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Review Article

The Development of Healthcare Measurement Tools: a Case Study of the Psoriasis Area and Severity Index

Raed Alhusayen[1]*

[1]University of Toronto

*Corresponding author: Raed Alhusayen, University of Toronto, 2075 Bayview Ave, Rm M1-700, Toronto, ON, Canada, M4N 3M5, Tel: +1 (416) 480-4908, Email: raed.alhusayen@sunnybrook.ca

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Abstract

The usefulness of measurement tools in healthcare depends on having sound methodological foundation. This paper examines the development and the evaluative properties of the Psoriasis Area and Severity Index against the well established methodologies for the development of measurement tools in healthcare research.

Keywords: Outcome Measures, Psoriasis, PASI, Research Methods

Introduction

The treatments for plaque psoriasis, which vary according to the severity of that disease, range from relatively inexpensive conservative topical therapies to systemic medications that cost thousands of dollars per course [1]. Dermatologists caring for those patients need a validated tool for assessing the severity of plaque psoriasis and for evaluating the response to treatment. There is no consensus about the definition of psoriasis severity, which differs according to the perception of the assessor [2-4]. For example, a patient might define the severity of his or her psoriasis according to its impact on daily life, a healthcare administrator would do so according to the cost of treatment and the use of resources, and a dermatologist might define psoriasis severity according to the extent and physical signs of that disease [1,3,5].

The distribution, size, and appearance of psoriatic lesions vary with disease severity and activity [6,7].In the absence of a laboratory marker, objectively assessing psoriatic disease severity is challenging, and clinicians must rely on the results of physical examination. Although some physicians rely on their memory to evaluate changes in a patient's psoriasis over time, others use drawings to mark the location of the skin lesions at the time of each assessment. However, that approach is not practical because hundreds of lesions might develop on 1 patient.

The 3 potential applications for healthcare measurements are discrimination, prediction, and evaluation [8]. Quality-of-life tools are discriminative measures used to classify individuals into groups according to the presence or absence of the disease of interest. Cancer staging, for example, is a predictive tool used to classify patients into groups according to the expected outcome. The psoriasis area and severity index (PASI) is an evaluative tool used to measure the change in the severity of psoriasis over time.

The PASI was developed to assess the effect of retinoid treatment on chronic plaque psoriasis [9]. When the PASI is used, the affected area and the characteristics of the psoriatic lesions are applied to a formula that yields a score ranging from 0 to 72 in which "0" represents no disease and "72" represents the worst possible disease [5]. That tool is considered the gold standard in defining the severity of plaque psoriasis, and most clinical trials that pertain to psoriasis base their findings on changes in the patient's PASI score [1,6]. Furthermore, it is used to validate new measures. Because the PASI was designed to be used in clinical trials, the feasibility of using it in

clinical practice is a reasonable concern. Although that measurement tool was developed to evaluate the response to a specific treatment (i.e. retinoid therapy), there is no reason to believe that the measurement of response to one treatment should be different from the measurement of response to other treatments.

Development of the PASI

In 1978, a published randomized controlled trial conducted by Fredriksson and Pettersson evaluated the efficacy of a new oral vitamin A derivative in the treatment of plaque psoriasis [9]. To assess the response to that treatment, those investigators introduced the PASI as a new measurement tool for assessing the severity of that disorder. The justification for developing a new tool for that purpose was the need for "... a more specific score system, than what is used in most clinical studies of topical antipsoriatic drugs, i.e., 'bad, moderate, good, excellent'." [9].

