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# Visual Assessment Tools and Therapeutic Implications for Acanthosis Nigricans

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## ABSTRACT

Acanthosis nigricans significantly impacts individuals with skin of color. No United States Food and Drug A dministration (FDA)-approved therapy exists for acanthosis nigricans. This review evaluates visual scoring tools for assessing acanthosis nigricans severity, focusing on their utility in monitoring therapy response in clinical trials. Our analysis included 5 visual scoring tools and revealed that the Acanthosis Nigricans Scoring Chart is the most effective tool for monitoring acanthosis nigricans severity in response to therapy, while the Acanthosis Nigricans Area and Severity Index also remains a strong option for split-neck trials. Future tools should match severity scores with detailed descriptions and images. The inclusion of lesion size in future assessment tools requires careful consideration due to variable reliability among evaluators. This study highlights the need for a universally accepted acanthosis nigricans severity assessment tool. Advancing such methods is crucial to developing effective treatments and addressing healthcare disparities, particularly for individuals with skin of color.

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## INTRODUCTION

Acanthosis nigricans (AN) is a common skin condition marked by hyperpigmented, velvety plaques.[1] In the United States, AN has a prevalence of 19.4%[2] and disproportionately impacts individuals with skin of color.[1] This prevalence highlights not only a wide-reaching healthcare concern but also an issue of healthcare inequity. AN is associated with significantly lower levels of self-esteem and higher rates of depression and anxiety.[3] Effective management of AN is crucial for alleviating physical symptoms and enhancing overall quality of life.

The recommended management for AN involves treating the underlying disorder.[1] However, treating the root cause does not always improve dermatologic symptoms.[4] For instance, in hyperinsulinemia-induced AN, oral antihyperglycemic agents may not lessen lesion severity.[4] This highlights the necessity of considering skin-directed therapies alongside managing the underlying condition, especially when standard treatments fail to alleviate symptoms.

Despite AN's increasing global prevalence,[1] the absence of United States Food and Drug Administration (FDA)-approved treatments for AN poses a significant challenge. Compounding this issue is the absence of a universally accepted visual assessment tool in the scientific community, which is crucial for assessing treatment efficacy in clinical trials.[5] Unlike AN, conditions like psoriasis and atopic dermatitis benefit from recognized tools like the Psoriasis Area and Severity Index (PASI) and the Eczema Area and Severity Index (EASI), respectively, aiding in treatment advancements. The absence of a similar tool for AN hinders the development and validation of effective treatments and complicates comparing outcomes across clinical trials.

In this review, we thoroughly evaluate current methods for monitoring AN severity. We focus on key visual aspects like lesion size, pigmentation, and texture. Our objective is to analyze the strengths and weaknesses of existing visual assessment tools. We will discuss these tools chronologically, from the earliest to the most recent.

**Concept and Comparison of Visual Scoring Tools**

Visual scoring tools are essential in dermatologic clinical trials for evaluating disease severity, monitoring progression, and measuring treatment responses. They are cost-effective, user-friendly, and can achieve high reliability. These tools are instrumental in facilitating evidence-based treatments by rigorously evaluating therapeutic outcomes.[6,7]

Table 1 compares visual scoring tools for AN, focusing on anatomical site coverage, clinical feature assessment, and

**TABLE 1.**

**Comparison of Visual Scoring Tools**

| Visual Tool | Anatomic Sites | Severity Evaluated | Ranked Utility[a] |
|---|---|---|---|
| Stuart's "acanthosis score" | Neck<br>Axilla<br>Antecubital<br>Intertriginous<br>Inner thigh | Not included | Fifth |
| Burke's Acanthosis Nigricans Scale | Neck<br>Axilla<br>Knuckles<br>Elbows<br>Knees | Neck (0-4)<br>Axilla (0-4)<br>Neck texture (0-3)<br>Knuckles (0-1)<br>Elbows (0-1)<br>Knees (0-1) | Third |
| Acanthosis Nigricans Area and Severity Index | Neck | Area (0-5)<br>Pigmentation (0-4)<br>Thickness (0-4) | Second |
| Scoring For Acanthosis Nigricans Severity | Neck and Nape<br>Axilla (R, L)<br>Groin<br>Mucosa<br>Trunk<br>Upper extremities<br>Lower extremities | Grades (1-4)<br>1: Hyperpigmentation ≤50%<br>2: Hyperpigmentation >50%<br>3: Grade 2 + velvety skin change<br>4: Grade 3 + papillomatous skin change | Fourth |
| Acanthosis Nigricans Scoring Chart | Any anatomic site | Skin Color (1-8)<br>Skin Texture (1-6) | First |

