SCANNING THE AGED TO MINIMIZE MISSED INJURY

EAST MULTICENTER PROSPECTIVE OBSERVATIONAL STUDY

STUDY PROTOCOL

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STUDY SUMMARY AND AIMS

Trauma-related resources in the United States are increasingly allocated to the workup and treatment of geriatric patients due to the aging population and their disproportionate morbidity and mortality burden. Presently, there is no standardized workup recommended for geriatric trauma patients, particularly to guide which patients should receive computed tomography (CT) imaging. This creates significant variation and inefficiency and can lead to a missed injuries, inefficient management, and increased costs from imaging overutilization. Existing tools identifying patients appropriate for CT imaging almost always use older age as a singular factor that triggers imaging and are therefore essentially worthless in this population. The main objective of our study is to utilize multi-institutional prospective observational data to derive a simple and sensitive decision rule for identification of clinically significant injury and guide safe use of CT imaging in geriatric blunt trauma patients.

Our **specific aims** are as follows:

- Aim 1: Derive a simple clinical decision rule for identification of clinically significant injury with 98% sensitivity to guide the use of whole-body CT in blunt trauma geriatric patients.
- Aim 2: Establish specific criteria to identify patient subgroups that would benefit from targeted CT imaging.
- Aim 3: Determine if whole-body CT is superior to targeted imaging for clinical outcomes such as delayed injury diagnosis, length of hospital stay, and mortality.

We are examining our own retrospective data to identify early predictors of clinically significant injury that would be identifiable with whole-body CT. However, the clinical history known *at the time* that imaging is ordered is not well documented for retrospective collection. We aim to bridge this gap with prospective multicenter data to gather specific variables, minimize internal biases, and achieve a sample size large enough for a highly sensitive tool. We ***hypothesize*** that patients who meet certain criteria – such as an initial GCS of 15, absence of physical exam findings, and absence of change in functional or mobility status – may safely undergo no imaging or targeted imaging without a concordant increase in risk of missed injury. Standardized imaging protocols will allow for faster diagnoses, fewer missed injuries, and proper resource allocation for our most severely injured geriatric patients.

BACKGROUND

Optimization of the workup of geriatric trauma patients is essential for both trauma patients and trauma centers. The elderly constitute the fastest growing segment of the population in the United States, and, concordantly, they represent a growing proportion of trauma center activations and account for one-third of trauma-specific expenditures[1–6]. Physiologic changes associated with advanced age present major challenges in the evaluation and management of geriatric trauma patients[1,2,7,8]. Pre-existing medical conditions further confound evaluation of geriatric trauma patients and predispose these patients to worse outcomes[6,9–11]. Despite this, workup of geriatric trauma patients is not standardized, particularly in deciding which imaging studies to obtain.

Clinical decision tools have been used for decades to identify patients who should receive imaging for trauma. These include the NEXUS II Rule or Canadian C-spine Rule. Unfortunately, these rules are not validated in the geriatric population[12–16]. Existing tools use age >60 or >65 as a blanket trigger for imaging regardless of other clinical factors, such as baseline altered mental status or chronic kidney disease, that may otherwise impact imaging decision-making[12,13]. Some single-institution studies challenge this blanket trigger. One suggests that abdominal CT imaging in elderly patients who sustain falls from standing is not warranted without supporting physical exam findings, and another suggests that whole-body CT imaging did not decrease hospital length of stay, expedite surgical intervention, or provide significant benefit compared to those who underwent selective imaging[17,18]. Although these studies are greatly limited, they pose insightful strategies that will benefit from further investigation. We acknowledge that not all patients will likely benefit from a whole-body scan, and our data collection tool would not only allow a secondary analysis to identify which patients should undergo whole-body imaging but also which patient groups would benefit from selective imaging.

For the purposes of this investigation, we have elected to define geriatric as age 65 or older. Chronological age is conventionally used to measure the ageing process, but there is wide variation in when and how physiology is affected by age. In the trauma community, we often use age as a proxy for frailty although frailty is associated with but not directly proportional to age. Nevertheless, age is a concrete and well-established data point immediately available on almost every patient and thus has previously been used as a trigger in the emergency department for similar studies on CT scanning. Research suggesting alternative age cut-offs remains limited and largely based on analyses of specific subpopulations. Lastly, many existing guidelines for CT imaging in the setting of traumatic injury systematically exclude patients 65 years and older or recommend imaging based on age criteria alone, such that the patient population of individuals aged 65 and over remains a blind spot in imaging guidelines.

