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Alcohol intoxication/dependence, ethnicity and utilization of health care resources in a level I trauma center

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Abstract

Objective—To evaluate the potential influence of acute intoxication and dependence to alcohol on extra-utilization of health care resources by ethnic minority trauma patients in a level I trauma center.

Methods—We analyzed the data of 1,493 patients enrolled in a study that evaluated the effectiveness of brief alcohol intervention among ethnic minority trauma patients. The database included detailed demographic, injury-related and drinking-related characteristics (including acute intoxication and alcohol dependency status). Patients were categorized into the following groups: non-intoxicate/non-dependent (NI/ND), non-intoxicated/dependent (NI/D), intoxicated/non-dependent (I/ND) and intoxicated/dependent (I/D). We compared utilization of several diagnostic and therapeutic procedures among these four categories. We placed special emphasis on ethnicity as a potential effect modifier.

Results—Relative to NI/ND trauma patients, I/ND patients (relative risk (RR): 1.8, 95% CI: 1.2-2.8) and I/D patients (RR: 2.4, 95% CI: 1.6-3.6) had significantly higher chance of being evaluated by abdominal ultrasound during the first 24 hours of hospital arrival. Similar pattern was observed for head CT scan (with the corresponding RRs of 2.1 and 2.6, respectively). Chance of admission to the intensive care unit (ICU) was not associated with intoxication/dependence status. Length of hospital stay was negatively associated with drinking status with the shortest length of stay for I/D. Including ethnicity in the models, did not change the results and conclusions.

Discussion—Acute intoxication and dependence to alcohol are both associated with more frequent utilization of selected health care resources and the utilization pattern was not associated with patient ethnicity. This emphasizes on the importance of routine screening for drinking problems among all trauma patients, regardless of their blood alcohol level in the ED.

Introduction

Studies have consistently demonstrated that risky drinking³³ is strongly associated with a higher frequency of emergency department (ED) visits and hospitalization^{10, 12, 29, 30, 32}. Alcohol is involved in approximately half of all trauma admissions^{17, 34, 36, 40, 41} in Level 1 and 2 trauma centers. Yet, studies have seldom evaluated the potential influence of acute

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intoxication and dependence to alcohol on over-utilization of health care resources by trauma patients.

Acute intoxication and medical evaluations in the ED

Acute intoxication often complicates the medical work-up required to rule out a potential undetected injury³². Often times, the patient either does not remember or is not able to give a good medical history or cooperate with the trauma team during medical examination³². Therefore, physicians cannot always rely on the patient's response to medical evaluations. As a result, even in a non-complicated injury, physicians often utilize more advanced techniques in order to rule out the presence of potentially unidentified injuries³².

In addition to an increased number of diagnostic procedures conducted at the time of ED arrival, monitoring response to treatment is also more challenging. Even in the absence of abnormal findings in primary medical evaluations, intoxicated patients are often hospitalized for 24 hour observation and they might have a higher chance of being admitted to the ICU³². Moreover, for those under observation in surgical wards or ICUs, medical teams often cannot rely on serial physical exams for detecting covert injuries. As a result, more advanced techniques such as serial CT scans or more invasive procedures such as insertion of an intracranial pressure monitor might be required³².

Alcohol dependence and trauma care

Studies have consistently demonstrated that multiple organ damages due to long term alcohol overconsumption, the pattern that is frequently seen among alcohol dependents, could negatively influence body's response to injury²². In addition, the sudden cessation of alcohol consumption might predispose alcohol dependents to an alcohol withdrawal syndrome (AWS) or even delirium tremens^{6, 23} which can complicate the treatment process. Unfortunately, in spite of the high prevalence of AWS among trauma patients^{27, 44} a significant proportion of the patients are undiagnosed⁸. If alcohol use disorders are not diagnosed, the patient might go through unnecessary and costly evaluations that might postpone timely management of the disease^{27, 43, 44}. Even when alcohol dependence is diagnosed, the patient might require extra care to cope with the signs and symptoms of alcohol withdrawal^{6, 8}. This often requires longer length of hospital stay^{27, 44} which further predisposes the patient to complications such as hospital acquired pneumonia^{6, 7, 14, 15}.