[a]Visual tools were ranked based on their reliability, effectiveness in clinical trials, and validation through objective digital methods.

**TABLE 2.**

**Comparison of Intra-Rater and Inter-Rater Reliability[a]**

| | Range of Intra-Rater Reliability Among Users | Range of Inter-Rater Reliability Among Users |
|---|---|---|
| Acanthosis Nigricans Area and Severity Index (ANASI) | ANASI Total Score:<br>excellent (ICC = 0.918-0.977)<br><br>Area Index:<br>poor to excellent (κ = 0.149-0.923)<br><br>Pigmentation Index:<br>poor to good (κ = 0.220-0.625)<br><br>Thickness Index:<br>poor to good (κ = 0-0.717) | ANASI Total Score:<br>excellent (ICC = 0.834-0.911)<br><br>Area Index:<br>poor to excellent (ICC = 0.326-0.750)<br><br>Pigmentation Index:<br>fair to good (ICC = 0.438-0.692)<br><br>Thickness Index:<br>fair to good (ICC = 0.432-0.705) |
| Acanthosis Nigricans Scoring Chart (ANSC) | ANSC Total Score:<br>excellent (ICC = 0.878-0.965)<br><br>Skin Color Domain:<br>excellent (ICC = 0.838-0.953)<br><br>Skin Texture Domain:<br>good to excellent (ICC = 0.636-0.897) | ANSC Total Score:<br>excellent (ICC = 0.828-0.961)<br><br>Skin Color Domain:<br>excellent (ICC = 0.838-0.953)<br><br>Skin Texture Domain:<br>good to excellent (ICC = 0.636-0.897) |

[a]Reliability values denoted as Cohen's kappa (κ) and intraclass correlation coefficient (ICC) are categorized as follows: less than 0.40 = poor, between 0.40 and 0.59 = fair, between 0.60 and 0.74 = good, and between 0.75 and 1.00 = excellent.

**TABLE 3.**

| Reliability Definitions | |
|---|---|
| **Terminology** | **Definition** |
| Intra-rater reliability | How consistently the same person rates an item over time. |
| Inter-rater reliability | The degree of agreement among two or more raters evaluating an item. |
| Cohen's kappa | A statistic used to quantify intra- and inter-rater reliability for qualitative data that typically ranges from 0 (no agreement) to 1 (perfect agreement)[a] |
| Intraclass Correlation Coefficient | A statistic used to quantify intra- and inter-rater reliability for quantitative data that ranges from 0 (no agreement) to 1 (perfect agreement). |

[a]Negative kappa values, although rare, indicate agreement is below what would be expected by chance.

a ranking of their applicability in clinical trials for evaluating treatment response. Table 2 reports the reliability of the 2 top-ranked tools using the Intraclass Correlation Coefficient (ICC) and Cohen's kappa (κ) from the authors' original articles.[8,9] Definitions of reliability are detailed in Table 3.

**Stuart's Acanthosis Score**

Stuart's "acanthosis score,"[10] established in 1986, measures AN severity and its association with insulin resistance, hyperandrogenemia, and obesity rather than evaluating treatment outcomes. The scale ranges from 0 (no evidence of AN) to 4 (severe manifestation). It assesses 5 anatomical areas: neck, axillae, antecubital area, intertriginous regions, and inner thigh. Scores from each area are totaled for an overall comprehensive score.

