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Feasibility of Informed Consent for Computed Tomography in Acute Trauma Patients

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ABSTRACT

Background: Computed tomography (CT) is common for trauma victims, but is usually done without informing patients of potential risks or obtaining informed consent.

Objective: The objective of this study was to determine the feasibility of two elements (time and normal level of alertness) necessary for informed consent for CT in adult trauma patients.

Methods: We conducted this prospective observational, two-phase cohort study at two urban, Level I trauma centers. In the first phase, we determined the median time needed to obtain informed consent for CT by performing sham consent on 11 injured patients at each site. In the second phase, we observed all adult trauma activation cases that presented during specified time blocks and recorded Glasgow Coma Scale (GCS) scores and the time available for consent (TAC) for CT—defined as the time between the end of the secondary trauma survey and when the patient left the resuscitation room to go to CT. We defined, a priori, feasible consent cases as those in which the patient had a GCS of 15 and a TAC greater than the median sham consent time at that site.

Results: The median times for sham CT consent at the two sites were 3:36 and 2:09 minutes:seconds (range = 1:12–4:54). Of the 729 trauma patients enrolled during phase II, 646 (89%) had a CT scan, and of these 646 patients, 461 (71.4% [95% confidence interval = 67.8%– 74.7%]) met feasible consent criteria. Of the 185 patients who failed to meet feasible consent criteria, 171 (92.4%) had a GCS < 15, one (0.5%) had a TAC less than the sham consent time, and 13 (7.0%) had both.

Conclusion: We found that informed consent for CT was likely feasible in over two-thirds of acute, adult trauma patients.

This paper explores the intersection between rapid growth in diagnostic radiation imaging and potential increased shared patient/physician decision making. The virtue of shared decision making is increasingly recognized in practice and in theory.[1]

Emergency department (ED) use of computerized tomography (CT) has increased threefold in the past two decades without corresponding increases in the incidence of hospital admissions or diagnoses of life-threatening illness.[2–4] CT scanning exposes patients to potentially harmful ionizing radiation, as well as risks associated with intravenous contrast exposure with chest and abdominal/pelvis CT.[2–4] Patients are exposed to as much as 119 times more radiation from a chest CT scan compared to a chest

X-ray, and the ionizing radiation exposure from CT scans has been associated with increases in the risk of cancer in a dose-dependent relationship.[2,5–8]

Respect for patient autonomy requires informed consent for procedures that carry risk whenever possible. For the most part, CT in trauma currently is ordered under the principle of *implied consent* without informing patients of risks or costs. We have previously demonstrated that most patients want to discuss radiation risks (and costs) prior to receiving trauma CT and that approximately half of patients would choose to forego imaging in scenarios with low risk of detecting life-threatening injury.[2] Citing multiple barriers including limited time for discussion, Robey et al.[9] reported that, although 74% of emergency medicine physicians feel that radiation exposure should be explained in most cases, they do so with only 24% of patients.

With a long-term goal of improving patient knowledge, autonomy, and shared decision making in their care, we sought to determine how often informed consent for CT may be feasible in adult ED trauma patients. In trauma settings, two of the primary components of feasibility for informed consent are time and level of alertness of patients. The specific objective of this study was therefore to determine the percentage of acute trauma patients who had time available for informed consent and who had a normal level of alertness.

METHODS

We conducted this prospective observational, two-phase study at two urban, Level I trauma centers in California from August to November 2015. In the first phase, we determined the median time (and range) needed to obtain informed consent for CT by performing sham consent on 11 injured patients at each site. We prepared a sham consent for CT based on the consent forms for elective abdominal contrast CT used at each hospital (Data Supplement S1, available as supporting information in the online version of of record of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13164/full). Sham consent patients were a convenience sample of adult ED trauma patients who did not receive CT, e.g., patients who had minor falls. Using stopwatches, we timed sham consents from the beginning of the reading of the form, through any questions the patients had, to the completion of signatures on the form.