Ethnicity and utilization of health care resources

Several studies have demonstrated that ethnicity is significantly associated with disparities in receiving health care in the United States^{1, 4, 11}. However, while injuries are the leading cause of mortality and morbidity in individuals younger than 45 years old¹⁶, few studies have focused on health care disparities among trauma patients. These few studies have mainly examined traumatic brain injuries, because of their high mortality and substantial morbidity^{3, 9, 20, 21, 28, 42} and have often considered utilization of rehabilitation services as the main outcome of interest⁴². As a result of this approach, potential differences in utilization of resources during hospitalization have not received the attention they deserve. In addition, there is no study that has evaluated the influence of acute or chronic alcohol problems on utilization of resources by hospitalized ethnic minority trauma patients.

In this study, we evaluated if high blood alcohol concentration (BAC) at the time of hospital arrival and dependence to alcohol, are associated with higher utilization of health care resources for Whites, Hispanics and Blacks in an urban level I trauma center.

Methods

The methodology in this trial has been described in detail elsewhere³⁸. Briefly, the “Multidisciplinary Approach to Reduce Injury and Alcohol Use (MARIA)” was designed to evaluate the effectiveness of a brief intervention (BI) in reducing alcohol consumption and injury recidivism among Whites, Blacks and Hispanics admitted to a Level I trauma center. Since the main objective of the study was comparison of effectiveness of BI among minorities, Blacks and Hispanics were oversampled.

In this trial, trained research assistants screened trauma patients based on the following four criteria: a) BAC level in the ED, b) self-reported drinking within 6 hours prior to injury, c) positive on one or more items of the CAGE questionnaire in the last year¹³ and d) drinking pattern beyond drinking limits guidelines (four drinks per occasion for women and five for men)³⁵. CAGE is a four item questionnaire that asks patients about their feeling in regards to: the necessity of cutting (C in CAGE) the number of drinks; getting annoyed (A in CAGE) because of other people's criticism of their drinking behavior; guilt (G in CAGE) because of inappropriate drinking; drinking alcohol early in the morning as an eye opener (E in CAGE)¹³. A total of 1,493 trauma patients were included in the study. The baseline interview collected comprehensive data on demographic characteristics, risk perception and history of risky behaviors, history of alcohol and non-alcohol related injuries, alcohol consumption and physical, social and legal problems associated with alcohol or drug use, including indicators of alcohol or drug abuse and dependence.

Ethnic identification: This was based on subjects' responses to four questions. First participants were asked if they were Hispanic, Spanish or Latino. Those who answered yes were asked about their original Spanish-speaking country. The third question asked about the race (White, Black, Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native) of the participant. If more than one race was mentioned, participants were then asked about the race group that described them the best.

Alcohol dependence status was assessed at baseline using the Composite International Diagnostic Interview (CIDI)². Drug use and dependence was assessed at baseline using the World Health Organizations Composite International Diagnostic Interview Short Form (CIDI-SF)²⁶. Identification of the mechanism and intentional nature of the injury was based on subjects' self-report about the way the injury occurred. Severity of injury was measured using the Injury Severity Score (ISS)⁵.

Based on the BAC in the ED and dependence status, we categorized patients into four categories: non-intoxicated (BAC<0.08%) /non-dependent; non-intoxicated/dependent; intoxicated (BAC≥0.08%)/non-dependent; intoxicated/dependent.

Identification of the utilized resources was based on the reported International Classification of Disease (ICD-9) procedure codes reflected in the trauma registry. Since many different procedures could be reported for each individual, we decided to focus on the utilization of the following resources, which were most commonly reported for the MARIA patients based on our preliminary analysis of the data: abdominal ultrasonography (88.76); CT scan of head (87.03), abdomen (87.41) and thorax (88.01); urinary catheter (59.8) and endotracheal intubation (96.04).

Our preliminary analyses of the data demonstrated that on average less than 3% of the patients received a procedure more than two times. Therefore, for each procedure code, we created a dummy variable that was equal to “1” if a patient had utilized the resource ≥ 1 time; “0” otherwise. To evaluate if the risk of ICU admission was associated with

intoxication/dependence status, we created a binary variable that was equal to “1” if a patient was admitted to the ICU; “0” otherwise.