Undertriage is problematic in geriatric patients, which contributes to missed injuries and poorer outcomes[1,8,19,20]. Since ground-level falls, the most common mechanism among geriatric trauma patients, are low-energy, these patients may not trigger trauma activations, transport to designated trauma facilities, or thorough physical evaluation[7,9,11,20–23]. Partly to offset unconscious age bias, lack of comfort in geriatric medical management, and blanket decision tools, these patients frequently undergo whole-body CT imaging[19,24]. However, potentially unnecessary imaging is not without risk. These may reveal clinically insignificant incidental findings that trigger costly workup and management, potentially invasive testing, longer hospitalizations, and subsequent increases in morbidity and mortality. We hypothesize that those who do not meet the criteria of our decision rule will not have increased risk of potentially missed injuries, length of stay, morbidity, or trauma-related mortality.

METHODS

Study design:
This is a multicenter prospective observational study of geriatric patients who sustained blunt trauma. This study will be purely observational and does not involve study-based therapeutic interventions. Variables to be obtained outside the registry have been carefully selected to minimize data collection.

Data will be collected at two time points:

1. on patient presentation to the trauma bay, and
2. after discharge, when registry data is complete.

Data from the first time point will be recorded on a data collection sheet or can be embedded into a participating trauma center's initial history and physical exam to simplify workflow. This data will include patient mechanism of injury, vital signs in the field and upon arrival to the trauma bay, available medical history, medications, and physical exam findings. In addition, we will collect geriatric-specific information about residence and functional status. Importantly, we will collect if any information is unavailable prior to placement of imaging orders, as this is often the case and impacts decision making. We will also note the initial imaging studies that were obtained.

Data from the second time point will be obtained primarily via the institutional trauma registries, with a few additional study-specific data points. Outcome variables will be collected, including injuries identified, need for additional diagnostic CT imaging studies, treatments administered for each scanned body region, hospital length of stay, intensive care unit length of stay, and discharge disposition.

Date range:
April 1, 2021 to December 31, 2021

Anticipated Enrollment and Sample Size Derivation:
9,000 patients in 10-15 centers (600-900 patients per center, and an anticipated 9 months of data collection)

Our institution evaluates approximately 100 geriatric patients per month, and about one-third have a clinically significant injury to the head, neck, face, spine, or torso (not including orthopedic or external body region injuries) that requires admission, observation, surgery, or other treatment. Our institution has a low threshold for activation of geriatric trauma patients and thus we anticipate the negative workup rate might be higher than other institutions. Assuming volumes of each center that are similar to MetroHealth, nine months of data collection from each center would reach our target volume.

We would use 2/3 of the sample for derivation and 1/3 for validation of our rule. Enrolling 9,000 patients would yield a derivation sample of 6,000 and a validation sample of 3,000. Assuming 33% have a clinically significant injury, nearly 2,000 patients in the derivation cohort and nearly 1,000 in the validation cohort would have the outcome of interest. A rule that yields 98% sensitivity and 50% specificity (with 33% prevalence of a clinically significant injury) would lead to a negative predictive value of 98% (95% CI 97.4%-98.6%) and a positive predictive value of 48% (95% CI of 47.4-49.0%). If the prevalence of a clinically significant injury is lower than 33%, this would increase the negative predictive value of our test.*

* Sample size calculated using medcalc.org. "Exact" Clopper-Pearson confidence intervals are presented for sensitivity and specificity. Standard logit confidence intervals are presented for positive and negative predictive values, as described by Mercaldo et al (Mercaldo ND, Lau KF, Zhou XH (2007) Confidence intervals for predictive values with an emphasis to case-control studies. Statistics in Medicine 26:2170-2183.)

Inclusion criteria:

1. Patients age 65 or greater, included in the trauma center's registry
2. Blunt trauma mechanism
3. Trauma team activations (triggering full or limited trauma surgery team response)
4. Trauma consults (triggering evaluation by trauma surgery team)

Exclusion criteria:

1. Patients age 64 or less
2. Penetrating trauma mechanism
3. Burn trauma mechanism
4. Lower trauma activations (that do not, at any point, trigger trauma surgery team evaluation)

Variables:

Our main outcome variable is any clinically significant injury in the head, neck, and torso. We broadly define this as any injury that leads to a distinct change in management. A change in clinical management is defined as a treatment or clinical decision that would not have been implemented if the imaging had not been performed.

Data for our primary outcome will be collected in a binary fashion: *Yes, a clinically significant injury was found*, or *No, a clinically significant injury was not found*.

To further define the 'severity' of these injuries, we categorize clinical management in the following way, organized from least to most invasive:

- ED treatment with outpatient follow up (e.g. C-collar placement and outpatient appointment with Orthopedics-Spine)
- Monitoring in a regular nursing floor setting (e.g. regular floor care with serial labs or serial physical exams)
- Admission to an ICU for critical care needs
- Procedure or operation (including surgery, endoscopy, and Interventional Radiology procedures)

For patients with multiple initial management decisions, such as admission to ICU and procedural intervention, we will log the most invasive therapy.

