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High Frequency Ultrasound Sacral Images in the Critically Ill: Tissue characteristics versus visual evaluation

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Abstract

Purpose—High frequency ultrasound (HFUS) systems may identify tissue injury. We compared HFUS tissue characteristics (dermal thickness and dermal density) with visual image examination.

Methods—Longitudinal study in critically ill mechanically ventilated adults, from 3 ICUs (Surgical Trauma, Medical Respiratory, Neuroscience) enrolled within 24 hours of airway intubation. Sacral HFUS images were obtained daily for up to 7 days. Expert evaluation of the best image per day was completed and compared to HFUS generated tissue characteristics (dermal thickness and dermal density).

Results—Of the 113 subjects with 1614 comparisons analyzed, 73.2% to 84% were normal, and 6.3% to 11.8% of the comparisons had injury present but no change was noted in the injury observed. There were no significant differences in one-day comparisons among type of injury and mean dermal thickness ($p = 0.6645$) or dermal median intensity (adjusted $p = 0.06$ – 0.17). All other day-to-day comparisons were similarly non-significant.

Conclusions—We found no association among dermal density, dermal thickness and visual examination of changes in sacral HFUS images for any day-to-day comparison. The use of sacral

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Conflicts of interest: none

HFUS as a screening tool for the development of tissue injury is in its infancy. Additional comparative studies should be conducted to identify its future clinical usefulness.

Keywords

high frequency ultrasound; pressure ulcers; evaluation; critical care

Ultrasonography has been widely used in clinical practice as an inexpensive, non-invasive and portable diagnostic tool. High frequency ultrasound (HFUS) using a –20MHz probe has been used to provide images for both dermatologic practice and research^{1–3} with more limited data available about the use of HFUS to evaluate tissue characteristics in the development of pressure ulcers (PUs).^{4–9}

In mechanically ventilated, critically ill patients, pressure ulcer risk is high and may result in negative patient outcomes and increased health care costs.^{10–14} Methods to quantitatively evaluate patients at risk or identify early stages of pressure ulcer development, especially the more elusive, deep tissue injuries are limited.^{4,15} Certain deep tissue injuries may develop through a “deep-to-superficial” pattern resulting in delayed clinical recognition of significant and often extensive tissue injury and changes.^{4,16} Deep tissue injury and the resulting inflammation may cause tissue edema and tissue changes that may be identified using HFUS.^{4,8} Recently, Aliano et al.¹⁷ found in 20 patients with pressure ulcers that all had some evidence of deep tissue injury upon ultrasound examination. Since deep tissue ulcers are difficult to recognize, identification of quantitative measures to determine risk and early stage tissue injury, which may be invisible to visual skin examination, would be clinically useful.

In addition to producing HFUS images for visual evaluation, HFUS systems provide quantitative data and objective measurements to show contrast between healthy tissue and tissue with change, which may assist in the detection of subtle changes over time that may not be identified by visual assessment of images alone.¹⁸ The most common tissue characteristics are dermal thickness and dermal density (also referred to as echogenicity).^{19–21} However, there are no data that compare changes in these tissue characteristics (dermal thickness and dermal density) to changes found using visual evaluation of the HFUS scan to determine the usefulness of these HFUS objective tissue measures for early identification of tissue injury. Therefore this secondary analysis of data from a larger study,²² will compare sacral HFUS tissue characteristics (dermal thickness and dermal density) with visual examination of the HFUS image.

METHODS

Sample and Setting

The parent study, from which this analysis was derived, was a descriptive, longitudinal study of skin integrity of 150 intubated and mechanically ventilated adult patients from a medical respiratory ICU (MRICU), surgical trauma ICU (STICU) or neuroscience ICU (NSICU) to describe the relationship between backrest elevation, tissue interface pressure and skin integrity.²² The study was approved by the university Institutional Review Board (IRB) and

informed consent was obtained from the subject's legally authorized representative (LAR). Because the parent study included use of a pressure mapping system that may enhance skin moisture, exclusion criteria included patients who had significant skin moisture risk as determined by the Braden scale of "constantly moist".²³ Subjects were enrolled in the study within 24 hours of airway intubation and sacral HFUSs were obtained daily for up to seven days. Data were collected from February 2010 through May 2012.