Stuart's "acanthosis score,"[10] the first tool to evaluate AN severity, has limited utility. It lacks assessment of key aspects like skin pigmentation, texture, and lesion size and does not provide descriptive criteria or clinical images for each severity score. Additionally, its reliability and validity are not well-established, and it has not been utilized in clinical trials, casting doubt on its effectiveness in therapeutic studies. Given these limitations, among the 5 tools evaluated, Stuart's appears to have the least utility in therapeutic clinical trials for AN.

**Burke's Acanthosis Nigricans Scale**

Developed in 1999, Burke's scale[11] assesses AN severity, linking it with insulin resistance, hypertension, and obesity. It evaluates 5 anatomical regions: neck, axilla, knuckles, elbows, and knees. The scale includes a severity score for the neck and axillae (0 to 4), neck texture (0 to 3), and a binary grade for the knuckles, elbows, and knees (0 for absent, 1 for present). Each score is defined by descriptive clinical features of AN. The neck texture score, although graded from 0 to 3, is excluded from the total score to avoid overemphasizing the neck, yielding a maximum score of 11.

The inter-rater reliability of Burke's scale showed variation among evaluators for neck severity (κ = 0.53-0.68), axilla severity (κ = 0.27-0.39), neck texture (κ = 0.03-0.51), knuckle severity (κ = 0.20-0.55), elbow severity (κ = 0.20-0.52), and knee severity (κ = -0.04-0.34).[11]

Burke's scale[11] stands out among the scoring tools evaluated for providing detailed descriptions of AN across severity scores. Its limitation, however, is the omission of skin texture and pigmentation in the final scoring, limiting its comprehensive assessment of AN. Although this scale has been used in clinical trials to link AN severity with health parameters in children and adolescents,[12,13] its only application in evaluating topical skin-directed treatment efficacy was in 1 clinical trial.[14] These factors contribute to Burke's scale being ranked third among the 5 tools assessed.

**Acanthosis Nigricans Area and Severity Index**

Developed in 2017, the Acanthosis Nigricans Area and Severity Index (ANASI)[15] evaluates AN severity on the neck and tracks changes in response to therapy. Designed for split-neck studies, it allows for direct comparative analysis by treating each neck side differently, making it suitable for controlled and head-to-head comparative trials. ANASI considers lesion size, pigmentation intensity, and thickness, assigning separate scores to the left and right sides of the neck.

The ANASI provides guidelines to calculate the total neck area and the area impacted by AN, thus determining the percentage of neck involvement as per the Area (A) Index. This index ranges from 0 (no involvement) to 5 (70-100% involvement), with intermediate scores for less than 10% involvement (1), 10 to 29% involvement (2), 30 to 49% involvement (3), and 50 to 69% involvement (4). Pigmentation (P) and Thickness (T) are scored from 0 (none/absent) to 4 (severe), including gradations for mild (1), moderate (2), and marked (3). The final ANASI score, which can reach up to 40 points, is calculated by combining the P and T scores and multiplying the sum with the A index. This procedure is carried out separately for each side of the neck, resulting in distinct scores for the left and right sides.[15]

The ANASI showed high intra-rater reliability (ICC = 0.918-0.977), indicating strong consistency in individual assessments over time. However, there was notable variability in the intra-rater reliability for specific indices: area (κ = 0.149-0.923), pigmentation (κ = 0.220-0.625), and thickness (κ = 0-0.717), reflecting varying degrees of agreement from none to almost perfect.[8]

In the study's[8] therapeutic group, inter-rater reliability for pre-treated AN lesions varied among evaluators for the total ANASI score (ICC = 0.834-0.879), area index (ICC = 0.326-0.568), pigmentation index (ICC = 0.438-0.570), and thickness index (ICC = 0.432-0.640). For post-treated lesions, reliability improved for the total ANASI score (ICC = 0.850-0.911), area index (ICC = 0.576-0.750), pigmentation index (ICC = 0.560-0.692), and thickness index (ICC = 0.581-0.705). These results underscore the tool's reliable performance in overall scoring while also pointing to variability in assessing specific lesion characteristics such as area, pigmentation, and thickness.