In the second phase, we observed consecutive adult trauma activation cases that presented to the two trauma centers during specified 4-hour blocks of time, including day and night blocks to account for potential delays in CT with higher ED or trauma volume. We recorded patient demographics, Glasgow Coma Scale (GCS) scores as determined by treating physicians, and time available for consent (TAC) for CT, which was defined as the stopwatch determined time (seconds) between the end of the secondary trauma survey (after rolling the patient to check for spine tenderness and posterior injury) and when the patient left the resuscitation room to go to CT. If the TAC exceeded 5 minutes, times were rounded to the nearest minute. If more than one GCS was noted, we used the worst (lowest) value.

At one site, we recorded times for procedures that could be considered distractions occurring during the TAC, such as X-rays, splints, reductions, ultrasounds, electrocardiograms, placement of chest tubes and central lines, and other procedures. Trauma providers were unaware of the study and of our TAC observations. We defined, a priori, feasible consent cases as those in which the patient had a GCS of 15 and a TAC more than the median sham consent time at that site. We obtained institutional board approval for this study at both sites.

RESULTS

The median times for sham CT informed consents for the 22 patients from the two sites during phase I of the study were 3:36 and 2:09 minutes:seconds, with a combined mean of 2:58. The longest sham times from each site were 4:54 and 4:00. Of the 729 trauma-activated patients enrolled during phase two, 646 (89%) had a CT scan. Patient characteristics are described in Table 1.

The median patient GCS was 15 (interquartile ratio [IQR] = 14–15); 462 (71.5%) of patients had a GCS of 15, 104 (16.1%) had a GCS of 14, and 80 (12.4%) had a GCS of less than 14. The median and mean TACs were 14 (IQR = 9–24) and 20 minutes, respectively. Of the 646 patients who had CT, 461 patients (71.4% [95% confidence interval {CI} = 67.8%–74.7%]) met feasible consent criteria with both sufficient time and adequate mental status (Figure 1). Of the 185 patients who did not meet feasible consent criteria, 171 (92.4%) had a GCS < 15, one (0.5%) had a TAC less than the sham consent time, and 13 (7.0%) had both a GCS < 15 and a TAC less than the median sham consent time.

Even when using the longest sham consent time (4:54), 450 patients (69.7% [95% CI 66.0%–73.1%]) would have met feasibility criteria for CT consent. When

Table 1
Characteristics of 646 Phase II Trauma Patients Who Underwent CT Scans

Age (y), median (IQR)	52 (32–74)
Male	(350) 54%
Female	(296) 46%
Post-CT hospital admission	(316) 49%
Post-CT surgery	(28) 3%
Blunt injury	(622) 96%
Motor vehicle accident	(152) 23%
Motorcycle accident	(59) 9%
Fall	(256) 40%
Pedestrian vs. motor vehicle	(58) 9%
Blunt trauma from assault	(38) 6%
Bicycle accident	(59) 9%
Penetrating injury	(24) 4%
Gunshot wound	(8) 1.5%
Stab wound	(16) 2.5%

IQR = interquartile range.

reducing TAC by the times potentially affected by distractions, four additional patients no longer met feasible criteria. The primary distracters were plain X-rays, splints and reductions, and ultrasounds, which distracted for an average of 3, 6, and 5 minutes respectively.

DISCUSSION

Informing patients of healthcare-associated risks whenever possible is a key component of patient-centered care and autonomy. It is clear that CT, especially contrast CT of the torso, incurs real risks (and costs) that approximate the magnitude of low-risk diagnostic procedures and treatments (lumbar puncture and blood transfusion) for which consent is standard practice. In fact, informed consent is routinely obtained for elective outpatient contrast CT. An underlying premise behind this research is that many trauma CTs are not truly too emergent to preclude informed consent. In this regard, we have demonstrated that time for consent was rarely a limiting factor and informed consent is likely feasible in over two-thirds of acute trauma patients.

Other investigators have shown that informed consent for nontrauma abdominal CT in the ED is associated with decreased CT utilization.[10] When considered with our previous work showing that many patients would choose to forego CT in low-risk-for-injury scenarios, our new findings suggest that a program of informed consent for trauma CT may similarly decrease utilization, while additionally honoring patient autonomy. In terms of implementation of such a program, our findings suggest that GCS may serve as the primary screening tool to determine potential consent feasibility, without the need to consider time constraints in most cases. Even when injuries or vision difficulties impede patients' abilities to read and sign an informed consent sheet, clinicians may still verbally obtain and document consent.

