Ultrasound to Detect Pressure-related Deep Tissue Injuries in Adults Admitted via the Emergency Department: A Prospective, Descriptive, Pilot Study

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Abstract
Stage 4 pressure ulcers (PUs) start with tissue death at the level of the bone, also known as deep tissue injury (DTI). Studies have shown the appearance of DTI on the skin is delayed for several days after the original pressure-related injury to the deep soft tissues. Studies also suggest DTI can be seen using ultrasound (US) technology. A prospective, descriptive, correlational pilot study was conducted to evaluate the use of US technology to detect DTI in the soft tissues that are not visible on the skin upon hospital admission. Study participants included a convenience sample of 33 persons at risk for PUs (ie, Braden score <18) admitted through the emergency department. Each participant had US scans of 13 common PU body sites. All scans were documented in the radiologist report in the electronic medical record. Creatinine phosphokinase, calcium levels, and urine myoglobin levels also were assessed upon enrollment. Skin failure risk factors (SFRFs), including fever, hypotension, weight loss, coagulopathy, and acidosis/respiratory failure, also were documented. Patients were examined for skin PUs every day for 7 days after US scan. Twenty-three (23) patients completed the study. US scans identified pressure necrosis at 2 levels: bone (54 positive [US+]) and subcutaneous (SC); 79 US+, respectively). US+ bone sites resulted in 5 PUs appearing 6 to 7 days post-admission (sensitivity = 100%, specificity 84.7%, positive predictive value 10%, and negative predictive value 100%), indicating all DTI that later became purple skin DTI were detected by the US. US+ SC sites, located immediately under the skin, yielded 5 PUs appearing on day 2 after admission (sensitivity 100%, specificity 74.8%, positive predictive value 6.3%, and negative predictive value 100%). The participants with PU occurrence in both bone and SC groups had low Braden scores (bone group mean = 13.25, SC group mean = 11.2). Study patients who were positive for PU also had >4 SFRFs. Creatinine phosphokinase, calcium, and myoglobin levels were inconsistent and did not correlate with US+ scans. These observations warrant larger studies to confirm findings and optimize the validity of US screening for DTI in select populations, which may help improve protocols of care and PU admission documentation. The preliminary results suggest inclusion of the Braden Scale score and known PU risk factors may improve the positive predictive value of this test.

Keywords: pilot study, ultrasound, pressure ulcer, sensitivity, specificity

Index: Ostomy Wound Management 2017;63(3):36–46

Potential Conflicts of Interest: none disclosed

CLARIFICATION: The study was conducted using the definition of pressure ulcers and deep tissue injury in place at the time; hence, that is the definition used in manuscript for clarity/consistency.
The estimated United States and Canada pressure ulcer (PU) hospital admittance and facility-acquired prevalence rates for 2008 and 2009 were 13.5% and 6% (90 398) and 12.3% and 5% (92 408), respectively. The effect of PUs in the United States is described by Lyder et al in a report from the national Medicare Patient Safety Monitoring System study:

Of the 51 842 individuals in the MPSMS 2006/07 sample, 2313 (4.5%) developed at least 1 new PU during their hospitalization. The mortality risk-adjusted odds ratios were 2.81 (95% confidence interval [CI] = 2.44-3.23) for in-hospital mortality, 1.69 (95% CI = 1.61-1.77) for mortality within 30 days after discharge, and 1.33 (95% CI = 1.23-1.45) for readmission within 30 days. The hospital risk-adjusted main length of stay was 4.8 days (95% CI = 4.7-5.0 days) for individuals who did not develop PUs and 11.2 days (95% CI = 10.19-11.4) for those with hospital-acquired PUs (P <.001). The Northeast region and Missouri had the highest incidence rates (4.6% and 5.9%, respectively).

The report by Lyder et al found PUs, morbidity, and mortality are closely inter-related.

Predicting which patients are most susceptible to PU or pressure injury (PI) formation is accomplished in several ways. The Braden Scale is one of the most reliable risk assessment tools used to identify patients’ susceptibility to PUs. It consists of 6 measurement categories centered primarily around mobility, along with incontinence, nutrition, and sensation. The Braden score ranges from 6 to 23 — the lower the score, the higher the risk, with the “tipping point” estimated to be a score of 18. The Braden Scale has been found to be fairly accurate as to the score under which most PUs occur. The comparison by Fulbrook and Andersen to the Conscious level, Mobility, Haemodynamics, Oxygenation, Nutrition (COMHON) Index, which includes 3 PU prediction scales on interrater reliability, suggests an overlap between PU development and critical care issues, low mobility, and nutritional conditions.