Additional variables of interest include:

1. Data at presentation:
    a. Demographics (name, date of birth, gender, race)
    b. Clinical information about injury (mechanism of injury, date and time of injury, vitals, GCS, physical exam findings)
    c. Medical history including baseline medical comorbidities, cognitive status, and medications
    d. Functional data, including the patient's living status (home, assisted living, nursing facility, homeless), functional status (independent, partly dependent, fully dependent), impaired mobility (i.e. use of an assistive device such as a wheeled walker or wheelchair), vision or hearing impairment
    e. Signs of neglect on presentation (as a surrogate for impaired functional status and increased dependence on others)
    f. Unknowns (we will intentionally collect whether these data points are unknown at the time of initial evaluation)
2. Data from workup: initial CT scans performed, imaging findings, laboratory data

3. Data from hospital stay: delayed diagnostic imaging obtained and associated findings, injuries identified, clinically significant interventions (operative intervention, non-operative procedure, observation), ISS, LOS, discharge disposition, and mortality

These additional variables will be examined as secondary outcomes and explanatory variables to further understand our main outcome variable. The type of change in clinical management (outpatient management, inpatient floor, inpatient ICU, or procedural or surgical intervention) will help us understand the severity of the clinically significant injury that is identified. In addition, collection of data regarding missed injuries will help us understand the consequences of missed injuries and the time course of identification of these injuries with selective CT imaging.

Notably, missed injuries cannot be a main outcome of interest because there is no denominator and it is presumed that not all missed injuries will be identified at the index hospitalization.

Data Collection:
Data collection will occur at two distinct phases: the first phase is at the time of initial evaluation by a trauma surgery team, and the second phase is after the patient's hospital stay. Data collection forms will be provided to each participating site to assist with and optimize data collection.

Data from each institution will be collected in a password protected cloud-based system. Each site team will have a unique identifier that allows them access. Upon review of all collected data, analysis will include identifying missing data and consider imputation if >10% of the data is missing. Analysis of the data will begin once the data are consolidated.

Methodologic Justifications:
Our desired decision rule should have a high sensitivity as well as a maximum possible specificity in order to minimize missed injuries.

As described in the "Anticipated Enrollment and Sample Size Derivation" section, our sample of patients will be split into testing and validation cohorts, saving the validation cohort to test the model. We will use the testing cohort to identify elements of the physical exam and history that strongly correlate with clinically significant injuries or that strongly correlate with having no clinically significant injuries.

Mathematical modeling involving regression, classification and regression trees, and association rule mining will identify constellations of findings on presentation that have a very low association with a clinically significant injury found on imaging. These items will be added to the clinical decision tool which would essentially allow patients with these presentation and examination findings to forgo scanning. To emphasize, only variables present prior to initial imaging studies are obtained will be used to create the decision rule. As items are added to the tool, the specificity will increase and the false positive rate will decrease. Simultaneously, however, the sensitivity will decrease (as this strategy will miss some injuries and introduce false negatives). We would, by design, not allow the sensitivity to fall below 98% but add as many factors as possible with very few associated injuries to increase the specificity as high as possible without falling below the 98% sensitivity threshold.

Once the model is created, we will then validate the findings on the reserved validation cohort to ensure that the sensitivity and specificity are accurate. If the validation shows poor sensitivity or specificity, we will re-split the cohort randomly and start again to create a better model.

One of the challenges this study faces is selection bias which is why it has been designed as a multi-center study. We expect significant institutional and clinician-based variation in patient imaging. This variation means that we expect to include patients who are not scanned who would otherwise have been scanned at

other institutions and vice versa. By collecting physical exam characteristics in addition to the CT images obtained, we will be able to account and mathematically adjust for variation using modeling and propensity scoring. While this does not eliminate all bias, we can use existing variation in practice to our advantage to create comparable comparison groups to estimate the rate and severity of missed injuries in patients who were not scanned. Once we create a clinical decision rule from the widely collected observational data, we can proceed with prospective validation. Because no such tool currently exists or has been proposed, this large observational study is a step which cannot be skipped to adequately investigate this important question.

CONSENT PROCEDURES

This is an observational prospective study designed to record data on patients managed per institutional standard of care. A waiver of informed consent is requested. Data will be collected and transferred to a secured database without identifying patient information.

RISK AND BENEFIT ANALYSIS

Information from this study will be used to optimize imaging and subsequent managing of geriatric patients who sustain blunt trauma, which will result in significant benefit. No more than minimal risk is involved in this study. As this is an observational prospective study, there is no direct patient contact and no alteration in patient care. Identifiable information and other protected health information will be stored on secured and password protected cloud-based drives and will be maintained for a minimum of three years, per IRB regulations.

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