Measures

High Frequency Ultrasound Scans. Sacral tissue was evaluated using a high (20MHz) frequency ultrasound dermal scanning system (EPISCAN, Longport, Inc, Glen Mills, PA). The EPISCAN settings on all images were as per manufacturer's recommendation for sacral scans and were consistent to insure uniformity of measurement between images: size – 512×1024; TGC srt = 0%; pos = 16.0; depth = 10.2mm; TGC = 10%; gain = 20%. However, in this critically ill population, it was not possible to obtain scans in the prone position as recommended by the manufacturer, rather HFUS sacral images were obtained in patient side-lying positions as close to a side-lying, 90 degree lateral rotation as possible, based on the clinical condition of the patient. All sacral scans were therefore obtained in the lateral position with the subject turned from 60 to 90 degrees.

Tissue Characteristics (dermal thickness, dermal density). Use of HFUS to evaluate tissue injury has indicated that patterns of fluid accumulation or edema within dermal and hypodermal tissue may be early indicators of tissue injury.^{7,8,24,25} Changes in dermal and hypodermal thickness (in millimeters) and dermal and hypodermal layer density (median signal intensity distribution) may reflect tissue inflammation.²⁶ EPISCAN HFUS software-generated measurements include measures for layer thickness and layer density.^{9,27,28} Layer thickness is a measure of the width of the layer (dermal and hypodermal), therefore in non-chronic skin conditions, as inflammation and edema increases, layers become thicker.²⁶ In this study we evaluated only sacral dermal thickness as a measure of inflammation. Three thickness measurements were obtained for each image and the average of the three were used in the analysis. Interrater reliability of the three measurements was excellent with an average deviation of 0.03mm over all subjects and a range from 0–0.92mm.

Dermal density measured in this study is the median signal intensity distribution of the image. Colours represent the intensity of the signal reflected from the tissue and therefore the structure of the tissue. Statistical analysis of the colour distribution may detect subtle changes that cannot be reliably detected by the visual assessment of the images. The median intensity (or colour) is the intensity/colour at the center of the distribution profile.²⁹ Dermal density may decrease as fluid accumulates since the tissue would appear less dense in the ultrasound image.³⁰ Use of HFUS in the evaluation of tissue injury then is dependent on accurate measures (dermal and hypodermal layer thickness, dermal and hypodermal layer density) that may reflect changes or injury in the dermis or hypodermis layers. However the evaluation for this study focused only on the dermal layer as the hypodermal depth can reach beyond the limits of useful HFUS evaluation. Therefore the median signal intensity distribution was used as our measurement of dermal density.

HFUS Visual Evaluation. To assure process standardization and consistency between the two HFUS image evaluators, serial comparisons and evaluations of results occurred regularly. To select the best HFUS image for evaluation, all sacral images per patient per day were independently rated by each evaluator based on our previously published evaluation process.³¹ In that process we evaluated 241 HFUS sacral images in three analyses from the first 40 subjects for agreement between the two expert evaluators using criteria for overall image quality. We found agreement was good to substantial and is reported in detail elsewhere.³¹

When inconsistencies occurred, an agreed upon best image per patient per day was selected and used for evaluation. The best image for one patient in succession in order of patient day was then aligned on the computer monitor to facilitate recognition of changes from day to day in both edema and tissue change. Images were visually evaluated based on change from the previously available image and then gauged on the presence of edema as well as tissue change per patient per day and categorized as: normal; injury with no change; injury and improving; injury and worsening.

Procedure

The Medical Center Wound Care Program nurse practitioner and co-investigator (VL) or another co-investigator (RSB) who were both certified in EPISCAN evaluation trained all study personnel to obtain EPISCAN sacral images for the parent study. Training continued until the study personnel achieved full accuracy in following all recommended image processes (correct patient position, accurate probe location, identification of a good scan at the bedside) and performed return demonstrations. On a weekly basis, one expert investigator (RSB) reviewed the scans obtained by each study personnel and if any individual person submitted poor quality images remedial training was immediately begun. In addition study personnel were continuously monitored during onsite visits and re-training was conducted every 3 months or more frequently if needed.

In an evidence-and consensus-based guideline, Stechmiller et al.³² found that pressure ulcers develop within the first 72 hours of an ICU admission. Limited data are available that describe the complete time frame for pressure ulcer manifestation, especially for deep tissue injury.³³ Therefore, to document all potential sacral changes, HFUS images were obtained daily up to 7 days or until hospital discharge whichever occurred first. Palpation of the coccyx was used to determine location for the HFUS probe. The HFUS system creates and captures a series of images at 1-second intervals, the operator then adjusts the probe to produce an optimal scan. Several of the highest quality captured images were saved. The best scan per day was then identified as described above. In obtaining tissue characteristics from the HFUS images, a shape annotation was used to enclose the dermal layer from which the tissue characteristics were derived. Full dermal layer thickness measurements were obtained in a maximum of 3 equidistant locations inside the selected area for measurement.