Often, the sedative influences of alcohol disappear up to 24 hours after consumption. Therefore, we did not expect any significant difference in resource utilization because of acute intoxication after the first 24 hours of hospital arrival. However, patients with dependence to alcohol might experience signs and symptoms of alcohol withdrawal several hours after admission, because of lack of access to alcohol. As a result, we hypothesized that resource utilization in these patients would increase after the first 24 hours of hospital arrival. To evaluate these hypotheses, we created two sets of outcome variables that addressed resource utilization during or after the first 24 hours.

Finally, we added two continuous outcomes, namely length of ICU and hospital stay, to the list of the outcomes of interest evaluated in this study.

Data analysis approach

To evaluate the association between the exposures of interest and the binary outcomes before and after the 24 hour cutoff, we adopted a logistic regression approach. However, it has been demonstrated that in case-control or cross sectional studies with common outcomes (more than 10% frequency), the odds ratio (OR) might not be a good representative for the actual relative risk^{18, 31, 37}. Since some outcomes such as abdominal ultrasound and head CT scan were commonly reported for the patients in MARIA project, we used log-binomial regression model to directly calculate the risk ratios (RRs), rather than using logistic regression model and calculating ORs^{18, 31, 37}. We adjusted our estimates for the following variables: age, sex, ethnicity, insurance status, mechanism and severity of injury, and drug use/dependence status. Since one of the hypotheses of the study was evaluation of the modification effect of ethnicity on the association between intoxication/dependence status and resource utilization, we repeated the same analysis mentioned above, but added the interaction term between the exposure and ethnicity to the model.

Finally, we used linear regression models to evaluate the association between intoxication/dependence status and length of hospital or ICU stay (continuous outcomes) and adjusted our estimates for the same covariates mentioned above. However, since length of hospital and ICU stay were skewed, we log transformed these two variables. By adding the interaction term between intoxication/dependence status and ethnicity, we also evaluated the potential modification effect of ethnicity.

Results

Demographic characteristics of the study population

Whites, Hispanics and Blacks comprised 45%, 36% and 19% of the patients, respectively. Table 1 summarizes main demographic and alcohol-related characteristics of the patients for each ethnic group. In general, Hispanics were younger (mean age 29 years old) than Whites or Blacks and a higher proportion of them were male (89% vs. 78% among Whites and 81% among Blacks). Hispanics also had less education. While approximately 80% of the Whites and Blacks had at least some high school education, 65% of the Hispanics had less than high school education.

Table 1 also summarizes alcohol intoxication/dependence and drug use/dependence status for each ethnic group. As presented, a smaller proportion of the Hispanics were non-intoxicated/non-dependent (28%) in comparison to Whites (36%) or Blacks (36%). In addition, being intoxicated/dependent was more common among Hispanics, relative to other ethnic groups (31% vs. 27% in Whites or 24% in Blacks) ($p < 0.05$).

Most commonly utilized resources

On average, 4.9 (SD: 5.6) ICD-9 procedure codes were recorded for non-intoxicated/non-dependent patients, 5.2 (SD: 6.0) for non-intoxicated/dependent patients, 5.7 (SD: 6.3) for intoxicated/non-dependent patients and 5.6 (SD: 6.5) for intoxicated/dependent. Table 2 demonstrates that among Hispanics significantly higher number of ICD-9 procedure codes were reported for intoxicated/dependent patients, relative to non-intoxicated/non-dependent individuals ($\beta= 1.95$, 95% CI: 0.57- 3.33, $p=0.006$), even after adjustment for age, gender, insurance status, injury severity, ED assessment, mechanism of injury, and drug use.

Table 3 summarizes the frequency of the most commonly reported procedures for each ethnic group during the first 24 hours of hospital arrival and after that. As presented, during the first 24 hours, the use of abdominal ultrasound, CT scan of head, abdomen, and thorax and urinary catheter were significantly more common among White patients relative to Hispanics and Blacks. However, such associations were only observed for head CT-scan after the first 24 hours of hospital arrival (Table 3).