All these elements frequently coincide with changes in the general condition of patients seen with end of life. This observation was underscored by the consensus statement issued by the 2008 Skin Care At Life’s End (SCALE) Expert Panel. The consensus stated, “Like any other organ of the body, the skin (the largest organ) is subject to a loss of integrity due to internal and external insults …. not all pressure ulcers are avoidable,” and that PUs often are an unavoidable symptom of impending death. The concept skin failure has been discussed in the literature for almost 20 years in relation to unavoidable PUs. However, the concept and definition remained vague and difficult to research until the New York State (NYS) Department of Health in 2008–2011, as part of the NYS Patient Advisory and Safety Enhancement (NYPASE) initiative, assigned an Institutional Subcommittee that assembled a Panel of Pressure Ulcer Experts to examine predictive issues associated with PUs and deep tissue injuries (DTIs). The Panel defined skin failure as the rapid development of multiple pressure-related intact discolored areas of skin (PRIDAS), blanchable and nonblanchable (National Pressure Ulcer Advisory Panel® [NPUAP] Stage 1) and/or as DTI on patients with a Braden score of 15 or less. The Panel determined the risk factors associated with skin failure were 1 or more of the following 5 conditions: fever, unusual drop in blood pressure with systolic <110, ongoing unintentional weight loss, acidosis (including respiratory failure), and coagulopathy. In other words, the NYPASE Panel of Pressure Ulcer Experts attributed PUs directly to patient acuity levels (ie, systemic physical crisis), determining that the clinician cannot dissociate decline in mobility, nutrition, and sensation from the systemic diseases underlying these outward manifestations. These underlying diseases are usually progressive (eg, neurological disabilities, cardiovascular failure, and respiratory failure), although younger, healthy, stable individuals can suffer a serious accident or infection that can set the same systemic failure in motion with the same near-death phenomena, including PIs.

PUs that develop in health care settings are frequently litigated and exact large financial awards to the victims. Also, since October 2008, health care expenditures related to nosocomial PUs were no longer reimbursed by the Centers for Medicare and Medicaid Services (CMS); this position became the standard for other insurance programs. Usually, items not covered by the patient’s insurance are billed to the patients but because hospitals are considered at fault for nosocomial pressure ulcers, these costs are usually not billed but are absorbed by the institution providing care.
Presentation. PUs initially present as a PRIDAS, with redness in fair people and dark brown/purple in people with darker skin pigmentation. According to early PU investigations by Witkowski11,12 using biopsies and pathology examination of multiple PUs of varying stages, a nonblanchable Stage 1 PU/PRIDAS can be a precursor of the purple DTI occurring over significant vascular damage. Lyder, one of the originators of the NPUAP staging system and author of a paper on the conceptualization of the Stage 1 PUs,13 explains the consensus definition of the Stage 1 PU as an intact area of skin with nonblanchable erythema because this term denotes serious disruption of the vasculature underneath; whereas, the term blanchable is significant for an intact vasculature and, therefore, no irreversible damage to the skin. Because there was no way to assess the actual extent of the tissue destruction below the skin at the time of the first publication of the Pressure Ulcer Staging System,14 a Stage 1 ulcer could be covering tissue that was already dead or dying. Forensic studies by Bass15 on corpses have shown that, at room temperature, it takes 6 to 7 days for the general decomposition of dead tissues on a corpse, in the form of purple skin discoloration, to appear. These findings suggest seriously ill patients can be admitted to a facility with pressure-related dead areas of deep tissue that can go undetected for days before the purple skin necrosis in the form of a DTI (a purple/maroon ulcer) appears. This then will be labeled a facility-acquired PI and subject to regulatory oversight as a DU/PRIDAS. The resulting analysis combined “warm” PRIDAS with blanchable and nonblanchable, and “cool” PRIDAS with blanchable and nonblanchable. None (0%) of the warm/blanchable PRIDAS progressed to necrosis, as opposed to 65.38% of cool/nonblanchable PRIDAS that did progress to necrosis (P < .001) — DTIs that appeared on day 6 or 7. Combined cool and blanchable PRIDAS resulted in additional 21.8% necrosis, signifying the blanching of the cool PRIDAS most likely occurred because of lividity in the localized dead tissues, not from an intact vasculature. Temperature assessment can reflect the condition only of the tissues immediately underneath the skin and not down to the bone level unless the skin is right over the bone.

Ultrasound (US). An animal study by Moghimi et al22 employed high-frequency US (20 MHz) to assess full-thickness, experimentally created DTI on the hip bones of guinea pigs and tissue decomposition from the level of the bone as it tracked to the skin. Digital photographs also were taken of the superficial skin changes on the same days as the US images (days 3, 7, 14, and 21). An interesting finding that parallels the timing of the findings in the skin temperature study by Farid et al19 on humans was the appearance of the purple skin changes on the seventh day after the initial injury. Moghimi et al21 also documented and correlated the skin color change with the penetration of the tissue decomposition through the fascia underlying the subcutaneous layer seen on US on the seventh day.

