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The theory and practice of pressure ulcer/injury risk assessment and early detection: a critical discussion

Abstract

Pressure ulcer/injury risk assessment is widely considered as an essential component in clinical practice. It is a complex and broad concept including different approaches such as clinical judgement, using standardized risk assessment instruments, skin assessments or using devices to measure skin or tissues properties. A distinction between pressure ulcer/injury risk assessment and early detection is important. Pressure ulcer/injury risk measures the individual susceptibility to develop a pressure ulcer/injury under a specific exposure (primary prevention) and early detection includes the assessment of early (sub)clinical signs and symptoms to prevent progression and to support healing (secondary prevention). Pressure ulcer/injury risk is measured using prognostic/risk factors or prognostic models. Every risk estimate is a probability statement containing varying degrees of uncertainty. It follows, that every clinical decision based on risk estimates contains uncertainty, too. Indeed, pressure ulcer risk assessment and prevention is a complex intervention, where delivery contains several interacting components. There is a huge body of evidence indicating that risk assessment, outcomes of risk assessment, the selection of preventive interventions, and pressure ulceration are not well connected. Methods for prognostic model development and testing in pressure ulcer/injury risk research must be improved following state-of-the-art methodological standards. Despite these challenges, we do have substantial knowledge about pressure ulcer/injury risk factors that helps to make better clinical decisions. A striking next step in development of pressure ulcer/injury risk prediction might be the combination of clinical and other predictors for more individualized care. Any prognostic test or procedure must lead to better prevention at acceptable costs.

Key words

Pressure injury, pressure ulcer, risk assessment, early diagnosis

INTRODUCTION

Pressure ulcers/injuries (PUs) are localised skin and underlying soft tissue damage, wounds or necrosis due to prolonged pressure, or pressure in combination with shear.[1] They typically occur over bony prominences or due to the prolonged contact with medical devices.[2] Underlying pathways of PU development include deformation damage leading directly to cell death, ischaemia and reperfusion inury and impaired lymphatic function.[2-4] Like many other health problems and diseases, PUs seem to be as old as mankind itself [5] and recent systematic reviews indicate high prevalence and incidence across various populations and settings.[6-9]

Because of the severity of this unwanted condition and the substantial impact on individuals and healthcare systems, PU prevention is critical.[2] State-of-the-art PU prevention includes risk assessment, skin and tissue assessment, and preventive interventions including but not limited to repositioning and early mobilization, use of special support surfaces, skin care or nutrition.[2] Because of the importance of effective prevention, various quality and patient safety indicators have been proposed to measure the quality of PU prevention whereby PU incidence is most often used.[10] PU occurrence has also been identified as one core outcome to be measured in clinical PU prevention trials.[11] However, despite available clinical practice guidelines[2 12 13] and high quality evidence summaries,[14-16] there are many areas in PU prevention where the quality of evidence is low, where evidence is missing or difficult to generate leading to ongoing debates and controversies about best clinical practice.[17 18] One such area is PU risk assessment.

PU risk assessment is a complex and broad concept including different approaches such as clinical judgement, using standardized risk assessment instruments, skin assessments looking at erythema or using devices to measure skin or tissues properties such as temperature or oedema.[2] The concept of risk describes the probability with which a health outcome will occur.[19] Per definition probabilities range from 0 to 1, but because they are probabilities, they are never 0 or 1. Related to PUs, even the best risk assessment method cannot predict with certainty whether a PU will develop or not. Every risk estimate is a probability statement containing varying degrees of uncertainty. It follows, that every clinical decision based on PU risk estimates (e.g. allocation of special support

surfaces) contains uncertainty, too, which contributes to the ongoing discussion of over- and undersupply of PU preventive measures.

When considering PU prevention and management it is important to make a distinction between PU risk assessment and PU early detection (Table 1). PU risk estimates the individual susceptibility to develop a PU under a specific exposure. The skin and underlying tissues are intact and the diagnosis is a predictive statement. The overall preventive goal is to keep the skin and tissues intact (primary prevention). Early detection includes the assessment of early (sub)clinical signs and symptoms (e.g. oedema, erythema, pain, blood or tissue markers) to prevent progression and to support healing (secondary prevention).

