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Report of the Skin Research Working Groups from the GRAPPA 2021 Annual Meeting

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ABSTRACT. The International Dermatology Outcome Measures (IDEOM) initiative presented an update on their progress related to instruments for psoriasis (PsO) and psoriatic arthritis (PsA) patient-centered outcome measures at the 2021 annual meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA). The Treatment Satisfaction working group presented the development of a 7-item treatment satisfaction questionnaire specific for dermatological conditions. The group is beginning by assessing the validity and reliability of the instrument in PsO patient populations, with the ultimate goal of validating it for use in multiple dermatological diseases. The Musculoskeletal Symptoms working group discussed how implementation of a screening measurement tool in patients with PsO can help identify unknown diagnoses of PsA or prevent worsening of symptoms.

Key Indexing Terms: GRAPPA, outcome assessment, psoriasis, psoriatic arthritis

The International Dermatology Outcomes Measures (IDEOM) Initiative

IDEOM is a nonprofit organization comprising physicians, researchers, government agencies, patients, and pharmaceutical companies directed toward improving patient-centered outcomes and treatments for dermatologic conditions. Within the IDEOM initiative, working groups were created to target the core domains measured in psoriasis (PsO) clinical trials and organized for specific dermatologic conditions, such as psoriatic disease (PsD), hidradenitis suppurativa, vitiligo, acne, actinic keratoses, cutaneous T cell lymphoma, and itch. At the 2021 GRAPPA annual meeting, the Treatment Satisfaction working group and the Musculoskeletal (MSK) Symptoms working group presented updates on their research. Then, leaders of the PsD working group, which encompasses PsO and psoriatic arthritis (PsA), presented updates and developments made over the past year for PsO clinical trial instruments.

Treatment Satisfaction Working Group Update

Dr. April Armstrong presented an update on IDEOM and GRAPPA's progress by an international team of patients and healthcare professionals to develop the Dermatology Treatment Satisfaction Instrument. The patient-reported outcome (PRO) measure instrument was created to accurately and succinctly assess satisfaction for use in clinics, clinical trials, and general research. The existing iteration of the instrument was developed for patients with PsO and is currently being validated in that population.

The project began with the identification of a core domain set for use in assessing PsO in clinical trials.[1] It was determined that developing an instrument to measure treatment satisfaction was a priority. The Treatment Satisfaction working group then conducted a literature review appraising the existing treatment satisfaction instruments using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) methodology.[2] The review found none of the identified 11 instruments were validated satisfactorily for PsO using the critical measurements of consistency, reliability, content and structural validity, and responsiveness.[3] Thus, nominal group discussions with patients with PsO were held to determine relevant items for the instrument. This critical drafting stage was followed by the removal of duplicates, item categorization, instrument creation, and cognitive evaluation to ensure that the items were clear and relatable to patients. The current iteration of the instrument asks about *one* skin medication used to treat *one* skin condition (PsO). Respondents answer 7 questions on a

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unipolar scale ranging from 1 = Not Satisfied to 5 = Completely Satisfied in the categories of effectiveness, convenience, and overall satisfaction.

The instrument is currently being validated in a multicenter study (University of Southern California, Brigham and Women's Hospital, and Mount Sinai Health System) enrolling 120 patients with PsO. Participants complete a survey on day 1 including existing patient questionnaires: the 9-item Treatment Satisfaction Questionnaire for Medication (TSQM-9), the Dermatology Life Quality Index (DLQI), a patient self-reported physician global assessment (PGA), and the Dermatology Treatment Satisfaction Instrument.

Following the conclusion of the study, the instrument will be assessed for construct validity, known-groups validity, internal consistency, and test-retest reliability. To test validity, hypotheses will be formed prior to assessing the subjects with the goal of correctly predicting the strength of correlation after analysis. Construct validity will be assessed using the Spearman correlation coefficient comparing the Dermatology Treatment Satisfaction Instrument with existing instruments (TSQM-9, DLQI, PGA, PASI). Known-groups validity will be assessed by grouping the patients based on disease severity using the PASI, BSA, and PGA to hypothesize how they will score on the Dermatology Treatment Satisfaction Instrument, and ANOVA analysis will be performed to compare the hypotheses to the actual scores. Internal consistency will be measured using Cronbach α to measure the degree to which scores of individual items in the Dermatology Treatment Satisfaction Instrument correlate with one another. Test-retest reliability for the instrument will be assessed for subjects whose disease severity, as measured by the patient-reported PGA, has not changed between the day 1 and day 14 surveys. This analysis will use the intraclass correlation coefficient to determine reliability.

Significant advances have been made in bringing treatment satisfaction in dermatology to this point. In the upcoming year, we will continue to finalize the Dermatology Treatment Satisfaction Instrument for broader use.