In a prospective, observational study, Aoi et al23 used US to scan DTI on the skin surface and reported predictable underlying changes in the deep and subcutaneous tissues in humans during the process of decomposition of those tissues as they converted to unstageable PUs. DTIs on 12 participants were studied using serial US from the initial appearance of the purple ulcer to necrotic draining lesions. The patterns associated with DTI necrosis of the soft tissue consistently

Background

In an observational, retrospective, correlational study, Farid et al19 used the forensic concept that dead tissue loses heat when compared to normal tissue that can maintain its heat.20 The authors examined patients in an acute care facility who had reddened areas that had been examined using skin temperatures of PRIDAS and temperatures of normal, surrounding skin within 2 cm of the PRIDAS. The temperature of tissues yields clues to the tissue underlying the PRIDAS regarding viability (warmer than surrounding skin) or nonviability (cooler than surrounding skin).21 A highly accurate infrared digital camera was used to measure the temperatures and clearly identify PRIDAS in surrounding skin that appeared normal to the naked eye. The study also recorded blanching versus nonblanching, as well as the number of PRIDAS that became necrotic (ie, a purple DTI) and the number of days from the day the PRIDAS was originally assessed. Per protocol, only 1 PRIDAS per patient was entered into the study and a total of 85 patients/PRIDAS were examined and followed. The resulting analysis combined “warm” PRIDAS with blanchable and nonblanchable, and “cool” PRIDAS with blanchable and nonblanchable. None (0%) of the warm/blanchable PRIDAS progressed to necrosis, as opposed to 65.38% of cool/nonblanchable PRIDAS that did progress to necrosis (P < .001) — DTIs that appeared on day 6 or 7. Combined cool and blanchable PRIDAS resulted in additional 21.8% necrosis, signifying the blanching of the cool PRIDAS most likely occurred because of lividity in the localized dead tissues, not from an intact vasculature. Temperature assessment can reflect the condition only of the tissues immediately underneath the skin and not down to the bone level unless the skin is right over the bone.

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observed by the investigators on US were discontinuous fascia (interruptions in the normally smooth lines of the fascia) and heterogeneous hypoechogenic areas (mixed translucent and dense), also characteristic of an underlying Stage 4 ulcer. This study was important because it confirmed the US changes seen in the underlying tissues were not changes by progression (changes caused by repeated trauma — ie, pressure/shearing) but by the process of decomposition of tissues already dead.

Andersen and Karlsmark studied 15 PUs and classified characteristics of the injuries according to shades of red to measure color, skin temperatures, and skin elasticity (ie, retraction time) versus using US scanning for predicting PI severity. Each method was compared to an adjacent area of unaffected skin 5 cm from the test area. The authors found US was the most valuable tool for measuring the amount of pressure the skin was subjected to as opposed to the actual prediction of the eventual PU severity. Although the type and sensitivity of the US technology used were not discussed in the publication, the investigators measured the amount of edema in the dermal layers seen on US as their criteria for calculating the amount of pressure.

An observational, prospective study conducted by Quintavalle et al compared high-resolution US images obtained from 119 long-term-care facility residents with Braden Scale scores of 18 or less with images obtained from 15 healthy volunteers. Common PU sites scanned included the heels, sacrum, and ischial tuberosity. The US device used was portable; the images did not penetrate deeper than the dermal layers of the skin and the device was sensitive enough to characterize edema in the epidermal, dermal, and subdermal layers (edema in the latter 2 layers occurred simultaneously wherever it occurred). Documentation of the clinical assessment finding for erythema was reviewed, recorded, and compared with the high-resolution US finding for each specific site. Of the 630 US images obtained, 55.3% revealed abnormal edema in the layers when compared to US images of the same locations taken on the normal, healthy volunteers. No accompanying documentation of redness or other visible abnormalities of the skin was noted for 79.7% of the abnormal US scans. The study did not extend to follow-up outcomes regarding the appearance of PUs that correlated with the abnormal US scans.

The clinical examination conducted in a case study published by Steeds of a comatose 20-year-old heroin addict revealed a warm swelling on the patient’s right, lower extremity calf muscle. Urine and blood studies were consistent with a rhabdomyolysis. Steeds used hospital-grade US technology (transducers that generate a transmission frequency range of 2.5 – 12 mHz, which produces clearer images at deeper tissue penetrations) upon admission to the emergency department (ED) to examine the affected calf. The scanning revealed multiple hyperechoic foci (dense white areas on US) consistent with early rhabdomyolysis related either to diabetic muscle infarction or compression (pressure, compartment syndrome). The significance of the case study is that US can detect soft tissue changes and damage within 24 hours; the changes appear as hyperechoic (white dense areas capturing the intense muscle contraction [rigor mortis] that occurs within a few hours of the muscle dying) as opposed to the hypoechogenic (translucent dark areas) changes seen later after the tissues decompose and liquify (myoglobinuria [tea-colored urine] occurs within 6 hours of muscle death, signifying the breakdown/liquefaction of decomposing muscle). The hypoechogenic decomposition can be seen on hospital-grade US images starting at the level of the bone where the surrounding core temperatures of the viable tissues are warmer and advance more slowly as the surrounding viable tissue becomes cooler toward the coolest area (ie, the surface of the dead skin exposed to cool ambient temperatures).