The PASI uses the affected body area and lesion characteristics to determine a global PASI score [10]. The following description of the score is derived from original research by Fredriksson and Pettersson and a further explanation by Exum and colleagues [9-11]. To derive a PASI score, body area is first categorized into 4 separate regions: the head (h), the upper extremities (u), the trunk (t), and the lower extremities (l), which account for 10%, 20%, 30%, and 40%of the total body area, respectively. The affected area (A) for each of those 4 regions is determined (ie, Ah, Au, At, and Al) and is assigned a numerical value from 0 to 6 where 0 represents no involvement, 1 represents < l0%, 2 represents 10% to<30%, 3 represents 30% to < 50%,4 represents 50% to < 70%, 5 represents 70% to < 90%, and 6 represents 90% to 100%. Lesion severity is defined by 3 physical characteristics: erythema (E), infiltration (I), and desquamation (D). Each of those characteristics is rated separately for each of the 4 body areas by using a 5-point scale in which 0 represents no involvement, 1 represents slight involvement, 2 represents moderate involvement, 3 represents striking involvement, and 4 represents exceptionally striking involvement. The ratings for those characteristics are added for each body area, multiplied by the PASI area score, and then multiplied by the appropriate weight for the particular body region. Those scores are then added to determine the final PASI score. Thus the formula for calculating the PASI can be written as follows:

PASI = O.lAh(Eh + Ih + Dh) + 0.2Au(Eu + Iu + Du) + 0.3At(Et + It + Dt) + 0.4Al(El + Il + Dl)

The process that Fredriksson and Pettersson followed to develop the PASI is not clear. They indicated that the items of that tool were selected based on clinical judgement and they have offered no discussion about item generation or reduction [9]. It is not clear whether the variables and their weights were chosen after consultation with experts and stakeholders or were chosen only by the authors.

Because information about the development of the PASI is limited, an overview of the ideal process of developing an evaluative clinical index will be provided in this article [12].That process, in which a blended approach of psychometric and clinimetric techniques is used, is summarized as follows:

Item generation: Several methods have been suggested for item generation. The main sources for item generation are literature searches, clinical experience, and the experience of a group of experts [13].It seems that the developers of the PASI used their clinical experience to select the items used in that tool. Although that is an important step, ideally 2 other steps are required: (1) searching the literature to identify the clinical signs used to evaluate the activity of plaque psoriasis, and (2) conducting personal or electronic interviews with experts in the field. Following those steps will yield an extensive list of potential variables for inclusion in the item reduction stage.

Item scaling: The choices available to clinicians to answer each of the items must be diverse enough to be sensitive to change [8]. Although a dichotomous item is optimal for a discriminative or prognostic tool, it is inappropriate in an evaluative tool. The aforementioned 5-point scale of the PASI is a reasonable choice, but that will be further tested in the item analysis stage.

Item reduction: A group of clinicians expert in the field should be convened to select the final items from the list generated in the item generation phase [13]. It has been suggested that the consensus group technique is superior to other group techniques such as the nominal group technique or the Delphi method [14]. The selected items should undergo item analysis by testing the tool on a sample of patients among whom the severity of psoriasis varies greatly. This will provide information about ceiling or floor effects and no-response items. If any of those problems is discovered, the affected items should be adjusted and examined again on a new sample. Because the various items in the PASI represent a single domain, disease activity in the skin, a high degree of internal consistency is expected. However, the use of internal consistency in evaluative measures has been questioned [8,13]. The rationale is that evaluative indices do not need to be correlated at a single point of time but rather, they should be consistent in the way in which they measure change over 2 points in time. Furthermore, increasing the number of items, which usually results in a higher estimate of internal consistency, carries the risk of including items that are not sensitive to change. Instead of the internal consistency, the emphasis should be on the ability of the items to detect change [8]. Although inter-

nal consistency is of lesser importance, it still needs to be addressed because it provides valuable information about the correlation between the different items and between the items and the overall score. In summary, striking a balance between internal consistency, the ability of the instrument to detect change and feasibility is more appropriate than relying solely on any one of those factors.

Sensibility of the PASI

The sensibility of the PASI can be examined according to the principles proposed by Bombardier and Deyo[15,16].