Resource utilization during the first 24 hours of hospital arrival

In order to evaluate if intoxication/dependence status was associated with the utilization of each resource mentioned in Table 3, we conducted six log binomial analyses. The six models considered use (vs. lack of use) of each resource during the first 24 hours of hospital arrival as the binary outcome of interest, and alcohol intoxication/dependence status as the main exposure. In these models (Table 4) we adjusted our estimates for age, gender, ethnicity, insurance status, type and mechanism of injury, injury severity score, and drug use/dependence status. Intoxicated/non-dependent patients (RR: 1.79, 95% CI: 1.15-2.80) and intoxicated/dependent patients (RR: 2.41, 95% CI: 1.60-3.60) had significantly higher chance of being evaluated by abdominal ultrasound during the first 24 hours of hospital arrival, relative to non-intoxicated/non-dependent trauma patients (Table 4). While mechanism and severity of injury were associated with the outcome, ethnicity, insurance status and drug use/dependence were not. Similar patterns were observed for head CT scan and urinary tract catheterization during the first 24 hours of ED arrival. Alcohol intoxication/dependence status was not significantly associated with other outcomes in this analysis.

The models with interaction term between intoxication/dependence and ethnicity did not demonstrate any significant modification effect for ethnicity (results are not presented).

Resource utilization after the first 24 hours of hospital arrival

There was no statistically significant association between alcohol intoxication/dependence status and resource utilization after the first 24 hour of hospital arrival.

ICU admission

Using the same log-binomial analysis approach mentioned above and after adjustment for the same variables, we found that ICU admission was not significantly associated with intoxication/dependence status. In addition, we were not able to detect any significant modification effect for ethnicity.

Length of ICU stay

Results of a linear regression analysis adjusted for age, gender, ethnicity, insurance status, mechanism of injury, ISS and drug use/disorder status demonstrated that log transformed length of ICU stay, for patients who were admitted to ICU, was not significantly associated with intoxication/dependence status (Table 5). The model with the interaction term for

intoxication/dependence and ethnicity did not demonstrate a significant modification effect for ethnicity.

Length of hospital stay

Intoxicated/non-dependent patients and intoxicated/dependent patients had significantly shorter log transformed length of hospital stay, relative to non-intoxicated/non-dependent individuals (Table 5). Similar to length of ICU stay, length of hospital stay was not significantly influenced by modification effect of ethnicity either.

Discussion

Our study demonstrated that intoxication/dependence status was significantly associated with higher chance of utilizing abdominal ultrasound, head CT scan and urinary catheter during the first 24 hours of hospital arrival. In addition, significantly higher number of ICD-9 procedure codes was reported for Hispanics in comparison to Whites or Blacks, although utilization of the most commonly used procedures was not different among different ethnic groups.

Before discussing the main findings, we would like to review the limitations of the study. First, since patients should be able to respond to the study questionnaire, seriously injured patients and especially patients with severe traumatic brain injury were not included in the study. Although these patients generally comprise a small proportion of injured patients, they consume significant proportion of the utilized resources¹⁶. Second, in spite of the large number of the subjects in this study, patients were recruited from a large urban level 1 trauma center. Therefore, generalizability of the results to smaller hospitals might be limited.

In spite of these limitations, our study had several strengths. First, we evaluated the influence of drinking problems *beyond alcohol intoxication*, on utilized resources in a level I trauma center. A few previous studies that have addressed the issue, have only focused on the potential influence of acute intoxication on resource utilization^{19, 24, 25}. For example, Jurkovich and colleagues reported that intoxicated patients were more likely to be intubated in the field or emergency department (relative risk (RR) = 1.3, 95% (CI)= 1.1-1.5) or require intracranial pressure monitor (RR = 1.4, 95% CI = 1.1-1.8)²⁵ as compared to non-intoxicated patients. Lack of association between intoxication status and these procedures in our study could be partially explained by lower severity of injury in our study.

In addition, while Jurkovich and colleagues wisely compared the potential influence of acute intoxication on early (first 24 hours of hospital arrival) and late trauma fatality²⁴, none of the previous studies have evaluated utilization of the resources during these time periods. This approach gave us a unique opportunity to differentiate between potential over utilization of resources mainly because of acute intoxication or alcohol dependence.

The first significant finding of the study was the association between intoxication/dependence and the number of the reported ICD-9 procedure codes for Hispanics and not for other ethnic groups. Lack of access to underlying health conditions of the Hispanic patients does not allow us to attribute the larger number of the reported ICD-9 codes to the more frequent co-existing health problems in this ethnic group. However, a potential language barrier between patients and physicians might play a role. In other words, potential communication problems encourage physicians to more frequently utilize procedures that would have not been used if the language barrier had not existed.