Nam et al utilized both US and a technique described as photoacoustic imaging (a noninvasive, painless procedure) to assess the effectiveness of an engineered tissue graft on burn wounds. These techniques facilitated quantification of the amount of granulation tissue and allowed measurement of the progress and speed of healing as compared to burns with autografts or without any graft.

Hamaluik et al demonstrated how the stiffness of the dying muscle resulting from DTI can provide early information on deep tissue damage using numerical characterization of quasistatic US elastography. When using elastography, US technology can detect the change in muscle tissue elasticity that occurs as the scanner is moved from normal tissue to dead or damaged tissue. This information, added to the changes seen on the scan, enables the radiologist to identify the nature of the changes noted on the scan. The importance of this mathematical calculation and finite-element model of sonographic B-mode imaging and tissue deformation is the expectation that injured tissue can be identified much earlier (before the tissue dies) in hopes of providing intervention preventing irreversible damage. This ability underscores US as an ideal technology to utilize in the search for soft tissue infarcts, injuries such as DTIs, and other shearing injuries seen in sports and vehicle accidents and muscle-wasting diseases.

Rhabdomyolysis. Animal studies by Linder-Ganz and Gefen using magnetic resonancy imaging (MRI) to assess experimental pressure and shear effects on the hind limb muscles in rats revealed muscle tissue is extremely sensitive to pressure, ischemia, and deformation (lateral elongation of the muscle fibers caused by shear), similar to the forces that cause DTI resulting in PUs. When a significant amount of muscle dies (rhabdomyolysis) anywhere in the body, an initial, slow release of muscle protein (myoglobins) into the surrounding intact vasculature occurs, causing the first systemic effect (ie, dark myoglobinuria) within 6 hours after muscle death and then a concomitant rise in the serum creatinine phosphokinase (CK) starting within the first 12 hours. The
levels then peak in the next 12 hours to 3 days, slowly returning to normal over the next few days after muscle death.\textsuperscript{32-34} The large myoglobin molecules in the urine can cause damage to the kidney tubules unless detected (a combination of a rise in blood urea nitrogen and creatinine and noted dark urine and/or urine myoglobin assays) and treated, usually with increased intravenous fluids to flush the myoglobins through the tubules into the urine. Depending on the levels of CK early in the process, the patient also may be placed on continuous renal replacement therapy or dialysis.\textsuperscript{35} For reasons not clearly understood, several clinical observations\textsuperscript{32-34} report a drop in the serum calcium (Ca++) levels frequently accompanies elevated CK levels in cases of rhabdomyolysis.

Rhabdomyolysis also can occur in pressure-related DTI. A case study by Levine\textsuperscript{36} describes a young man who lay unconscious on the floor for several hours; severe pressure muscle necrosis resulted from his wallet in his back pocket. When he reached the ED, myoglobinuria and elevated CK were noted.

The primary purpose of this study was to determine whether US performed in the ED can detect pressure-related deep tissue necrosis in subcutaneous (SC) connective tissue and in muscle overlying the bone as an early predictor of subsequent visible signs of full-thickness pressure ulceration of the skin (specifically, purple DTI) within 2 to 7 days of US detection. If this was the case, it was anticipated the radiologist could determine whether lesions were present on admission and thus not facility-acquired, should they later appear as necrotic DTIs on the skin. The study also was conducted to determine whether incidental findings of other soft tissue abnormalities that may or may not be implicated in the patients’ overall symptomology and complaints could be visualized and reported to help generate early diagnosis of serious conditions. Lastly, the study was performed to evaluate if US examination of the soft tissues on the sacral/buttock areas of the body on these patients would rule out PUs in cases of skin conditions that mimic facility-acquired PUs.

Methods

A prospective, descriptive, observational pilot study was conducted in a 650-bed acute care facility in New York, NY. The facility serves a primarily residential community of 450,000 people, predominantly small business owners, professionals, government service blue-collar workers, and their families. Fourteen (14) skilled nursing facilities also serve this community.

Sample. The study involved a convenience sample of adult patients (minimum age 21 years) seen at the ED of Staten Island University Hospital (SIUH) who were admitted with a Braden score of 18 or less. The period of enrollment extended from September 2012 to October 2014. Exclusion criteria applied to patients with soft tissue trauma, DTI, and/or full-thickness PUs involving all 13 US study screening sites and patients who were too ill to be moved to allow access for the US scanning. If the patient had at least 1 of the 13 sites free of PUs and was able to be moved for US access, the patient could be approached for enrollment in the study. All sampled patients had Braden scores of 18 or below; scores were routinely assessed and recorded in the emergency triage department by the registered nurses assigned to the triage area. The decision for admission to the hospital was made before approaching patient for consent.

