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Validity of pressure ulcer diagnosis using digital photography

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Abstract

The purpose of this study was to evaluate the validity of digital photographs for the assessment of the presence of pressure ulcers stage 2 or higher. Participants were 48 patients (28 white and 20 black) with pressure ulcers identified in the course of a wound specialist's routine clinical practice at the University of Maryland Medical Center. One pressure ulcer and one unaffected skin area were photographed on each participating patient. The gold standard diagnosis (stage 2 pressure ulcer vs. stage 1 or no pressure ulcer) was recorded by the wound specialist based on bedside examination. The photographs were reviewed blindly by another wound expert. The sensitivity of the blinded assessment was 97% (95% confidence interval [CI] 91–100%). The specificity was 97% (95% CI 92–100%). The sensitivity and specificity were both 100% in the white patients. In black patients, the sensitivity and specificity were 92% (95% CI 75–100%) and 93% (95% CI 82–100%), respectively. These results suggest that the use of photographic images to assess the presence or absence of a pressure ulcer stage 2 or higher has a high degree of validity. Since blinded outcome assessment is one of the cornerstones of good clinical trial design, photography offers the potential to strengthen future studies.

Elderly patients with pressure ulcers experience pain, diminished quality of life, longer hospital stays, and potentially serious complications.^{1–3} Pressure ulcers in the hospital setting are considered to be a preventable complication and Medicare has announced plans to stop reimbursing hospitals for the cost of treating hospital-acquired pressure ulcers.⁴ This move by Medicare, as well as other national initiatives,^{5–7} will likely increase interest in the development and evaluation of interventions to reduce pressure ulcer incidence.

The use of randomized controlled trials (RCTs) is the preferred method for obtaining definitive information about the safety, effectiveness, and cost of pressure ulcer prevention strategies. One such prevention strategy involves the use of pressure-reducing support surfaces such as overlays, replacement mattresses, and heel protectors. Blinding of observers in RCTs of this type of pressure ulcer prevention device is difficult because the presence or absence of the devices, which are usually on the patient's bed, chair, and/or body, is obvious to the examiner who conducts the pressure ulcer assessment. Temporarily removing all devices or moving patients out of their rooms before each assessment can be excessively burdensome to patients, care providers, and research staff.⁸

Lack of blinding of the outcome assessment has been cited as one of the major weaknesses of the literature on the effectiveness of support surfaces for the prevention of pressure ulcers.⁹ Only a few randomized studies have used blinded outcome assessment. Blinding was used in three trials of operating table support surfaces;¹⁰⁻¹² blinding in this type of trial is feasible because the pressure ulcer assessment is carried out postoperatively, after the patient has been removed from the support surface. In four trials of wheelchair cushions,¹³⁻¹⁶ the cushions being compared had an identical outer covering that, according to the authors, made it possible to blind the assessors. No other trials of support surfaces have used blinded outcome assessments.

The use of a digital photography protocol represents a possible solution to the problem of blinding in RCTs of pressure ulcer prevention devices. With such a protocol, research staff take digital photographs, at each assessment visit, of a standard set of anatomic sites for all patients in both the experimental and control groups. Standard definitions of the boundary and orientation of the area to be photographed are used. Care is taken by the photographer to ensure that pressure-redistributing devices are not visible in the photo so that blinding can be maintained. The photographs are then assessed by two or more blinded expert adjudicators and their consensus diagnosis is used as the primary outcome measure.

A protocol such as this is only appropriate if the assessment of pressure ulcer status based on photographs accurately reflects the patient's true pressure ulcer status. The goal of this study was to evaluate the validity of digital photographs for assessing the presence of pressure ulcers stage 2 or higher in the context of randomized trials of pressure ulcer prevention interventions.