Another significant finding of the study was the association between intoxication and dependence status and higher utilization rate of abdominal ultrasound, head CT and urinary

tract catheter during the first 24 hours of hospital arrival. In addition, intoxication and dependence had distinct influence on utilization rate. In other words, intoxicated/dependent patients had the highest chance for utilizing these resources, followed by intoxicated/non-dependents and non-intoxicated/dependent patients. We didn't observe any significant association between the exposures of interest and utilization of other resources and especially not after the 24 hours. Although the small number of the subjects that have utilized other resources might have restricted us to detect small but significant differences among exposure groups, the RRs very close to one and the CIs that were not very wide weaken this potential explanation. Mechanism of injury (e.g. motor vehicle collision, violence), the injured body organ (e.g. head injury), availability and feasibility of use of a service such as abdominal ultrasound and the potential influence of acute or chronic alcohol consumption on the body response to injury are probably among the most important factors that determine the use or frequency of use of different resources. Future studies should focus on the relative importance of these variables on resource utilization.

We also found that intoxication/dependence status was not associated with the probability of being admitted in the ICU. Unfortunately, inadequacies of the existing data limit our ability to interpret these findings. However, one potential explanation is that studies have demonstrated that severity of injury is one of the most important predictors for ICU admission among injured patients (57). In other words, ISS is in the causal pathway between an injury and chance of ICU admission. Therefore, adjustment for ISS decreases the strength of the positive association between the injury and ICU admission.

In regards to the length of hospital stay, in general, intoxicated patients have a higher chance of being hospitalized than non-intoxicated patients³². In other words, a patient could be treated and released from the ED had s/he not been under the influence of alcohol. As a result, as soon as the sedative influences of alcohol disappear, the patient gets discharged. This issue might show itself as a negative association between length of hospital stay and intoxication status. Another potential explanation for shorter length of hospital stay among alcohol dependents could be the excessive desire of these patients to consume alcohol while they are hospitalized. Since hospitals do not provide alcohol and patients experience the undesirable consequences of alcohol withdrawal, they prefer to leave hospital even against medical advice. In addition, physicians might be more inclined to discharge alcohol dependents as soon as their medical conditions allow to prevent potential problems that their misbehavior can cause for other patients and medical staff.

Finally, our study did not demonstrate any significant difference in utilization of the services based on the ethnicity. In other words, adjusting for other variables, White, Hispanic and Black trauma patients in our trauma center had equal opportunity to utilize the existing resources. This was in contrast to some other studies that reported disparity in utilization of health care services among trauma patients^{3, 9, 20, 21, 28, 42}. However, in comparison of our results with the results of published literature, we have to take the following issues into consideration. First, we focused on utilization of the resources during hospitalization. However, others have mainly focused on utilization of rehabilitative services after hospital discharge^{3, 9, 20, 21, 28, 42}. As a result, the settings are not comparable. Second, most of other studies have used National Trauma Data Bank (NTDB) which is a conglomerate of more than 600 small and large hospitals^{3, 9, 20, 21, 28, 42}. While using data from several hospitals could be extremely valuable, analysis of mutli-center databases is challenging. Roudsari and colleagues demonstrated how not taking into account the clustering of patients within trauma centers during analysis or the high proportion of missing data in the NTDB could affect the results and interpretation of a study³⁹.

In conclusion, our analyses demonstrated that acute intoxication and dependence to alcohol are associated with overutilization of certain health care resources. This over utilization was not influenced by patients' ethnicity.

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Table 1

Distribution of the demographic and alcohol/drug-related characteristics of the trauma patients enrolled in the MARIA project *

	White (N=668)	Hispanic (N=537)	Black (N=288)
Mean age (years) *	35	29	38
Male (%) *	78	89	81
Marital status (%) *			
Single, never married	43	47	47
Married, living with lifetime partner	27	33	24
Separated or not living with spouse	31	19	29
Education status (%) *			
Less than high school	23	65	26
Some high school	37	22	52
More than High school	39	13	21
Insured (%) *	46	24	33
Alcohol consumption pattern (%) *			
Non-intoxicated/non-dependent	36	28	36
Non-intoxicated/dependent	13	17	16
Intoxicated/non-dependent	24	24	24
Intoxicated/dependent	27	31	24
Drug consumption pattern (%) *			
Neither user nor dependent	50	61	49
User, but not dependent	37	30	40
Dependent	13	10	11
Mechanism of injury (%) *			
Motor Vehicle Collision	40	38	32
Assault	6	12	11
Falls	20	14	18
Motorcycle collision	14	4	3
Gunshot wounds	3	9	9
Stab Wound	3	6	11
Others	14	17	16