This project was reviewed and approved by the Staten Island University Hospital Institutional Review Board (IRB). All participants or their legal authorized representative (LAR) provided signed, informed consent except when the patient was incapable of consenting and no LAR was present; in such situations, a waiver of documentation of consent was granted by the IRB to perform telephone consent with an LAR/health care proxy. Decisional capacity was determined from interaction with the patient and/or results of a physical exam, admitting history, or review of a patient’s medical record.

Instruments.

US. The US technology used 2.5 MHz transducer frequency for large patients (BMI >30) to 12 MHz transducer frequency for smaller patients. Different ranges of frequency produce different levels of penetration. The narrower range (2.5 MHz) penetrates deeper (ideal for scanning of organs and deep soft tissue;) the broader range (12 MHz) diffuses over a broader area of body surface and does not penetrate...
### SCANNING WORKSHEET

(S=sacrum, RB1=right upper buttock, RB2=right lower buttock, LB1=left upper buttock, LB2=left lower buttock, RGT=right greater trochanter, LGT=left greater trochanter, RLA=right lateral ankle, LLA=left lateral ankle, RH=right heel, LH=left heel, RLF=right lateral foot, LLF=left lateral foot)

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Figure 2. Ultrasound Scanning Worksheet.
as deep (best used for scanning on small, thin adults or on pediatric patients).\textsuperscript{37,38}

Before the beginning of the study, 4 US technicians, selected by the radiologist, were taught the difference between the appearance of rashes, abrasions, and bruises and DTIs. The technicians were instructed to avoid scanning any sites with dressings in place. Also, the technicians were given the radiologist’s and CWON investigators’ contact information so either could help them until they felt more competent in their assessments. The same radiologist read and documented on all the scans and the same CWON enrolled patients and did the follow-up skin assessments. The sites scanned for the study included the sacrum, upper buttocks (left and right), lower buttocks (left and right), hips (left and right), lateral malleoli (left and right), lateral foot areas (left and right), and heels (left and right). The size of the DTI was noted by the radiologist in cm and entered into the patients’ medical record. The study included the sacrum, upper buttocks (left and right), lateral malleoli (left and right), lateral foot areas (left and right), and heels (left and right). The size of the DTI was noted by the radiologist in cm and entered into the patients’ medical record (EMR).

The primary outcome variables for each eligible site included whether the US was negative (-) or positive (+) for DTI and, whether a PU was or was not visible within 7 days after admission (PU-, PU+). The absence or presence of a follow-up PU was considered the reference “gold standard” in this study because, in order to calculate the sensitivity of the US to the presence of DTI in the deep tissues, it had to be demonstrated that the appearance of a PU days afterward corresponded to an US+ scan and that specificity when a PU did not appear afterward corresponded to an US- scan. It was expected US+ scans would occur without the appearance of PU afterward (lower than 100% specificity) due to the body’s potential to heal wounds deep in the soft tissues in the same way it heals open wounds on the skin, depending on the fluctuating general condition of the person.

Documentation. A Scanning Worksheet was used by the technicians to alert the radiologist to the scans with any abnormal findings and to record any skin findings that precluded scanning (see Figure 2). This worksheet featured an area for the technician to enter remarks for each of the 13 sites that could indicate if the scan revealed soft tissue abnormalities.

Methodology. The study CWON investigator identified patients with Braden scores <18 in the ED who were being admitted as inpatients. After informed consent was obtained, blood and urine were collected to assess CK and Ca++ levels and myoglobins in the urine (UMGU). An order for a non-vascular lower extremity US scan (this specific MD order wording was used to alert all levels of the sonography personnel this was a study patient so the US would not be billed) was obtained from the covering physician. The US technician used the scanning worksheet to record any visual skin/wound findings on any of the 13 US sites and noted if any of the sites were excluded from scanning. The radiologist investigator entered an official report of the US findings that included lesion size into the patient’s electronic medical record (EMR). The study enrollment and the US scans were scheduled only on weekdays when all necessary personnel were available.