Sacral images were obtained in the early morning whenever possible but were also coordinated with the patient's usual care activities so as to not disturb the patients unnecessarily. Due to critical illness or care requirements, subjects may not have been

available to obtain images during every study day. Subsequent statistical analysis incorporated these multiple observations as patient-specific repeated measurements.

Data Analysis

Based on our previous work, the best image per patient day was used for evaluation.³¹ The two experts (RSB, TL) evaluated each EPISCAN image for each patient day and where differences in evaluation occurred, they conferred until agreement on the evaluation was reached. Changes in the image were evaluated based on change from the previous image and then categorized by type of injury as normal (no injury), injury with no change, injury and improving, injury and worsening. Individual changes in dermal thickness and dermal density (median intensity) were computed as single one-day, two-, three-, four-, five-, six and 7-day changes by subtracting the former day's measurement from the later day's measurement. Therefore, each subject had up to 7 single day comparisons. Day 0 was the day of study admission, with day 1 as the day after study admission, resulting in the 7 single day comparisons (day 0 to day 1, day 1 to day 2, day 2 to day 3 etc. to day 6 to day 7), 6 two day comparisons (day 0 to day 1, day 1 to day 3, day 2 to day 4, etc.), and so forth up to one single 7 day comparison (day 0 to day 7). Daily image change based on the expert tissue evaluations of type of injury (normal, injury with no change, injury and improving, and injury and worsening) were then linked to image measurements (dermal thickness, dermal median density).

The extent of data and type of injury for each patient was observed. A mixed (regression) model was used to examine the relationships between type of injury of normal, injury with no change, injury and improving, and injury and worsening with respect to mean dermal thickness and dermal median intensity. Separate models were built for the outcomes of dermal thickness and median intensity as well as for one, two, three, four, five, six and seven day changes. Repeated observations of one-day (or two day, etc.) changes were modeled using a random effect and patient BMI, APACHE score upon admission, age, race, and gender were considered as covariates. The main effect of type of injury was further examined using contrast statements which compared either mean dermal thickness or dermal median intensity between the four types of injury to determine whether or not dermal thickness or median intensity varied by type of injury (normal, injury with no change, injury and improving, and injury and worsening). An experiment-wise alpha level was set to 0.05 and a Bonferroni correction was applied to comparisons among the four types of injury. All computations were completed using SASv9.2.

RESULTS

Subjects and Images

Subjects were primarily male, essentially evenly distributed between White and African Americans and were primarily MRICU patients (Table 1). Time to study enrollment from airway intubation was 0.60 days on average. In general, patients were middle aged (mean=56 yrs, SD=17.5), overweight (mean=27.87 kg/m², SD=6.59) and had a mean APACHE score of 78.44 that ranged from 20 to 154 (Table 1). For the 136 subjects, there were a total of 1088 possible study subject days, however due to unavailability of subjects

(critical condition, off the unit, care issues, etc.) data was available for 786 study subject days, with a mean of 5.78 study days per subject. Missing or poor sacral HFUS imaging further reduced available data for analysis. Thus, out of the 136 subjects with a potential for 952 one-day comparisons, there are 113 subjects with a total of 467 one-day comparisons, 348 two-day comparisons with remaining available data shown in Table 2.

Including all comparisons from one-day comparisons (day 0 to day 1, day 1 to 2, day 2 to 3, day 3 to 4 etc.) through seven-day comparisons (day 0 to day 7), there were a total of 1614 comparisons analyzed (Table 2). The majority of these comparisons, however, were normal, that is the type of injury was evaluated as normal (no injury) throughout all comparisons (ranging from 73.2% to 84% of the comparisons), or there was injury present but no change was noted in the injury observed, ranging from 6.3% to 11.8% of the comparisons (Table 2).

Comparison of Tissue Characteristics and Image Evaluation

There were no significant effects among the covariates of BMI, apache score, age, race and gender on either mean dermal thickness or dermal median intensity in any day comparison model, 1-day through 7-day. For the one-day comparison model, there were no significant differences among type of injury in mean dermal thickness ($p = 0.6645$) however the average dermal median intensity was much higher (about 4 units; Table 3) when injury was worsening ($p = 0.0669$). Unadjusted p-values comparing mean dermal median intensity for one-day comparisons when injury was worsening (mean = 3.91, SE = 1.58) to 1) when injury was improving (mean = -0.70, SE = 1.39), or 2) when there was no change in injury (mean = -0.14, SE = 1.25), or 3) when no injury was observed (mean = -0.10, SE = 0.81), ranged from 0.010 to 0.028, however, the associated Bonferroni adjusted p-values were not significant (adjusted p 0.06–0.17). There were no significant differences among type of injury for mean dermal thickness or dermal median intensity in the two-day comparisons ($p = 0.9826$ for dermal thickness and 0.4853 for median intensity). Model results for larger multiple day comparisons (3 day, 4 day, 5 day and 6 day changes) were similarly non-significant for both mean dermal thickness and dermal median intensity.

