Practical Assessment of Psoriasis Clinical Severity in both Clinical Trials and Clinical Practice Settings: A Report from the GRAPPA 2016 Annual Meeting

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ABSTRACT. At the 2016 annual meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), we presented the case for quantitatively assessing the extent of both psoriasis and psoriatic arthritis in the clinical setting, with a particular focus on the validation and expanded novel use of the PGAxBSA (static physician's global assessment × body surface area of involvement) in the era of targeted metrics. Herein, we summarize our presentation. (J Rheumatol 2017;44:691–2; doi:10.3899/jrheum.170147)

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The Psoriasis Area and Severity Index (PASI) has remained the gold standard in the objective assessment of plaque psoriasis severity; however, it has multiple faults limiting its use in clinical practice. The PASI is typically used for clinical trials and in moderate to severe plaque disease. Limitations of the PASI include (1) the need for complex calculations, (2) time-consuming/cumbersome documentation, (3) values that are poorly understood by most clinicians, and (4) non-linearity with poor sensitivity to change and poor discrimination at lower score ranges[1,2].

The PGAxBSA (static physician's global assessment × body surface area of involvement) represents a practical method for quantifying skin disease severity not only in clinical trials, but particularly in the clinic setting. Several versions of the static physician's global assessment (sPGA) measure plaque psoriasis characteristics (severity of erythema, elevation, scaling), but they do not provide an overall measure of psoriasis severity because they do not account for the BSA. The PGAxBSA is a composite tool that addresses the deficiencies of the PASI as well as the sPGA, while assessing both disease severity and extent in a highly feasible way. The PGAxBSA has been validated in several studies; most notably, the PGAxBSA was found to have a Spearman correlation coefficient with the PASI of $r = 0.87$ ($p < 0.001$)[2]. Ongoing work is being done to assess validity measures beyond simple correlation with the PASI.

At the 2016 annual meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis, we presented the case for quantitatively assessing the extent of skin disease in both psoriasis and psoriatic arthritis in the clinical setting, with a particular focus on the validation and expanded novel use of the PGAxBSA for assessing clinical response of psoriasis in the era of targeted metrics. Valid but simple, highly feasible measures are of ever-increasing importance, such as the PGAxBSA, easily identified by healthcare providers and easily understood by providers, patients, regulators, and payers. The PGAxBSA helps to improve communication between physicians and patients, and facilitates shared discussion of disease severity and improvement over time. It represents a number that can be easily supplied for prior authorizations, quantifies the case mix of a provider or practice, and is useful for the Physician Quality Reporting System and in the setting of registries (i.e., DataDerm efforts by the American Academy of Dermatology). The PGAxBSA could also be used in clinical performance/value-based care models to demonstrate case mix and treatment success in an era of physician tiering and narrow networks. Payers have expressed a desire for clinically meaningful outcome measures that can be obtained in the clinical practice setting, which can be used to justify cost and make costs more predictable[3].

In addition to previously mentioned PGAxBSA validation studies, several peer-reviewed publications have used the PGAxBSA as a primary outcome measure[4,5,6,7]. The simplicity of the PGAxBSA allows for its potential use in a number of novel applications, such as defining a useful minimal disease criteria for treat-to-target strategies. In the era of treat-to-target goals, the PGAxBSA would also allow

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patients to be partners in their care. As well as good correlation of the PGAxBSA with PASI scores, work to date has shown sensitivity to changes from baseline[2,8]. Ongoing work by our group will evaluate correlation of PGAxBSA cutoffs with minimal disease activity and other key target endpoints[9].

Several challenges remain, including agreement as a community on which of multiple current static PGA scales should be used for PGAxBSA measurements. The PGAxBSA does not include a patient-reported outcome, which would need to be collected separately, and of which none exist at present that are practical to provide disease-specific outcomes in the clinical practice setting. Another potential challenge is our ability to effectively implement use of a simplified measure such as the PGAxBSA in the dermatology and non-dermatology office (e.g., in rheumatology).

The PGAxBSA represents a practical, feasible method for quantifying skin disease severity in an era of ever increasing emphasis on disease quantification metrics for use by providers, payers, industry, regulators, and others. Ongoing work by our group seeks to establish PGAxBSA cutoff values as outcomes for treat-to-target strategies and future remission/minimal disease activity criteria.

REFERENCES

1. van de Kerkhof PC. On the limitations of the psoriasis area and severity index (PASI). Br J Dermatol 1992;126:205.
2. Walsh JA, McFadden M, Woodcock J, Clegg DO, Helliwell P, Dommasch E, et al. Product of the physician global assessment and body surface area: a simple static measure of psoriasis severity in a longitudinal cohort. J Am Acad Dermatol 2013;69:931-7.
3. Greb JE, Merola J, Garg A, Latella J, Howard L, Acharya N, et al. The Psoriatic Disease Payer Advisory Panel. J Drugs Dermatol 2016;15:641-4.
4. Greb JE, Garber C, Gottlieb AB. Effect of psoriatic arthritis on treatment response in patients with moderate to severe psoriasis. J Drugs Dermatol 2016;15:917-22.
5. Sorensen EP, Fanucci KA, Saraiya A, Volf E, Au SC, Argobi Y, et al. Tumor necrosis factor inhibitor primary failure predicts decreased ustekinumab efficacy in psoriasis patients. J Drugs Dermatol 2015;14:893-8.
6. Garber C, Plotnikova N, Au SC, Sorensen EP, Gottlieb A. Biologic and conventional systemic therapies show similar safety and efficacy in elderly and adult patients with moderate to severe psoriasis. J Drugs Dermatol 2015;14:846-52.
7. Buzney CD, Peterman C, Saraiya A, Au SC, Dumont N, Mansfield R, et al. Clearance of psoriasis: the impact of private versus public insurance. J Drugs Dermatol 2015;14:119-25.
8. Chiesa Fuxench ZC, Callis Duffin K, Siegel M, Van Voorhees AS, Gelfand JM. Validity of the Simple-Measure for Assessing Psoriasis Activity (S-MAPA) for objectively evaluating disease severity in patients with plaque psoriasis. J Am Acad Dermatol 2015;73:868-70.
9. Callis Duffin K, Papp KA, Bagel J, Levi E, Chen R, Gottlieb AB. Evaluation of the physician global assessment and body surface area composite tool for assessing psoriasis response to apremilast therapy: results from ESTEEM 1 and ESTEEM 2. J Drugs Dermatol 2017 (in press).