The CWON investigator performed daily skin inspections during the week following the scans; the last assessment was done on day 7. The patient’s EMR was reviewed during the 7-day study for any documented skin assessments done by the nurses on the patient’s unit. The CWON investigator kept a log of all study data for each participant. This included the Braden score at the time of entry into the ED in addition to a list of skin failure risk factors (SFRFs)\textsuperscript{a} the patient exhibited and the patient’s chief complaint upon the arrival in the ED. Most of the information collected was used in the statistical analysis to see if it corroborated with the Braden score and to determine its value to predict DTI formation. Each SFRF was given a number: 1 = Braden score <15, 2 = fever, 3 = hypotension, 4 = weight loss, 5 = coagulopathy (eg, presence or absence of deep vein thrombosis, bleeding episodes, abnormal clotting factors), and 6 = acidosis and/or respiratory failure. When entered into the patient’s log, the corresponding number was used to identify which factors were present. Each patient’s log listed an official report of the US findings included whether the US was negative (-) or positive (+) for DTI and, whether a PU was or was not visible within 7 days after admission (PU-, PU+). The absence or presence of a follow-up PU was considered the reference “gold standard” in this study because, in order to calculate the sensitivity of the US to the presence of DTI in the deep tissues, it had to be demonstrated that the appearance of a PU days afterward corresponded to an US+ scan and that specificity when a PU did not appear afterward corresponded to an US- scan. It was expected US+ scans would occur without the appearance of PU afterward (lower than 100% specificity) due to the body’s potential to heal wounds deep in the soft tissues in the same way it heals open wounds on the skin, depending on the fluctuating general condition of the person.

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![Figure 3. An ultrasound scan of a pressure-related deep tissue injury in the subcutaneous space (blue arrows). The pink arrow indicates the distal surface of the deep tissue injury originating from the bone level, erupting through the fascia into the subcutaneous space, and the green arrow indicates the discontinuous fascia near the origin of the deep tissue, both characteristic of deep tissue injuries originating at the bone.](image-url)
Results

Of the 33 patients enrolled, 3 did not have US scans and 7 were discharged from the facility before a follow-up assessment could be done, leaving 23 participants who completed the US and the 1-week follow-up skin assessments. A total of 299 sites were scanned (13 sites per patient). US findings were recorded for any soft tissue damage detected on scanning; these were found in the deep musculature at the level of the bone and/or in the SC fat (see Figure 3).

Of the 50 sites scanned that were US+ for DTI at the bone, 5 resulted in necrotic PU lesions on the skin, all noted on days 6 or 7 of the follow-up skin assessments (see Table 1). Of the 299 sites scanned, 249 sites were US- for DTI at the bone; none of those sites resulted in corresponding skin DTI. The resulting calculated sensitivity was 5/5 = 100% (47.8%, 100.0%) and the specificity was 249/294 = 84.7% (80.1%, 88.6%). The PPV was 5/50 = 10.0% (3.3%, 21.8%), and the NPV was 249/249 = 100.0% (98.5%, 100.0%). Overall accuracy for detecting DTI at the bone level was 254/299 = 84.9%.

Of the 299 US scans, 79 were positive for DTI in the SC layers and 5 of those scans resulted in necrotic skin lesions (DTI) within 2 days after the scanning. Of the 79 US+ scans in the SC layers (total 79 positive SC US scans out of a total 299 sites scanned), 74 did not result in skin lesions (see Table 2). The calculated sensitivity was 5/5 = 100.0% (47.8%, 100.0%), the specificity was 220/220 = 100% (98.3%, 100.0%), the PPV was 5/50 = 10.0% (3.3%, 21.8%), and the NPV was 249/249 = 100.0% (98.5%, 100.0%). Overall accuracy for detecting DTI at the bone level was 220/220 = 100% (98.3%, 100.0%).

The laboratory data (Ca++, CK, and UMGU) yielded inconsistent results. Two (2) of the 5 patients who had positive US at the bone level and resulting DTI 6 to 7 days after admission scanning had abnormally elevated CK (743 and 1845) and depressed Ca++ levels (7.5 and 7.2); 1 also had positive UMGU (+59). All other Ca++ and UMGUs were negative for all remaining patients. Four (4) additional patients who had US+ at the bone but were negative for follow-up DTIs on the skin had elevated CK levels.

Findings for the patients who were US+ DTI at the bone and corresponding visible skin PUs were correlated with their Braden scores: 4 out of 5 had Braden scores <15 (mean = 10.5), and 1 out of 5 had a Braden score >15 (score of 16). All patients who had US+ SC scans with positive skin necrosis (5 out of 5) had Braden scores <15 (mean = 11.2). Among the patients who were negative for PUs on the skin, the Braden scores ranged from 12 to 18 (mean 16.1). Only 1 of the 23 participants had negative US scans of all 13 scanning sites at both levels. Lesion sizes, although documented in the radiologist’s EMR report, were not used in the study.

For the purposes of statistical analysis, a Braden score of 15 or below was listed as the number 1 SRF in a list of 6. Among the 5 patients whose skin ulcers originated from US+ DTIs at the bone, 3 had 4 SRFs, 1 had 5 SRFs, and 1 had 3 SRFs (mean = 4.0). Among the 5 patients whose skin ulcers originated in the SC layer, 3 had all 6 SRFs, 1 had 4 SRFs, and 1 had 2 SRFs (mean = 4.8). Participants with US+ scans that were negative for skin PU averaged 1.9 SRFs. Only 3 of the 23 participants did not exhibit any of the SRFs; they had a mean Braden score of 17.5. Of these, 1 had no US+ sites and 2 had US+ DTI sites. All 3 who did not have SRFs were negative for skin PU.