DISCUSSION

This secondary analysis of data from a larger study,²² compared sacral HFUS tissue characteristics (dermal thickness and dermal density) with visual examination of the sacral HFUS image over multiple day-to-day comparisons, up through study day 7 for 113 critically ill subjects. We found no association among dermal density, dermal thickness and visual examination of changes in sacral HFUS images for any day-to-day comparison.

The subjects were critically ill, mechanically ventilated and represented a variety of types of critical illness (medical, surgical, neurologic) and were therefore at greater risk for tissue injury,^{10,34,35} however when HFUS images were evaluated, the vast majority of these evaluations showed normal images or no change in the HFUS image over the study period.

Data to identify the time frame for the onset of tissue injury is limited. Gefen et al.³³ evaluated data from three models (surgical patients who developed tissue injury; animal studies of tissue viability after loading and in vitro models in cell cultures and tissue-

engineered constructs) and found that subdermal tissue injury under bony prominences very likely occurs between the first hour and 4 to 6 hours after sustained loading. Other authors have found in animal models that visual skin changes may not occur until day 7 after tissue loading.⁴ Since the actual timing of sustained tissue loading is unknown, we evaluated tissue changes as close to airway intubation and mechanical ventilation as possible, when the risk for tissue injury may increase,³⁶ as well as tissue changes throughout the entire study period. Even with this comprehensive evaluation of tissue change, we were unable to observe any association among HFUS tissue characteristics (dermal thickness and dermal density) with visual changes in the HFUS image.

Recently Aliano et al.¹⁷ evaluated 20 patients admitted with sacral pressure ulcers using high-frequency ultrasound (although used 12MHZ vs 20MHZ used in our study) to identify evidence deep tissue injury. All patients were found to have some evidence of deep tissue injury using ultrasound. However they reported descriptions of hypo-echogenicity rather than the tissue characteristics we used here, making comparisons across studies difficult.

Measures of tissue characteristics (dermal thickness and dermal density) may vary significantly among subjects and conditions making evaluation of these changes during tissue injury more difficult. Recently we reported sacral tissue characteristics (dermal thickness and dermal density)³⁷ in a sample of normal volunteers, in three different positions (prone, 60 and 90 degrees). For those in the 60 and 90 degree positions (similar to study subjects) mean dermal thickness measurements ranged from 2.61 to 2.65 (SD 0.54) while mean dermal density (median intensity) ranged from 110.44 to 112.29 with wide variability (SDs ranging from 9.0 to 9.09). HFUS manufacturers specify a measurement error range of $\pm 1\%$. The changes we found for dermal thickness in this sample during the multiple day comparisons were well within the range we found in normal volunteers (i.e. all changes less than 0.526). Changes found during multiple comparisons for dermal density were all less than 8.22 and less than the variability found in the normal sample in similar positions. Although others have reported skin characteristics using HFUS including thickness,^{19,21,28} these have not, to our knowledge, included sacral dermal thickness. In addition, just prior to data collection, the study units implemented a protocol using a sacral adhesive pad. The pad may have reduced skin shear possibly leading to the reduction of pressure ulcers.

Common and standard HFUS measures of tissue injury are not available. For this relatively new technology in the evaluation of tissue injury, the use of the single measurement of dermal thickness and dermal density (median intensity) as we have reported here, is not universal. Other authors have reported pixel distribution analysis using the ratio of low echogenic pixels (LEP) to total pixels (TP) to reflect changes in dermal water content.^{5,6,38} Use of this ratio may reduce the variability found we found in dermal density. Other have used HFUS image evaluation comparison to photography and use of neural networks decision systems in guinea pigs²⁷ to detect pressure ulcer phases, although both HFUS and photographs must be available for this methods.

The use of HFUS as a screening and monitoring tool for the development of tissue injury, although attractive, as an easy to use, non-invasive tool is in the infancy of its use and comparative studies and common measures and language must be developed.

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IMPLICATIONS FOR CLINICAL PRACTICE

- Identification of early tissue injury prior to the development of pressure ulcers is ideal.
- Common and standard HFUS measures of tissue injury are not available.
- There was no association between sacral HFUS tissue characteristics and visual examination of changes in sacral HFUS images.
- Additional comparative studies should be conducted to identify HFUS clinical usefulness.