The ANASI has been utilized in controlled and head-to-head clinical trials to evaluate AN severity in response to therapy. These trials encompass various comparisons: a fractional $CO_2$ laser against a 70% glycolic acid peel,[15] a 70% glycolic acid peel against a saline control,[8] a fractional-ablative $CO_2$ laser against a 5% retinoic acid peel,[16] Q-switched neodymium-doped yttrium aluminum garnet (Nd:YAG) and potassium-titanyl-phosphate (KTP) lasers against a fractional $CO_2$ laser,[17] and a 15% trichloroacetic acid peel against a 35% glycolic acid peel.[18]

The ANASI stands out among the evaluated tools for its design in split-neck studies, high reliability among evaluators for the tool's total score, and incorporation of all key clinical features of AN (lesion size, pigmentation intensity, and thickness).[8] However, it exhibits variable reliability among evaluators in the A, P, and T indices,[8] potentially due to lacking detailed descriptions and clinical images for each severity score. Moreover, the A index's measurement guidelines may not fully consider individual anatomical variations, leading to inconsistencies for different neck shapes and sizes. Additionally, the term "thickness" in the ANASI is ambiguous, as it is unclear whether it refers to physical skin depth, which is typically measured by a biopsy, or to changes in skin texture. Despite these limitations, the ANASI's effectiveness in clinical trials for assessing AN severity in response to therapy secures its ranking as the second most useful tool among the 5 evaluated.

**Scoring for Acanthosis Nigricans Severity**

Developed in 2020, the Scoring for Acanthosis Nigricans Severity (SCANS)[19] assesses AN severity and its correlation with conditions like obesity and diabetes. It evaluates 6 anatomic areas: axillae (left/right), groin (left/right), neck (anterior neck/nape), mucosa (oral, conjunctiva, genitalia), trunk (including areola and umbilicus), and extremities. AN lesion severity in each area is graded on a 1 to 4 scale: Grade 1 for hyperpigmentation covering ≤50% of the area; Grade 2 for >50%; Grade 3 adds a velvety skin texture to Grade 2; and Grade 4 includes verrucous or papillomatous changes on top of Grade 3. Acrochordons contribute additional points to the overall score, with ≤15 acrochordons adding 0.5 points and >15 adding 1 point, leading to a total possible score of 0 to 46.[19]

The strength of the SCANS lies in assessing the largest number of anatomical sites and addressing the key clinical features of AN (hyperpigmentation, skin texture, and lesion area), thus enabling a comprehensive evaluation.[19] However, its binary categorization of lesion size (≤50% or >50% of the area)[19] may oversimplify severity assessments. The lack of intra- and inter-rater reliability data further raises concerns about its precision and consistency. Additionally, the inclusion of acrochordons in the scoring, although related to comorbid conditions, might not accurately reflect AN severity, particularly in cases with mild AN but numerous acrochordons. Also, the SCANS has yet to be utilized in clinical trials for evaluating AN severity in response to therapy. Considering these factors, SCANS is ranked fourth among the 5 tools evaluated for assessing AN severity in therapeutic contexts.

**Acanthosis Nigricans Scoring Chart**

The Acanthosis Nigricans Scoring Chart (ANSC),[9] issued in 2023,[20] evaluates AN severity in response to therapy across 2 domains: skin color and skin texture. The skin color domain, inspired by the Felix von Luschan skin color chart, ranges from 1 (very fair skin) to 8 (black skin). The skin texture domain is assessed on a 1 to 6 scale: 1 for normal texture without thickening; 2 for slightly pronounced markings without thickening; 3 for moderately pronounced markings with slight thickening; 4 for exaggerated markings with moderate thickening; 5 for velvety plaques with marked thickening; and 6 for bark-like skin with severe thickening. Each score is clearly defined and supported by a reference image for visual assessment. The total ANSC score ranges from 2 to 14.[9]

The ANSC showed the highest consistency in reliability, with excellent intra-rater reliability among evaluators for the total ANSC score (ICC = 0.878-0.965), skin color domain (ICC = 0.865-0.953), and skin texture domain (ICC = 0.801-0.941).[9] Similarly, excellent inter-rater reliability was observed for the total ANSC score (ICC = 0.828-0.961) and skin color domain (ICC = 0.838-0.953), while the skin texture domain exhibited moderate reliability (ICC = 0.636-0.897).[9]