Table 1. Distinction between pressure ulcer/injury risk assessment and ulcer/injury early detection

Both strategies are relevant and there are overlaps, but they follow different measurement principles and have unique challenges. In recent years, PU early detection received increasing attention in PU research[20-22] and clinical practice[2 23] and a number of reviews are available.[24-28] Therefore, the focus of this contribution is a critical discussion of the theory, practice and current challenges of PU risk assessment, and to discuss implications for risk assessment practice and research.

PRESSURE ULCER/INJURY RISK ASSESSMENT

Risk assessment is widely considered as an essential component in clinical practice to identify individuals who are susceptible to PU development. The basic programme theory is that once the individual risk has been identified, tailored individual PU prevention is implemented (Figure 1).[2]

> Fig 1. Programme theory for pressure ulcer risk assessment <

Although in theory this appears straightforward, in practice risk assessment is a complex intervention, where their delivery contains several interacting components,[29] including the assessment itself (and associated challenges regarding the concept of risk and how this is summarised and communicated), the potential outcomes and decisions about care interventions and their implementation set within the

context of complex health care environments that are responsible for the delivery of safe and quality care. There is a huge body of evidence indicating that risk assessment, outcomes of risk assessment, the selection of preventive interventions, and PU incidence are not well connected.[30-36] However, results of diagnostic or prognostic tests must improve clinical decision making, otherwise any risk measurement makes little sense.[37] Establishing evidence linkages between the different steps of the PU prevention (Figure 1) and evidence from adequately designed diagnostic randomized controlled trials are urgently needed.[30 37] To support this further work is also needed to gain a deeper understanding of 'what works, how, for whom, in what circumstances and to what extent.[38 39] Structured PU risk assessment is a resource to clinicians and its impact on care is dependent on how it is used in practice, which will differ according to context.[40] This requires an understanding of causality via consideration of context, mechanisms and outcome configurations or realist/programme theories, to clarify how different contexts elicit particular nursing team responses and give rise to different outcomes.[41] This approach is becoming more common in the evaluation of complex interventions [42] and is considered particularly appropriate for the evaluation of new interventions, to explore how an intervention can be adapted for different contexts and where trials have shown conflicting outcomes, to better understand why these inconsistences occur.[43]

Quantifying pressure ulcer/injury risk

In clinical research and practice, risks are measured using prognostic factors, often referred to as risk factors in the PU context. A prognostic factor is any variable that is associated with the probability of a subsequent health outcome among people with a particular health condition.[44] In the PU field, hundreds of prognostic factors have been proposed and are investigated.[2 45 46]

It is essential to point out that the strength and direction of associations of prognostic factors with subsequent PU development highly depends on the population and setting, because most factors are associated with each other and interact. For example, mobility and other common PU risk factors are associated with health and illness in general. This explains the various reports showing for example associations between PU risk and sarcopenia,[47] disease severity of patients admitted to intensive care units,[48] length of stay and outcomes in geriatric rehabilitation or internal medicine,[49 50]

or coronary artery disease.[51] PU risk may be regarded as a general marker of poor health, severe disease and functional impairments.[31]

Interaction describes a situation, when one prognostic factor modifies the effect of another with regard to the occurrence of an outcome.[52] In PU research this typically occurs, when the effect of immobility (prognostic factor) on PU development (outcome) differs depending whether the patient is placed on a support surface or not (effect modifier). Therefore, preventive interventions must be taken into account in every prognostic study, otherwise obtained prediction estimates and models are wrong or biased.[53 54]

Furthermore, the association of prognostic factors with risks of subsequent health outcomes do not automatically imply causality.[52 55] The majority of known PU risk factors do not cause pressure ulceration, rather increase or decrease the likelihood, but only if direct causal factors (e.g. immobility, poor perfusion) are present.[56] This conceptual distinction has major consequences for clinical practice and research. For example, only interventions aiming at reducing the magnitude and duration of mechanical loads (including repositioning, mobility promotion, offloading) will have direct and immediate preventive effects.[57] All other preventive interventions such as improving nutrition, the improvement of a diabetic metabolic state, or managing incontinence are indirect.

