The REDUCTION Protocol: An Ultra Low-Dose CT Scan for Fracture Evaluation with an Improved Patient Safety Profile

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Purpose: The key diagnostic modalities for orthopaedic trauma include plain radiograph (XR) and/or computed tomography (CT) imaging when greater detail is needed. This study aims to evaluate whether the Reduced Effective Dose Using Computed Tomography In Orthopaedic iNjury (REDUCTION) protocol is sufficient to detect, diagnose, and guide treatment for various fracture types as compared to conventional CT (C-CT) scan.

Methods: The REDUCTION protocol was developed as a quality improvement/patient safety measure at our academic medical center. 11 patients receiving this protocol were matched for fracture location, classification, gender, and age to patients with C-CT scans. Nine fellowship-trained orthopaedic traumatologists and 1 chief orthopaedic resident representing 5 academic Level I trauma centers were blinded to a set of de-identified CT images. The studies were evaluated twice, 4 weeks apart to allow for adequate washout. The set of images consisted of a series of key cuts representing 8 different fracture types in 5 locations (4 foot, 2 knee, 2 ankle, 2 elbow, and 1 hip fracture) and 22 total studies of the extremities, comprised of mixed C-CT and ultra low-dose CT (REDUCTION) images. Outcome measures included correct diagnosis, management plan, weight-bearing status (WBS), and adequacy of image quality. Descriptive statistics were used to assess sensitivity (Sn), specificity (Sp), positive predictive value (PPV), and negative predictive value (NPV) for the ultra low-dose CT. Interobserver and intraobserver reliability (kappa [κ] statistics) were calculated among observers.

Results: Mean estimated effective dose (ED) for REDUCTION studies versus C-CT was 0.03 mSv versus 0.43 mSv. The Sn, Sp, PPV, and NPV of REDUCTION protocol to detect all fractures was 0.86, 0.80, 0.98, and 0.36, but increased to 0.98, 0.80, 0.98, and 0.80 with occult fractures excluded. Interobserver and intraobserver reliability for diagnosis utilizing REDUCTION protocol ($\kappa = 0.75$, $\kappa = 0.67$) yielded substantial agreement among observers compared to C-CT ($\kappa = 0.85$, $\kappa = 0.82$). Interobserver agreement for treatment, treatment modality, WBS, and study quality utilizing REDUCTION protocol was moderate to near perfect ($\kappa = 0.67$, $\kappa = 0.67$, $\kappa = 0.56$, $\kappa = 0.89$) as compared to C-CT ($\kappa = 0.84$, $\kappa = 0.84$, $\kappa = 0.78$, $\kappa = 0.68$). Intraobserver agreement for the same outcomes were substantial to near perfect ($\kappa = 0.82$, $\kappa = 0.82$, $\kappa = 0.64$) as compared to C-CT ($\kappa = 0.82$, $\kappa = 0.89$, $\kappa = 0.28$). There was wide discrepancy in identifying an occult femoral neck fracture ($\kappa = 0.2$) using REDUCTION protocol, with only 30% of observers correctly identifying this fracture.

Conclusion: A mean ED of .03 mSV was achieved with the REDUCTION protocol, a 14x reduction as compared to C-CT, and less than half the ED for a standard XR of the chest (.08 mSv). Reliability statistics between the REDUCTION protocol and C-CT were comparable across images, indicating that the REDUCTION protocol could be readily interpreted by orthopaedic traumatologists. Evaluation of occult fractures may warrant C-CT for better

detail. Ultimately, the REDUCTION protocol appears to provide for high-fidelity images in appropriately selected patients.

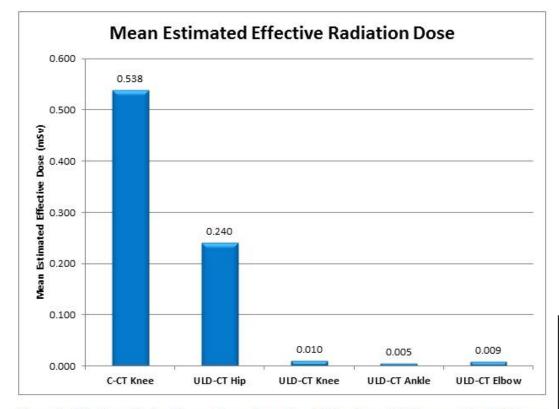


Figure 1. Effective radiation dosages for various extremity locations. C-CT= conventional CT scan; ULD-CT= ultra low dose CT scan

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.