MATERIAL AND METHODS

Patients with pressure ulcers were identified in the course of routine clinical practice by one author (J.L.S.), a wound specialist at the University of Maryland Medical Center who is certified as a wound ostomy continence nurse and has almost three decades of experience in pressure ulcer diagnosis, prevention, and treatment. One pressure ulcer and one unaffected skin area on each participating patient was photographed. Two digital photographs (distance and close-up) of each skin area were taken by a research coordinator who accompanied the wound specialist at the bedside; sample photographs showing a stage 4 pressure ulcer and an unaffected skin area are in Figure 1. A Sony® (San Diego, CA) digital still camera, model DSC-P100, was used. Photos were taken with full overhead room lighting and the camera was set for 5.1 megapixel images, forced flash, and multi-auto focus. Photos were composed such that the patient's face and any identifying marks were not visible. The gold standard diagnosis was recorded by the wound specialist based on her bedside examination of the patient. The photographs were assembled, copied to a compact disk, and submitted to another author (D.J.M.), a dermatologist and internationally recognized expert in wound assessment and treatment. The reviewer, who was in a different geographic location from the one where the patients were identified and the bedside diagnosis made, reviewed each pair of photos (distance and close-up) on a computer screen and recorded his assessment of the pressure ulcer stage (0=no pressure ulcer; 1-4=stage 1 to 4 pressure ulcer; 5=unstageable pressure ulcer). For the purpose of the analysis, both the bedside diagnosis and the photographic diagnosis of a pressure ulcer were dichotomized as stage 2 or higher (yes/no). The study was approved, and a waiver of consent granted, by the Institutional Review Board of the University of Maryland, Baltimore.

Sensitivity and specificity were calculated. Sensitivity was defined as the proportion of skin areas identified as a pressure ulcer at the bedside that were also identified as a pressure ulcer from the photograph. Specificity was defined as the proportion of skin areas identified as not a pressure ulcer at the bedside that were also identified as not a pressure ulcer from the photograph. Ninety-five percent confidence intervals for sensitivity and specificity were estimated based on 1,000 bootstrap samples.¹⁷ This method was utilized to account for data

sparseness and for potential correlation related to the fact that some participants contributed both a stage 1 pressure ulcer and an unaffected area to the specificity estimate.

RESULTS

A total of 48 patients participated, 28 white and 20 black. There were two pairs of photos for each patient, one of a pressure ulcer and one of an unaffected area, for a total of 96 pairs of photos. Because of technical problems, one pair of photos of a pressure ulcer was excluded. The remaining 95 pairs of photographs depicted 48 unaffected areas and 47 pressure ulcers (14 stage 1, 15 stage 2, two stage 3, 10 stage 4, and six unstageable). Of the 33 pressure ulcers stage 2 or higher (including unstageable), 32 were rated correctly from the photographs (sensitivity 97%, 95% confidence interval [CI] 91–100%) (see Table 1). Of the 62 pairs of photos that depicted a skin area with a stage 1 pressure ulcer or no pressure ulcer, 60 were correctly diagnosed from the photograph (specificity 97%, 95% CI 92–100%). Both the sensitivity and specificity were 100% in the white patients. The sensitivity and specificity were 92% (95% CI 75–100%) and 93% (95% CI 82–100%), respectively, in the black patients.

DISCUSSION

The results of this study support the validity of a photography protocol for the blinded assessment of the presence of pressure ulcers stage 2 or higher. Ninety-seven percent of pressure ulcers diagnosed at the bedside were detected on the photographs; 97% of areas judged to be unaffected at the bedside were identified as unaffected from the photographs. The results were only slightly less positive (92% sensitivity and 93% specificity) when limited to black patients, despite the fact that pressure ulcer detection in persons with darkly pigmented skin might be more challenging.¹⁸

Photography of wounds is used in telemedicine, where electronic transmission of digital images, in conjunction with relevant clinical data, makes it possible for expert consultants to assess wounds from a remote location. Several studies have assessed the accuracy of telemedicine systems for the assessment of healing and other clinical indicators in chronic wounds,¹⁹ surgical wounds,²⁰ and varied dermatological conditions.²¹ A study by Frantz and Johnson²² examined the use of stereophotography and computerized image analysis for the three-dimensional measurement of wound healing, and reported that their proposed method had high reliability. Houghton et al.²³ reported a high correlation between the photographic assessment of chronic pressure and vascular ulcers and the appearance of these wounds based on a clinical assessment at the bedside. Some studies have used photographs of pressure ulcers to assess validity and reliability of observers' assessments for research, clinical, and quality improvement purposes.^{24–30} However, no studies have examined the validity of photographs for the differentiation of pressure ulcers stage 2 or higher from unaffected areas in the context of prevention trials.

