IRB Proposal

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Title:

Use and Utility of Computed Tomographic (CT) Head and Neck Imaging Following Inpatient Falls

Study Purpose and Rationale:

Falls in the hospital setting are a common adverse event. It is estimated that on average, inpatients suffer 3 to 5 falls per 1000 bed-days, which represents about one million inpatient falls in the United States each year [1]. By this estimate, New York Presbetyrian-Columbia Hospital (a 977 bed facility) suffers from ~1000 to 1750 falls/year. However, most falls are not associated with significant physical disability—it is estimated that only 1-3% of falls result in fracture [1]. One study examining risk factors for serious injury following inpatient fall found that physical evidence of trauma and ambulatory status were independent predictors of injury being found on imaging [2].

One uncommon result of an inpatient fall is significant head trauma. Computed tomographic (CT) scans are sensitive for detecting serious injuries following falls, but their use is associated with monetary and non-monetary costs. In addition, it appears that across the use of CT imaging has rapidly increased over the last 10 years. According to the US Government Accountability Office, spending on CT imaging has more than doubled in the last decade, from $975 million in 2000 to $2.17 billion in 2007 [3]. CT use has increased at a rate higher than other imaging modalities; for example, the use of plain radiographs and ultrasounds during the same time-frame increased 65% [3].

Not only is it known that the use of CT imaging *in toto* has increased over the last decade, there is also data to suggest that the use of CT imaging for evaluation of trauma in the Emergency Department has increased as precipitously. One study recently performed a large retrospective cross-sectional analysis of emergency department visits from around the United States and examined proportion of visits for injury-related conditions during which imaging was obtained (CT or MRI) over the last decade (324,569 ED visits sampled) [4]. The study examined the rate at which a life-threatening condition was diagnosed, as well as clinical outcome including ICU admission.

The study found that the proportion of injury presentations that had imaging increased from 6% to 15%, representing an approximately three-fold increase ($p<0.001$) [4]. In addition, the study found that the percentage of the time that these ED presentations were ultimately diagnosed with a life-threatening condition (cervical spine fracture, skull fracture, intracranial bleed, liver laceration, spleen laceration) did not significantly change (1.7% in 1998, 2.0% in 2007). There was no change in proportion admitted to the hospital or ICU [4]. The authors conclude that

despite the fact that there was no increase in the prevalence of life-threatening conditions, the prevalence of CT imaging significantly increased, indicating that possibly needless scans were being performed.

Reasons for this increase in use are not entirely known. Possibilities include the increased availability of CT scanners, the speed of new-generation CT scanners, and concern regarding malpractice lawsuits from a missed diagnosis.

However, besides monetary costs, CT scans carry health risks, most notably the carcinogenic effects of radiation exposure. Some estimates have concluded that 1-2% or all cancers in the UK and the United States may be secondary to radiation from CT exposure [5]. CT head, although resulting in only 2 mSv of radiation dose (compared to 15 mSv for CT chest), still accounts for one of the top ten sources of radiation from imaging modalities [5], and it is estimated that 10 mSv of radiation will cause a 0.1% lifetime increased risk of solid cancer or leukemia.

Although there are evidence-based decision rules for adult patients with suspected brain injuries in the ED [6], no such data exist on decision making regarding inpatient falls. In addition, usage patterns for imaging following inpatient falls is also unknown. Therefore, the purpose of the present study is to analyze the use and utility of CT head and neck imaging on inpatients at CUMC after falls in house. More specifically, the study will analyze the proportion of patients who receive CT imaging after a fall, as well as analyze how often the imaging yields clinically useful information. The study will compare recent data to a previous time-point to assess whether the use of CT imaging following trauma has increased over time.

Study Design and Statistical Analysis:

This will be a retrospective cohort study in which the cohort will be recent cases of falls documented in the inpatient setting using the MERS system. Once this cohort has been identified, the radiologic history from these patients will be examined using the Clinical Data Warehouse, and the number of CT imaging received by these patients following the fall will be recorded. The radiology reports will then be examined, and the proportion of reports that find a clinically significant finding (fracture, significant bleed, contusion, edema) will be examined. This recent cohort will then be compared to a previous cohort from 10 years prior to the first cohort.

The primary outcomes will be the following:

1. Percent of patients who fell that received CT head/neck imaging
2. Percent of patients who fell showing a clinically significant findings (cerebral edema, contusions, skull fracture, intracranial hematoma, neck fracture)

I hypothesize that (for outcome 1), the percent of patients who fell that received CT imaging increased between the two time-points. I hypothesize that the percent of patients showing clinically significant findings (outcome 2) will remain unchanged.

Power analysis based on ED data [4] which showed ~6% CT imaging use in 1998 and ~15% in 2007 for ED patients presenting with trauma. Based on these numbers, using a chi square analysis, it would require approximately 203 patients to show a significant difference for outcome 1 (assuming power of 0.8 and the chance of a type 1 error to be 0.05).

For outcome 2, assuming a 2% rate of clinically significant findings [4], to show that the true rate is less than 5% it would take 526 patients.

As a secondary outcomes, risk factors predicting a serious injury will be examined to determine if there are ways to predict which patients are most appropriate for further imaging.

Study Procedure:

As this is a retrospective study, no additional procedures would be required for this study.

Study Drugs:

Not applicable.

Medical Device:

Not applicable.

Study Questionnaires

Not applicable.

Study Subjects

Inclusion criteria- any inpatient at CPMC from approximately the last year that sustained a fall for which a MERS was reported, as well as any inpatient from approximately 10 years ago with the same criterion .

Exclusion criteria- none

Recruitment of Subjects

This is a retrospective study that will not require recruitment of subjects.

Recruitment of Subjects

Not applicable.

Confidentiality of Study

All data will be depersonalized and securely stored.

Potential Conflict of Interest

There is no potential conflict of interest in this study.

Location of the Study

The study will occur only at CPMC.

Potential Risks

None

Potential Benefits

None

Works Cited

1. Clin Geriatr Med. 2010 Nov;26(4):645-92.
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3. US Government Accountability Office. MEDICARE part B imaging services: rapid spending growth and shift to physician offices indicate need for CMS to consider additional management practices. http://www.gao.gov/products/GAO-08-452.
4. JAMA. 2010 Oct 6;304(13):1465-71.
5. N Engl J Med. 2009 Aug 27;361(9):849-57.
6. N Engl J Med. 2000;343(2): 94-99