Discussion

This pilot study suggests US is a viable tool for screening for DTIs that are present on admission and not yet manifested on the skin surface. Of the 23 patients who finished the study, approximately 20% exhibited subsurface DTIs on US that later appeared on the skin as PUs. If the group is limited to persons with Braden scores 16 and under rather than 18 and under, the rate of pressure-related skin necrosis that was previously detected by US increases to 35%. As noted earlier, interest had been shown in exploring US to detect underlying pressure necrosis not yet visible on the skin, but this is the first study to utilize hospital-grade US with great penetration that could explore all layers of the soft tissue over bony prominences and the first to follow the participants to collect data on the skin outcomes. If found to have sufficient sensitivity and specificity in larger studies, especially positive predictive value, adding a DTI scan to the facility admission protocol for patients with a Braden score of 16 or less can document DTI on the patient before a PU develops in the early days after admission. The facility then would then have US documentation the lesion was present on admission even though it has yet to appear on the skin, assuming the wait time in the ED before admission is kept short. US would also provide the physician (the radiologist) documentation of the
examination, assessment, and PU diagnosis that is required by the CMS.

Another reason for US DTI scanning of patients Braden scores <15 and documenting other SFRFs is the diagnosis of rare soft tissue conditions that may help interpret the patient’s admission symptoms/complaints. Diabetic muscle infarctions (a form of rhabdomyolysis) can be detected on US within 6 hours of occurrence. The infarcted muscle can later ulcerate the skin and mimic PUs.

According to case studies, calciphylaxis may be misdiagnosed as pressure-related DTI; in this condition, parathyroid-related calcium emboli to the skin and soft tissues result in necrosis similar to PUs that occur in the subcutaneous layers. One of the current study patients who presented with DTI at the bone (the calciphylaxis lesions do not originate at the bone level) also had embolic SC lesions under a presenting rash (raising suspicion of calciphylaxis). A parathyroid hormone level was ordered by the ED physician, which confirmed the diagnosis. Calciphylaxis has the potential to be much more deadly than PUs and diabetic muscle infarction because it is progressive and late in the disease, large tracts of soft tissues die, making differential diagnosis crucial.

In this study, the sensitivity of US for detecting DTIs before they reach the skin was 100%. Although the specificity was 84%, 100% of the US sites did not become PUs on follow-up. The study data also revealed in bone sites that were US+ and subsequently PU+, the skin PU appeared on day 6 or 7. However, the more superficial US+ SC lesions that gave rise to a PU did so after only 2 days.

Although not included as part of this study, new damage theoretically can occur at the SC level after an US- was done on admission and can still appear on the skin within a 7-day follow-up assessment because the damage is closer to the skin. This might be observed in a larger study replicating this research and could be a factor in a false decrease in the sensitivity calculation. However, this US study clearly indicates deep tissue damage at the bone, in its advance toward the skin, takes 6 to 7 days for the PU to appear on the skin, even though the lesions on the scan appear to be in different distances between the bone and the skin.

Animal studies have noted dead muscle becomes stiff. It has been theorized the stiffness may cause a shearing edge and death of the soft tissue above it and the dead tissue may cause damage to tissues above it, progressing in the same process. However, if the principles of forensic science regarding decomposition described earlier are applied, another more plausible explanation can be proposed: the likelihood of advancing decomposition of tissue that is already dead from bone to skin that has been noted on US. In the study by Steeds, early US depiction of rhabdomyolysis from a diabetic muscle infarction included dense hyperechoic white lesions noted in scans taken within 24 hours of the muscle death. In their description of muscle death in the early postmortem period, Henssge et al noted dead muscle tightly contracts (rigor mortis) within the early hours of muscle death and the decomposition of the muscle cells subsequently releases the contraction. Within the first 12 hours in the living person with muscle death, the CK starts to rise as the dead muscle decomposes. Therefore, because the areas detected by US in this study were all hypoechoic, US was most likely performed after rapid decomposition at warm core temperatures at bone level and closer to room temperatures at SC level had occurred, and liquefication of the dead tissues was in progress (capillaries disintegrate within a few hours). In fact, although the ED physician’s decision to admit usually takes place within a few hours after arrival in the ED at this particular facility (SIUH), it usually is still another 2 to 3 hours before the actual admission can be done. However, once the decision to admit has been made, the patient is transferred to a holding area where patients with Braden scores <18 are placed on a specialty bed that has pressure-relieving technology. Patients who arrive in the ED and who are unable to reposition themselves are placed in a single-bed room within the ED itself with the same pressure-relief technology within 2 to 3 hours after arriving. The exact time spent in the ED up until the enrollment in the study was not recorded because these policies already were in place before the study had begun. However, all the study patients had been enrolled and had undergone scanning before 12 hours had passed; all participants were “same day” admissions and enrolled and scanned before 4 pm (the study personnel were only scheduled to work on the 8 am to 4 pm shift). Although the patients in this study had multiple medical conditions and all but 1 had multiple SFRFs, none of the study patients was critically unstable or needed to be transferred to the operating room or intensive care units more immediately upon arrival.