Table 1

Subject Characteristics (N = 136)

	N	%		
Gender				
Male	77	56.62		
Female	59	43.38		
Ethnicity				
AA	67	49.26		
White	66	48.53		
Unknown	3	2.21		
ICU *				
MRICU	56	41.18		
STICU	44	32.35		
NSICU	36	26.47		
	Mean	SD	Range	
Age	56.05	17.50	18–90	
Apache	78.44	26.97	20–154	
BMI	27.87	6.59	12–45	
Time from airway intubation to study admission (days)	0.60	0.28	0.01–1.33	

* MRICU = Medical Respiratory ICU; STICU = Surgical Trauma ICU; NSICU = Neuroscience

Table 2

Subjects with existing data stratified by the number of one-day through seven-day comparisons and by the type of injury observed (N = 113 subjects; N = 1614 comparisons)

Day comparisons	1 Day	2 Day	3 Day	4 Day	5 Day	6 Day	7 Day
Total # of Subjects with Comparisons	113	102	98	91	86	66	45
Total # of Day Comparisons	467	348	278	219	161	96	45
Type of Injury Observed	1 Day N (%)	2 Day N (%)	3 Day N (%)	4 Day N (%)	5 Day N (%)	6 Day N (%)	7 Day N (%)
Normal	342 (73.2)	259 (74.4)	204 (73.4)	166 (75.8)	127 (78.9)	77 (80.2)	37 (82.2)
Injury with no change	55 (11.8)	36 (10.3)	23 (8.3)	19 (8.7)	14 (8.7)	6 (6.3)	4 (8.9)
Injury and improving	40 (8.6)	33 (9.5)	29 (10.4)	21 (9.6)	13 (8.1)	10 (10.4)	1 (2.2)
Injury and worsening	30 (6.4)	20 (5.8)	22 (7.9)	13 (5.9)	7 (4.3)	3 (3.1)	3 (6.7)

Table 3

Model estimated mean change in thickness and median intensity by type of injury observed for all day comparisons*

	Type of Injury Observed in HFUS Image Visual Examination During Day-to-Day Comparisons							
	N	No Injury Mean (SE)	N	Injury-No Change Mean (SE)	N	Injury-Improving Mean (SE)	N	Injury-Worsening Mean (SE)
Thickness								
One day change (N=467)	342	0.005 (0.046)	55	-0.046 (0.072)	40	0.071 (0.079)	30	0.034 (0.092)
Two day change (N=348)	259	0.011 (0.056)	36	0.004 (0.093)	33	0.021 (0.093)	20	0.056 (0.119)
Three day change (N=278)	204	0.026 (0.060)	23	0.079 (0.106)	29	0.142 (0.094)	22	0.112 (0.108)
Four day change (N=219)	166	0.095 (0.077)	19	0.120 (0.120)	21	0.103 (0.112)	13	0.244 (0.144)
Five day change (N=161)	127	0.093 (0.097)	14	0.229 (0.161)	13	0.526 (0.144)	7	0.002 (0.202)
Six day change (N=96)	77	0.173 (0.112)	6	0.020 (0.218)	10	0.335 (0.160)	3	0.262 (0.277)
Seven day change (N=45)	37	0.309 (0.192)	4	0.150 (0.341)	1	0.057 (0.600)	3	0.401 (0.355)
Median Intensity								
One day change (N=467)	342	-0.098 (0.808)	55	-0.140 (1.251)	40	-0.700 (1.387)	30	3.910 (1.580)
Two day change (N=348)	259	-0.025 (0.907)	36	1.589 (1.507)	33	-1.340 (1.512)	20	0.836 (1.926)
Three day change (N=278)	204	0.689 (1.070)	23	0.465 (1.920)	29	-1.095 (1.700)	22	4.760 (1.960)
Four day change (N=219)	166	0.929 (1.275)	19	1.754 (2.078)	21	1.175 (1.937)	13	1.417 (2.520)
Five day change (N=161)	127	2.031 (1.623)	14	1.288 (2.725)	13	1.653 (2.518)	7	4.168 (3.573)
Six day change (N=96)	77	3.135 (2.125)	6	2.153 (4.051)	10	2.123 (2.959)	3	8.220 (5.142)
Seven day change (N=45)	37	1.481 (3.095)	4	2.664 (5.489)	1	3.336 (9.661)	3	3.072 (5.711)

* There were no significant differences among type of injury for mean dermal thickness or dermal median intensity for any one-day comparison or multiple day changes (2 day, 3 day, 4 day, 5 day, 6 day and 7 day changes).