This study has several limitations. First, the validity of the photographic assessment of pressure ulcers was evaluated in relation to a gold standard assessment that, itself, may not be perfectly valid. It seems likely that an expert wound specialist with many years of experience would provide an accurate assessment of pressure ulcer status and, in the absence of an established biological marker of pressure ulcer status, this type of expert clinical assessment is the best gold standard currently available. Still, the validity of the gold standard would have been stronger if it was based on an assessment by more than one examiner. In addition, while the validity of photographic assessment was similar in whites and blacks, we cannot address the concern that the diagnosis of pressure ulcers is more difficult in persons with dark skin. It is possible that pressure ulcers in black patients were underdiagnosed equally by the bedside observer and the photograph reviewer. Second, only one reviewer rated the photographs taken

at the bedside. Although the results of this study cannot be generalized to the universe of all reviewers, the study does provide preliminary evidence of validity that would have to be verified in the context of any specific RCT in which the method was to be used. Finally, the assessment was a fairly simple one, involving only the differentiation of skin areas with and without a pressure ulcer stage 2 or higher. Because there was no attempt to evaluate the accuracy of the description of the pressure ulcer's clinical characteristics (e.g., stage, eschar), the results of this study are not applicable to telemedicine where detailed information about the wound's appearance, cross-sectionally, and over time, is necessary to guide treatment.³¹ A related limitation is that this study does not shed light on the question of whether a photography protocol is effective at detecting stage 1 lesions where there is no skin breakdown. However, in many RCTs of pressure ulcer prevention interventions, the primary outcome of interest is the onset of pressure ulcers stage 2 or higher. The results of the current study suggest that in such RCTs, photography can be used to provide valid information on the dichotomous outcome variable; more detailed descriptive information about stage and clinical characteristics can be obtained by unblinded research staff.

Use of photography to assess the primary outcome variable in clinical trials of pressure ulcer prevention imposes several constraints. A set of standard anatomic sites must be selected and all selected sites must be photographed on all study participants so that the decision to perform photography is not based on the unblinded judgment of the researcher. This requirement could add significantly to the cost and complexity of study coordination. Patient's burden may be increased due to the extra time and patient repositioning that is needed. To assure the visual quality of the photographs, research staff must receive intensive training with emphasis on proper focus and lighting. To ensure consistency, staff must also be trained to follow standard specifications for framing and orienting the photographs, and to ensure that pressure-redistributing devices are not visible. Finally, the blinded expert adjudicators need to use similar software and hardware to view the photographs, and an image management system, possibly web based, needs to be developed to handle the digital photographs. The need for high-quality hardware, such as cameras and computers, and for an efficient and secure image management system can also add significantly to the cost.

In most published RCTs of support surfaces for the prevention of pressure ulcers, the outcome assessment has not been blinded, a fact that is cited as a significant weakness of this body of literature.^{9,32} The results of the current study suggest that the use of photographic images to assess the presence or absence of a pressure ulcer stage 2 or higher has a high degree of validity, although further studies with a stronger gold standard assessment and a larger number of raters would strengthen this conclusion. Since blinded outcome assessment is one of the cornerstones of good clinical trial design,³³ photography offers the potential to strengthen future RCTs and provide more conclusive evidence regarding the effectiveness of pressure ulcer prevention strategies.

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Figure 1.

(A). Example of a photograph used in the validation study, depicting an unaffected skin area.

(B). Example of a photograph used in the validation study, depicting a stage 4 pressure ulcer.

Table 1

Detection of pressure ulcer on photograph, by diagnosis of pressure ulcer at bedside

	Bedside diagnosis	
	Pressure ulcer	No pressure ulcer
Pressure ulcer detected on photograph	32	2
No pressure ulcer detected on photograph	1	60
Total	33	62

Pressure ulcer defined as stage 2 or higher, including unstageable.