Additional studies also are needed to ascertain whether invisible (on the skin) DTI detection is most optimally assessed using US or CT scanning of the same likely occurrence sites. A forensic investigation in preparation for a PU lawsuit a few years before the current study involved review of a CT scan of the abdomen of the plaintiff before admission to the hospital; the CT was performed to find the source of severe abdominal pain that was the reason for the admission. The plaintiff’s diagnosis was made and needed surgery was provided, but a week after the admission, the plaintiff developed a large purple DTI on the skin over the sacrum. The CT of the abdomen taken on admission showed significant disruption of the soft tissue over the sacral bones. Although this was not reported in the documentation of the CT scan, it was still noted as a significant piece of evidence in the case, and the case against the hospital was dropped.

CT scanning already has been examined in case series regarding diagnosis and detection of soft tissue aberrations after plastic surgery for sacral PUs, complications of sacral PUs, detection of rare abscesses associated with spinal cord injuries (SCIs), and quantifying changes in the gluteus maximus musculature after SCI. In addition, CT scanning has been demonstrated in case series to be a valuable addition to forensic
pathological investigations, replacing dissection in tracking the trajectory of deep ballistic penetration of the brain, thorax, and abdomen (ie, locations in the body where ballistic objects can be deflected off irregular bony structures).

Although US adds ~15 minutes to the physical examination, no radiation is involved, which makes it safe to do in an ED cubicle protected only by curtains and thin partitions. Using US enables the technician to change the imaging plane instantly without moving the patient. This capability is not currently present in CT scanning. Although both modalities can show details of soft tissues (as opposed to bone), only the CT scan can do a “still” scan of blood vessels, bone, fat, muscle and organs all at the same time. However, this capability is not necessary for DTI scanning.

Limitations

The major limitation of this study is the small number of participants and potentially important variables collected.

Implications

This study was conducted in the hospital setting and in the ED, which most closely aligns with the major potential for the application of the study — that is, for screening for “present on admission” DTI. The finding that 20 of the study participants with Braden scores 16 and under had soft tissue defects, many of them DTIs originating at the bone (potentially the forerunners of Stage 4 pressure injuries), may suggest many PUs start at home. In this study, it was found that approximately 20% of these participants had early, unseen by visual examination DTIs that became visible 6 to 7 days after admission but not all patients with US+ findings will develop a PU. Specifically, the positive predictive values were 10% for deep tissue and 6.3% for US+ findings in SC layers. Studies using large sample sizes are needed to confirm the results of this pilot study and evaluate patient variables in order to optimize patient selection to improve the positive predictive value of this test. In the meantime, facilities might want to consider the potential benefits of incorporating US DTI scans into their ED admission protocols for patients arriving with Braden scores 15 and under and with documentation of SFRFs, providing they would be willing to absorb the cost of extra radiology technicians and their training and with the understanding that the scans would not be billed.

Conclusion

In this pilot study, US of common PU sites could detect pressure-related DTIs that had the potential for full-thickness PU development. Although the participants scanned had Braden scores 18 or less, participants with Braden scores of 15 or less had the highest risk and PU development on the skin was confined to this segment of the study group. If larger studies confirm the results of
this study and the validity (PPV and NPV) of US screening can be optimized, instituting protocols for US DTI screening on admission may help improve PU prevention protocols for targeted populations and be effective for avoiding reimbursement fines for PUs that develop after the patient’s admission, decrease litigation, and decrease the costs of managing facility-acquired PUs.

Acknowledgments
The authors are grateful to the NYS DOH NYPASE Patient Safety Initiative Panel of Pressure Ulcer Experts for their voluntary, relentless contributions for more than 2 years in the pursuit of a pertinent, clinical definition of skin failure and the most significant systemic contributions to the development of said definition (“The Skin Failure Risk Factors”): John Maese, MD, MACP, FACEP, FHMSS, CHCQM; Thomas Fealey, MD, FACP; Mary Beth Francis, RN, MS, LNHA, FACHCA; Roseanne Burrell, BSN; George Harrington, MD, FACP; Debra LeBarron, RN, BS; Edward F. Dombroski, RPh, MA, MD; Anna Collelo, Esq; Peter Smith, MS, RN, FNP; Azza Ezzat, MS, FNPBC, DNP(c); Gary Giangola, MD, FACS; Adrienne Liander, MA, RN, CGNS-BC, LNHA; Jane Ellen Barr, MSN, CWOCN, ANP; Kathleen Francis, MSN, RN, CWOCN; and Marcy Suba, MS, RN, CWON.

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