The ANSC distinguishes itself among other tools as the only 1 validated with an objective digital tool, narrowband reflectance spectrophotometry,[9] which measures skin pigmentation.[5] This validation is evident in the strong correlation of the ANSC's skin color domain ($r > 0.6$) and a moderate correlation in the skin texture domain ($r = 0.4–0.6$) with this colorimeter.[9] While this validation is advantageous, there is a concern that the colorimeter, primarily focused on pigmentation, might not fully capture the textural changes characteristic of AN, potentially impacting the accuracy of validating the skin texture domain.[5]

The ANSC distinguishes itself from other scoring tools by including clinical photos for each severity score, which likely

contributes to its high intra- and inter-rater reliability. The tool's design focuses on skin color and texture without considering lesion size, enabling its application across various body parts.[9] However, the omission of lesion size in its assessment raises concerns about the tool's comprehensiveness. While its adaptability to multiple body areas is beneficial, the absence of a lesion size measurement might result in a less thorough evaluation of AN severity, potentially overlooking a significant aspect of AN's clinical presentation.

Despite its limitations, the ANSC has been effectively used in clinical trials, such as those comparing tretinoin 0.025% and 0.05% creams,[20] and salicylic acid (10%) cream with urea (10%) cream.[21] Its consistent delivery of high intra- and inter-rater reliability for the tool's total score and each domain, along with its validation through narrowband reflectance spectrophotometry, positions it as the most effective tool for monitoring AN severity in response to therapy.

## DISCUSSION

This review offers a comprehensive assessment of visual scoring tools for AN, highlighting both advancements and challenges in this field. Notably, these tools were developed with varying initial purposes: some, like Stuart's Scale, Burke's Scale, and the SCANS, were intended to explore links between AN severity and comorbidities, while others, such as the ANASI and ANSC, were designed to assess AN severity in response to therapy. While our focus is to evaluate the existing tools for monitoring AN severity in therapeutic contexts, including all these tools in our review enriches our understanding of what constitutes an effective assessment tool.

Among the evaluated tools, the ANASI and ANSC are particularly notable in clinical trials for monitoring AN severity. Both tools exhibited excellent intra- and inter-rater reliability in their overall scores. However, the ANASI showed variable reliability among evaluators in its Area, Pigmentation, and Thickness indices. In contrast, the ANSC consistently demonstrated strong reliability across its indices, including the skin color and texture domains, which is likely due to the inclusion of descriptions and clinical images for each severity level. Future tools can enhance their reliability by adopting similar features. Additionally, validating future skin pigmentation indices with narrowband reflectance spectrophotometry and skin texture domains with objective digital tools for measuring skin texture could further establish their effectiveness.[22]

Lesion size, a key feature of AN, has shown variable reliability among evaluators in tools like Burke's[11] scale and the ANASI.[8] This raises a dilemma: whether to include lesion size in severity scoring due to its dermatologic relevance or to exclude it, as in the ANSC,[9] due to inconsistent reliability across different scoring tools.

## CONCLUSION

This review underscores the importance of establishing a universal method for monitoring acanthosis nigricans (AN) severity in response to therapy. The Acanthosis Nigricans Scoring Chart (ANSC) stands out as the most effective tool, owing to its consistently high reliability across all measurements and its validation through objective measures. The Acanthosis Nigricans Area and Severity Index (ANASI), ranking second, also shows promise. Though the ANASI exhibits high reliability for its total score, the variability in its indices suggests the need for improvement; overall, it remains a strong candidate for split-neck studies. The quest for an ideal universal tool is imperative, particularly considering the lack of an FDA-approved therapy for AN. Advancing a universal assessment tool is crucial for propelling clinical trials forward, potentially culminating in the development of effective treatments for AN. Addressing this challenge is critical not only for dermatologic advancements but also for reducing healthcare disparities, especially among individuals with skin of color.

## DISCLOSURES

The authors have no conflicts of interest to disclose.

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