Our study was performed in two well-resourced American Level I trauma centers, with cultures of frequent CT to avoid missing any possible injury. In more austere settings without such readily available CT, consent for CT may be even more feasible with more time between initial patient evaluation and transport to the scanner. Furthermore, in settings with direct connection between CT use and out-of-pocket patient cost, informed consent with discussion of charges may have greater potential impact on CT utilization. Previously, we showed that, other factors being equal, a $1,000 out-of-pocket cost to patients substantially reduced noninjured subjects' desire to have CT.[2]

LIMITATIONS

Although we have demonstrated that consent *may* be feasible from the standpoint of time and level of alertness in a majority of trauma patients, we have not established other elements necessary for informed consent. Patients may be alert with a normal GCS, but still lack decision-making capacity or be unable to rationally balance the risks, benefits, and alternatives
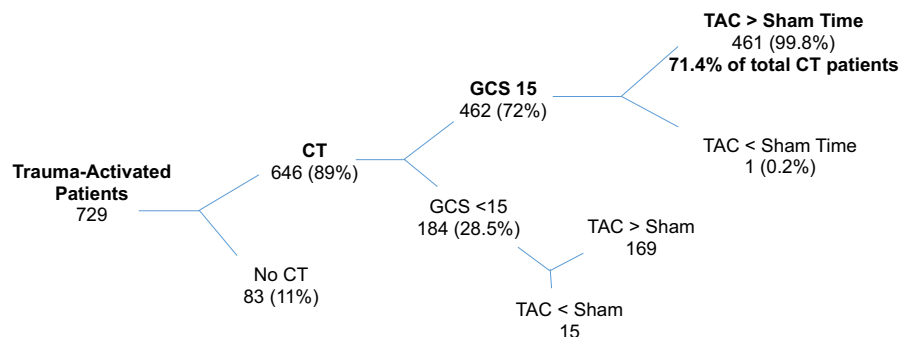

Figure 1. A diagram of trauma patients who had computed tomography (CT), a Glasgow Coma Score (GCS) of 15, and time available for consent (TAC) for CT that was greater than the sham time for consent at that site. [Color figure can be viewed at wileyonlinelibrary.com]

of trauma CT. This study was limited to two high-volume, urban Level I trauma centers. TAC at lower-volume centers may be shorter. Although other ED evaluations and procedures may have precluded obtaining consult, only 0.6% additional cases became nonfeasible for consent in this analysis. Given that sham consent times were derived from English-speaking, lower-acuity trauma patients, they may underestimate the time needed to obtain consent in more injured and more highly diverse trauma patient populations. However, a lower-acuity cohort of patients is precisely the group in whom informed consent would make the most intuitive sense. We are not advocating for informed consent in the critically ill, polytrauma patient, but rather in the less injured group who make up the majority of trauma patients.

We found great variability in the TAC, with a range of 0 to 241 minutes. This variability may be expected because of the many factors affecting timeliness of transport to CT, especially the availability of the CT scanner.

Finally, although we have characterized the patient components of desire for information and feasibility of informed consent, we did not survey physicians regarding their views on obtaining consent, and we did not observe physicians during the TAC. Given widely disparate viewpoints on the need for CT and what injuries can be missed in trauma evaluation,[11] the incorporation of informed consent and shared decision making for CT may meet resistance from certain physicians and specialties. With highly variable mechanisms of trauma affecting all patient age groups and anatomic regions, trauma scenarios are countless. A single consent document or process may not adequately detail the risks of failing to detect injury by foregoing CT. Even when consent is feasible, physicians may therefore believe that patients' risk/benefit equations are too complex to adequately explain on an individual basis and that the true risks of CT are too small to warrant providing this information.

CONCLUSIONS

Toward a goal of increasing physician/patient shared decision making in the ED, we have demonstrated that informed consent for CT may be feasible for over two-thirds of acute adult trauma patients. Future studies may evaluate the other components necessary for informed consent, as well as determine whether informed consent correlates with improved patient satisfaction and with safe, more discriminating CT utilization.

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Supporting Information

The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13164/full

Data Supplement S1. Consent for computed tomography (CT).