespective of serum alcohol concentrations, may possess the capacity to provide consent for research study participation [8]. In this study, participants were frequent ED users with alcohol use disorders. This finding is counterintuitive; in clinical practice, we usually assume acutely intoxicated patients do not have the capacity to make informed decisions about their health care. If the assumption that intoxicated patients lack

* Corresponding author at: Hennepin County Medical Center, Department of Emergency Medicine, EMS-825, 701 Park Avenue, Minneapolis, MN 55415, United States.
E-mail address: marc.martel@hcmed.org (M.L. Martel).

http://dx.doi.org/10.1016/j.ajem.2017.06.043
0735-6757/

capacity is in fact incorrect as suggested by the pilot study, current practice may be denying these patients autonomy in clinical and research decision making.

The objective of this trial was to assess the feasibility of using the UBACC in any alcohol intoxicated patient presenting to our ED, in order to determine their capacity for decision making. We sought to determine the generalizability and external validity of the pilot study results in a larger sample size, in a less narrowly defined cohort, and with consecutive patient enrollment.

2. Methods

2.1. Study setting and design

This was a prospective, observational study to assess the feasibility of the UBACC to determine capacity in clinically intoxicated ED patients, and their ability to provide meaningful consent for potential research participation. Specifically trained, undergraduate research associates were utilized for patient interviews and data collection.

The study was conducted at an urban, level one trauma center with approximately 110,000 ED patient visits per year. Enrollment was limited to patients presenting to a single unit in our ED specifically designed and staffed to manage patients acutely under the influence of alcohol or illicit substances. Patients are typically brought to the ED by police and paramedics, having been "found down" and presumed intoxicated. Rapid, focused evaluation is performed in this area of the ED to confirm acute intoxication, and to assess for concomitant medical or traumatic issues. Clinicians caring for the patients were not blinded to the research protocol, but were unaware of the study question, details of the assessment tool, or outcome measures.

2.2. Human subject compliance

The study was approved by the Human Subjects Research Committee and the protocol met criteria and was performed with a waiver of consent in accordance of 45 CFR 46.116. Although formally approved with this waiver, our Human Subjects Research Committee requested that the research associate interviewer read a brief statement explaining the special consent process (Fig. 1) to each participant prior to administration of the UBACC questionnaire (Table 1). Copies of these documents were provided to each subject upon their discharge from the ED.

2.3. Participants and data collection

Patients were prospectively screened and enrolled immediately upon arrival to the ED. Non-pregnant, English speaking patients aged 18 years or older with clinical evidence of acute alcohol intoxication as the predominant etiology of altered mental status were eligible. Patients were excluded if intoxication was due to a substance other than ethanol (negative breath alcohol concentration), if they had extreme agitation, if they overtly refused to answer any questions, or if the treating physician deemed the patient medically unstable. Patients were also excluded if they were known to have been previously enrolled in the study. Trained research associates screened all consecutive patients during 12-hour randomized blocks (7 am to 7 pm, or 7 pm to 7 am) between July 22, 2015 and September 29, 2015.

The study was not initiated until the patient had been deemed medically stable, typically by a nurse and resident physician or physician assistant. A trained research associate then verbally presented the UBACC questionnaire to the patient. Research associates were individually trained on the protocol by study coordinators. Specific instruction on interviewing intoxicated patients and administering the questionnaire was performed by one of two emergency physicians (authors MM, LK).

The 10 questions that constitute the UBACC include a mixture of short answers and yes/no responses. An uncomplicated, theoretical scenario about alcohol and drug use was developed and used as the basis for the UBACC screening questions. Per UBACC standards, predefined closed–ended prompts were used when patients were unsuccessful or unable to answer a question on the first attempt. If patients were unable to answer a UBACC question, the appropriate scripted follow up question was presented to assist the patient in generating the correct response. Whether the patient answered correctly on the first attempt, or after a prompt, they were given credit for correctly answering the question. A maximum of one prompt per question was allowed, as defined by the UBACC. If, after the prompt the patient still responded incorrectly, or was unable to respond, no credit was given for that question. Capacity to consent was defined by the ability to correctly answer all 10 UBACC questions [2,8].

Read aloud to each participant prior to performing questionnaire:

By completing this survey you are participating in a research study about your Emergency Department visit. Your participation is voluntary and may be withdrawn at any time without any consequence to you. If you have questions about this, please contact (principal investigator) at (email) or at (phone number). A copy of this survey will be provided to you when you are discharged.

We are doing this project to try and better understand how people make decisions about being involved in Emergency Department research. You can help us better understand how to treat people with chemical dependency problems. We may ask questions about your alcohol and drug use. We will review and gather some information from your medical record but your personal information will be kept completely confidential. None of your personal information will be shared or made public. There are no benefits to you for helping us, but you can help us learn and this may help others with similar problems in the future. There are no real risks except some questions might be personal or upset you.

Fig. 1. Summary informed consent statement read aloud to each participant prior to performing the UCSDBACC questionnaire.

Please cite this article as: Martel ML, et al, A brief assessment of capacity to consent instrument in acutely intoxicated emergency department patients, American Journal of Emergency Medicine (2016), http://dx.doi.org/10.1016/j.ajem.2017.06.043