Irrespectively from multiple associations and interaction, there is a huge body of evidence supporting the relevance of a number of prognostic factors for PU development including activity and mobility limitations, diabetes mellitus, perfusion and circulation, impaired nutritional status and many more.[2] Although useful for PU assessment and clinical decision making, there are at least two additional challenges:

(1) Many risk factors describe ‘systemic’ characteristics such as age, diabetes mellitus, or ‘skin maturity’ in children,[2] but PU development is always a local phenomenon. Most prognostic factors are not skin area specific and the actual PU risk depends on the actual loading condition while sitting, lying, standing or being exposed to medical devices.

(2) There is a huge body of evidence that ‘external’ mechanical loads (e.g. lying on a stiff support surface) lead to highly variable and individual internal local stresses and strains within loaded soft tissues.[58] For example, the anatomical shapes of the calcaneus or sacrum influence how much the

tissues in close proximity to these bones are deformed leading to different intrinsic PU risks.[59-61] A specific tolerance to soft tissue deformation damage is also highly likely.[62] It is currently impossible to determine this highly individual 'biomechanical risk'[59 63] externally or using any clinical predictor. Therefore, every currently known prognostic factor contains a large amount of error, because it is impossible to observe the actual degree of tissue deformation under the skin surface.

Standardized pressure ulcer/injury risk assessment instruments and scores

Standardized PU risk assessment instruments, scales or scores play an important role in risk assessment practice for decades.[2] The first standardized PU risk instrument was developed by Norton et al. in the 1960es.[64] In fact, this instrument was developed only for research purposes, but "… nurses expressed regret when these forms were removed from the wards on completion of the investigation."[64] Since then, these scales entered clinical practice. Today, there are probably more than 100 so-called risk assessment scales and new scales are still constantly being developed and existing instruments 'validated' and/or modified.[65-69] Their use in clinical practice is well established and is still supported by nurses, who value them as an aide memoir to support clinical judgement and an important mechanism for PU prevention.[70]

PU risk assessment instruments incorporate varying prognostic factors which are traditionally used to create an overall score to estimate PU risk. They are prognostic prediction models. Compared to single prognostic factors, prognostic prediction models estimate the individual probability of a future health outcome (here pressure ulceration) by combining information from multiple prognostic factors from an individual.[71 72] Criticisms of many risk assessment instruments include inadequate development methods (including lack of statistical modelling) and lack of conceptual framework and limited evidence of target population involvement during development i.e. clinical nurses and patient/carers, all of which have led to inconsistent prognostic/risk factor inclusion raising concern about their content validity.[54 73]

There is a huge and growing body of evidence about measurement properties of PU risk scores including reliability, sensitivity, specificity, predictive validity, and receiver operating characteristic curves. Evidence summaries indicate that these measurement properties vary widely[2 13] and

discussions about risk score measurement performance are ongoing. Similar to single prognostic factors, the population and setting substantially affect the discrimination ability to distinguish between individuals developing or not developing the outcome of interest. In general, the more homogenous a population (or study sample is), the less discrimination can be achieved by prediction models[71] also leading to low reliability.[74] Even if the relative measurement error in terms of reliability is low, the absolute measurement errors in terms of proportions of agreement or limits of agreement are much too high, to support any use of overall risk scores or cut-offs.[31 69 75] Therefore, similar to nearly every other measurement instrument in general, PU risk assessment scales cannot be 'validated' in terms of their predictive validity.[76] Validity or reliability estimates are not fixed properties of a score.[77] Under specific conditions, obtained risk scores may show certain measurement properties that will be fundamentally different in (slightly) other situations. If authors claim that a prediction model is clinically valuable, it should at least be studied in another independent study in a different physical location.[72] Newly developed scores should never be tested using the data set with which the score was developed.[77] Overall, methods for prognostic model development and testing in PU risk research seem to be flawed and do not follow methodological standards.[54] Further limitations are that studies often focus on assessing the predictive validity of only one instrument, rather than multiple models in the same study population for comparison.[78]

It is important to emphasize, that PU risk scores are causal indicators[79] or formative models (Figure 2).[80] The individual prognostic factors of the model determine the concept of PU risk; they are not effects or consequences of PU risk.[81] The individual factors may or may not be associated with each other but the concept of internal consistency does not apply. Therefore, although widely done,[82 83] it is inappropriate and meaningless to calculate or to interpret Cronbach's alpha or similar measures in the context of PU risk scores.