Purpose, population, and setting: The PASI is an evaluative tool that researchers can use to assess changes in psoriasis severity in the setting of clinical research. The randomized controlled study for which the PASI was developed consisted of individuals who were older than 18 years of age and had been diagnosed as having plaque psoriasis [9]. The results of that study showed that the PASI was effective in detecting the response to treatment. As a result, that index became the most commonly used tool in randomized controlled trials that studied the severity of psoriasis.

Content validity: As discussed previously in this article, there are different perspectives among stakeholders regarding the definition of psoriasis disease severity. The PASI represents the perspective of clinicians and researchers. This is implied by the use of clinical judgement in selecting the items used in that tool. Furthermore, those items consist of clinical signs of plaque psoriasis that are detected during the physical examination of the patient. No items in the PASI pertain to previous treatment, medication cost, or the impact of psoriasis on quality of life, all of which might be important to the patient. In addition, the PASI consists of a single domain. Erythema, induration, and scaling of the skin are items that reflect the severity of skin inflammation, which is the underlying process of plaque psoriasis. In patients with severe psoriasis, the skin lesions are more red and more indurated and are covered with a thicker scale than those in patients with less severe disease. Because psoriasis is not diagnostically revealed in the results of laboratory chemistry panels, the absence of physical signs is thought to indicate that the disease is in remission. Thus even though the development process of the PASI was not ideal, it seems a reasonable tool to use in clinical research, considering the conceptual framework and measurement needs of clinicians and researchers.

Face validity: Each item of the PASI (erythema, induration, scaling) is assigned a score between 0 and 4 for each anatomic site.Each score is multiplied by the percentage of the surface area of the anatomic site that is involved. The total of those scores is weighted by the percentage of the total body surface area for that anatomic site. A clear advantage of that tool is that all its items are expected to change with response to treatment. For example, one of the criticisms that PASI received was that it did not factor in nail involvement [17]. As nail findings are not expected to change within the 12-week assessment period, because of the duration of the nail cycle, this objection is not justified.

The fact that the items of the PASI were not properly tested raises the following concerns. First, although multiple response scoring is preferable to dichotomous scoring because of the evaluative purpose of the PASI, it is not clear whether the 5-point scoring is the most appropriate. Second, the definitions of the 5 different grades are not very clear. For example, grade 3 represents striking involvement and grade 4 represents exceptionally striking involvement. Third, scoring the variables for each anatomic site need to be reconsidered. It is unlikely that the time-consuming approach is superior to scoring the average for each variable (erythema, induration, scaling) for the entire body and multiplying the score by the body surface area involved. Fourth, weighting the anatomic site according to its contribution to the body surface area ignores the fact that the involvement of some anatomic sites is more important than others. For example, a patient whose entire face is covered with a psoriatic plaque is given the same score as that for a patient who has a similar lesion on his or her back. Similarly, the involvement of the palms is underestimated, given the potential impact of psoriatic plaque at those anatomic sites. That concern might be resolved by giving more weight to the face and the palms and feet.

Feasibility

The PASI is administered by a physician. The average dermatologist is familiar with the signs of psoriasis included in that tool, and the PASI does not require special equipment for its administration. However, researchers involved in clinical trials usually receive training about the use of the PASI before they enroll patients in a trial.

The time required to calculate the PASI score is another concern. The PASI was developed to be used in clinical studies. In such settings, clinicians and/or researchers have more time than that required for an appointment during which a routine physical examination is performed. Some data suggest that on average, less than 10 minutes is required to administer the PASI and that experienced dermatologists require relatively less time to perform such testing [5]. It is expected that there is a wide variation in the duration of follow up visits between practices but the average duration of dermatology outpatient visit in the US is 13.8 minutes [18]. This indicates that for the PASI to be incorporated into routine clinical practice special consideration should be given to time allocation for clinical visits involving the administration of the tool.

In Conclusion, although the PASI has reasonable validity, the lack of comprehensive development methodology resulted in some limitations of its evaluative characteristics. In addition, the feasibility of the PASI in clinical setting is conditional on adequate time allocation.

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