* p value for all comparisons <0.05

Table 2

Linear regression analysis evaluating the association between the number of reported ICD-9 procedure codes and alcohol intoxication/dependence status *

	Regression coefficient (95% CI)		
	White (N=668)	Hispanic (N=537)	Black (N=288)
Non-intoxicated/non-dependent	Reference	Reference	Reference
Non-intoxicated/dependent	1.00 (-0.58, 2.58)	1.37 (-0.26, 3.01)	.76 (-0.93, 2.44)
Intoxicated/non-dependent	0.50 (-0.70, 1.71)	1.18 (-0.31, 2.67)	0.55 (-0.91, 2.00)
Intoxicated/dependent	.62 (-0.57, 1.80)	1.95 (0.58, 3.33)	.58 (-0.81, 1.98)

* Adjusted for age, gender, insurance status, injury severity, ED assessment, mechanism of injury, and drug use

Table 3

Proportion (%) of the MARIA patients who utilized each resource at least one time

	Whites	Hispanics	Blacks
First 24 hours			
Abdomen Ultrasound *	59.6	48.2	37.9
Head CT scan *	50.2	39.1	29.5
Abdomen CT scan *	20.5	16.0	11.5
Thorax CT scan *	11.2	8.2	2.8
Urinary Catheter *	22.9	21.4	14.6
Endotracheal Intubation	14.1	16.4	11.8
After 24 hours			
Abdomen Ultrasound	2.4	1.1	1.4
Head CT scan *	8.4	4.8	2.1
Abdomen CT scan	4.0	2.2	2.1
Thorax CT scan	3.4	1.7	2.1
Urinary Catheter	1.7	1.5	1.0
Endotracheal Intubation	5.4	4.3	3.1

* Chi square p value comparing different ethnic groups < 0.01

Table 4

Results of the log binomial regression analysis evaluating the association between acute and chronic drinking problems and utilized resources during the first 24 hours of ED arrival *

	Risk Ratio (95% Confidence interval)							
	Abdomen US	Head CT scan	Abdomen CT scan	Thorax CT scan	Endotracheal Intubation	Urinary Catheter	Reference	Reference
Non-intoxicated/non-dependent	Reference	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Non-intoxicated/dependent	1.37 (0.83-2.24)	1.35 (0.84-2.17)	1.04 (0.60-1.81)	0.67 (0.28-1.58)	1.42 (0.76-2.64)	1.41 (0.67-2.31)		
Intoxicated/non-dependent	1.79 (1.15-2.80)	2.11 (1.35-3.28)	0.96 (0.61-1.51)	1.14 (0.57-2.26)	0.96 (0.57-1.54)	1.61 (1.12-2.41)		
Intoxicated/dependent	2.41 (1.60-3.60)	2.64 (1.74-4.00)	1.07 (0.69-1.67)	1.18 (0.67-2.07)	1.49 (0.94-2.37)	1.77 (1.22-2.73)		

* Adjusted for age, gender, ethnicity, mechanism and severity of injury, insurance status and drug use/dependence status

Table 5

Linear regression analysis, evaluating the association between intoxication/dependence status and length of ICU and hospital stay *

	Regression coefficient (95% CI)	
	Log length of ICU stay **	Log length of Hospital stay
Non-intoxicated/non-dependent	Reference	Reference
Non-intoxicated/dependent	0.28 (-0.9, 0.67)	-0.12 (-0.25, 0.01)
Intoxicated/non-dependent	0.08 (-0.25, 0.41)	-0.13 (-0.24, -0.01) ¹
Intoxicated/dependent	0.20 (-0.14, 0.55)	-0.21 (-0.31, -0.11) ²

* Adjusted for age, gender, ethnicity, mechanism and severity of injury, insurance status and drug use/dependence status

** Only patients admitted to ICU are included in the analysis (n=348)

¹ p < 0.05,

² p < 0.001