> Fig 2. The conceptual structure of pressure ulcer/injury prediction models <

Another major limitation of PU risk scores is that they consist of a fixed number of prognostic factors. Not every factor of the used score is relevant for everyone and there might be other factors not captured by the score relevant for the individual. The International Clinical Practice Guideline explicitly says, that a risk assessment tool "does not replace a comprehensive assessment conducted by an appropriately qualified health professional."[2]

Instead of using overall risk scores, a practical criticism of traditional risk assessment instruments, it has been proposed to focus on single items of these scores to guide clinical decision making.[67 84] This approach seems to be questionable too, because often the range of risk factors included is limited/variable and far from a comprehensive assessment.[2]

Finally, evidence about measurement properties is different from clinical effects or effectiveness. Even if single prognostic factors or prognostic models show good measurement properties, evidence about the clinical effectiveness is needed to answer the final question of clinical relevance regarding patient outcomes.[32 85]

Alternative approaches to measure pressure ulcer/injury risk

To overcome the many shortcomings of prognostic factors and models, there is a strong interest in alternative strategies. One is real-time pressure mapping.[2] It is a widely applied method, to visualize the amount of pressure at the skin support surface interface indicating areas of high compression. This information can be immediately used to reposition and/or off-load subjects or skin areas to reduce local pressure.[86] However, while there is a clear relationship between interface pressure, position, support surface and individual characteristics,[87-89] the association with internal soft tissue deformation and PU development seems to be weaker.[90 91] Therefore, possible interface pressure thresholds and durations are also unknown[92] and it is unclear how the interface pressure readings inform clinical decisions. Similar to standardised risk assessment scales, evidence linking pressure mapping with improved patient outcomes is weak.[2 93]

While there are a many parameters including skin and underlying soft tissue properties,[22 23] inflammatory local[28 94] or systemic blood markers[21] associated with (early) pressure ulceration, it is

much more complicated to find similar biomarkers measuring intrinsic PU risk when skin and tissues are intact. Systemic blood biomarkers including albumin have been proposed proposed,[2 95] but it is unlikely that any single chemical, biological or biophysical parameter or reading will have better predictive validity than any of the known clinical prognostic factors, because they face the same limitations as described above.

A more promising way may be measuring the individual resistance against mechanical loading. Compared to other biological systems, the functional capacity is much more meaningful to characterise the likely response of skin and soft tissues compared to snapshot or 'basal' measurements.[96-98] These tests involve artificial controlled stress, stimulus or irritation applied to the skin or tissue and are widely used in skin research.[99-105] Based on the reaction, conclusions can be drawn about the response, capacity and likely resistance. One popular approach in PU risk research is to measure blood flow responses to characterise microvascular function. For example in healthy individuals, moderate compression of the skin leads to vasodilation, which is called pressure induced vasodilation and considered to be a compensatory response. Evidence suggests, that the absence of this physiological response is associated with skin fragility and increased PU risk.[106 107] Recently, artificially induced reactive and heat hyperaemia responses were compared between patients with and without PUs[108] and other 'microvascular stress tests' might be possible.

The advantages of these functional parameters are that they capture highly individual characteristics leading to individual risk quantification and individualized prevention. On the other hand, evidence suggests, that there is a high degree of biological variability in skin responses after mechanical loading and irritation.[94 105 109] Another open question is to what extent the measurement of specific functional markers is meaningful with regard to the overall complex multifactorial PU development process.[2-4]

WHAT DOES THIS ALL MEAN FOR CLINICAL PRACTICE?

Optimal methods of PU risk assessment are unknown. Currently, a two step-approach is considered best practice (Figure 3)[2 73 110]: (1) As soon as possible after admission to care services or institutions, a

screening should be conducted. Although the concept of screening may have various meanings in healthcare, it mainly describes examinations or testing procedures in healthy people to detect 'something putatively prognostic'[111] to initiate prompt interventions. Regarding PU risk, screening includes a (fast) standardized assessment of *major risk factors* (such as mobility limitations) that are relevant for the population and setting.[2] (2) If a PU risk is likely, a comprehensive PU risk assessment needs to be conducted. This includes a detailed evaluation of major and condition specific risk factors.[2]

> Fig 3. Process of pressure ulcer/injury risk assessment <

Summaries of major and specific prognostic factors can be found in systematic reviews,[45 46] clinical guidelines[2] or diagnostic manuals such as the NANDA International.[112] Setting and population specific clinical algorithms[113-115] or risk assessment pathways[73] seem to be helpful to support this process. It is the responsibility of the organisation and management to select factors for screening and comprehensive assessment and to develop and implement a risk assessment pathway that fits to the respective service, setting and supports clinical decision making.[2 110 116]

There are two practical consequences of this two-step approach; one is that those who are clearly not at risk can be quickly screened out, without the need for a more time consuming comprehensive assessment (allowing more appropriate use of nurses time) and the other is that the screening step is not needed at all in high risk settings. For example in intensive care, in the operating room or in spinal cord injury patients it not helpful to perform regular screenings, because a PU risk can be assumed for everyone.

It should be kept in mind that the communication, perception and understanding of risks in healthcare is challenging in general. Evidence indicates that there seem to be particular differences between healthcare professionals and care receivers who are at PU risk.[117] This needs to be taken into account for care planning and implementation.

WHAT DOES THIS ALL MEAN FOR RESEARCH?

After decades of PU risk research it is important to adhere to highest methodological standards for identifying, developing and testing prognostic factors and models in the future. Compared to clinical effectiveness research, diagnostic and prognostic research also follows a stepwise approach.[118] (Table 2).

Table 2. Phases of clinical prognostic pressure ulcer/injury risk research

PU risk research should begin with the development of a theoretical model (phase 1). Various sources of evidence might be used including exploratory empirical studies. The next basic question is, whether subjects with PUs differ regarding candidate factors from subjects without PUs (phase 2a). Cross-sectional or case-control studies might be used and are widely applied in this this early stage. Next questions should be, whether subjects with certain test results have or will develop PUs. This should be followed by questions, whether the test results in the relevant population and setting discriminate between those who will develop a PU and those who will not. The only acceptable designs to describe this possible prediction are longitudinal (phase 2b). If prognostic factors are known already, phase 2b studies should be done immediately. Establishing any (additional) cross-sectional association is not helpful. These phase 2b studies should also look at measurement properties.[77 80] Finally, evidence is needed to show, if and how the testing procedure leads to better outcomes (phase 3) at acceptable costs (phase 4).

We firmly believe that the described phases should be followed subsequently. Depending on the prognostic factor and the underlying evidence it may be possible to combine phases 2a and b, but it makes no sense to look for example a health economic evaluation (phase 4) without showing the superiority of one prognostic procedure compare to another (phase 3). Any prognostic factor or model should be applied in clinical practice only, if all of the questions have been answered satisfactorily using appropriate designs[55 72] and reporting.[77 119] High certainty evidence needs to be established between prognostic factors and PU development.[120]

Especially phase 3 studies are challenging, because it maybe difficult to connect prognostic factors or models directly with PU development (Figure 1).[32] These studies must develop/evaluate clearly defined diagnostic pathways or decision algorithms. The results of the prognostic factor or model must inform PU prevention practice.[37]

There is a huge body of evidence about prognostic factors for PU development. Therefore, there might not be a need for finding new predictors, but to develop better models following state-of-the-art methods.[54] Neither clinical predictors nor biomarkers alone will substantially significantly improve PU prediction compared to what we already have today. Most likely, it will come to a combination of different clinical, biological, or biophysical predictors in the future.[94]

CONCLUSIONS

PU risk assessment was, is, and will remain a critical first step in PU prevention. After decades of PU risk research we must acknowledge the underlying uncertainty of each prognostic factor or model and that an 'objective' or best assessment does not exist. Despite this uncertainty, we do have substantial knowledge about PU risk factors that helps to make better clinical decisions that support PU prevention. The challenge is, how this existing knowledge is translated locally. A striking next step in development of PU risk prediction might be the combination of clinical and other (e.g., tissue markers) predictors for more individualized care and how these can be implemented in healthcare organisations to improve processes of care and outcomes. Any prognostic test or procedure must lead to better prevention at acceptable costs.

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