Musculoskeletal Symptoms Working Group Update

Dr. Joseph Merola presented the progress on the 8-item IDEOM musculoskeletal (MSK-8) instrument on behalf of the IDEOM MSK Symptoms working group. The MSK-8 was developed in response to both the published IDEOM Core Domain Set for PsO trials, which included a core domain of PsA symptoms, as well as a working consensus algorithm published in 2020 that laid out a framework for approaching PsA symptom measurement in the context of clinical trials.[1] Through a Delphi consensus process, it was provisionally decided that a subject with PsO who entered a clinical study without known PsA would receive a screening questionnaire, and those who screened positive or had an already existing rheumatologist diagnosis of PsA would receive a validated PsA symptom measurement tool, the Psoriatic Arthritis Impact of Disease-9 (PsAID-9) (or Routine Assessment of Patient Index Data 3 [RAPID-3] as an acceptable alternative).

While this framework still offers value to the psoriatic research community, 2 challenges were noted to the existing model as proposed. It was noted that (1) the relative lack of sensitivity/specificity of existing PsA screening tools and (2) the language of the question stem in instruments such as the PsAID (in which the term "psoriatic arthritis" frequently appeared facing a subject population who may or may not be aware that they have PsA) may lead to difficulty in implementation and data interpretation. To that end, the MSK Symptoms working group was reimagined and tasked with the development of an MSK symptom measurement tool to capture both relevant symptoms and the effect of those symptoms on health-related quality of life.

The development of this tool, currently named the IDEOM MSK-8, was based on the PsAID, the PsA-Disk (a visual instrument for evaluating PsA), and other relevant instruments. A core group of disease state experts first selected items most relevant to the MSK symptoms domain (ie, pain, fatigue, work/leisure impact, functional capacity, discomfort, sleep disturbance, depression/anxiety, and morning stiffness), and modified question stems to remove the term "psoriatic arthritis." This step of question stem modification was the key to represent the unknown PsA diagnosis status that may be encountered among subjects with PsO. The next step involved a cognitive evaluation of a preliminary draft instrument through an online survey that included patient research partners (PRPs) with PsO and/or PsA. IDEOM previously trained PRPs on how to evaluate the content validity (relevance, comprehensiveness, and comprehensibility) and feasibility of instruments.

During the virtual IDEOM annual meeting in 2021, polling through an online survey and live discussions was used to modify the IDEOM MSK-8. Relevant stakeholders involved in the virtual meeting included PRPs, dermatologists, rheumatologists, industry representatives, and patient advocacy groups. Importantly, the future direction for the instrument with regard to its validation and potential use were reviewed at the meeting. There is early indication that in addition to clinical research uses, clinical practice applications likely exist and will be explored in the near future.

The current version of the IDEOM MSK-8 includes a novel question stem for MSK symptoms, 3 symptom measurement items, and 5 impact of MSK symptoms items covering fatigue, emotional distress, sleep disturbance, work/leisure impact, and functional impact. The details of the instrument itself, instrument development, and validation have been submitted and are currently under review.

Immediate agenda items include the in-clinic and real-world validation of the MSK-8 in the context of combined clinic settings where dermatologists and rheumatologists can serve as the gold standard for diagnosis of participants. Definitions for clinically meaningful disease activity will be considered akin to the acceptable disease state cut-offs published for the PsAID-9/12 instrument. The group is actively engaged in considering the exploratory use of the MSK-8 in the conduct of industry-sponsored PsO clinical trials as well as active PsO registries, given the value of measuring change over time in this context, and adjacent to a screening measure such as the validated Psoriasis Epidemiology Screening Tool (PEST). An earlier version of

PEST was included in the National Psoriasis Foundation's annual health survey in which around 1400 patients took part within the US, providing some early insights into the burden of MSK symptoms in this population. The MSK working group also sees value outside of plaque PsO in measuring MSK symptoms among subjects with pustular PsO, autoinflammatory variants such as SAPHO (synovitis, acne, pustulosis, hyperostosis, and osteitis) syndrome, hidradenitis suppurative, inflammatory bowel disease, and other relevant disease states.

Updates On Other Instruments for Psoriasis

Progress on integrating the PEST and PsAID into the EPIC system, by Dr. Alice Gottlieb. PsA is the major comorbidity of patients with PsO and can be disabling.[4,5] A delay in diagnosis of PsA of > 6 months is associated with increased MSK morbidity and disability.[5] In most patients, cutaneous disease precedes PsA by 10–12 years.[4] Therefore, dermatologists can be the first healthcare provider (HCP) to detect PsA, yet it remains frequently underdiagnosed.[6] Early diagnosis of PsO is important, as numerous therapies to treat and prevent disease progression are available. Thus, dermatologists can prevent disability by initiating early treatment. Also, the first decision point in choosing a treatment option for PsO is knowing whether a patient has PsA. Dermatologists should be screening their patients with PsO for PsA at every visit. In order to aid dermatologists (and other HCPs) in the diagnosis of PsA and to encourage a treat-to-target approach, the IDEOM group used PRO measures to screen for PsA and to provide a treat-to-target algorithm for PsA.[7]

The PEST is a 5-question instrument completed by patients.[8] A score of ≥ 3 suggests the patient may have PsA and should be formally evaluated for PsA. It is available in multiple languages and for use on multiple digital devices and computers on the GRAPPA app at no charge (https://apps.apple.com/us/app/grappa-app/id1346646781).

The PsAID-12 questionnaire is a validated PsA symptom questionnaire, which is translated into multiple languages, can be used on multiple digital devices, and is available on the GRAPPA app at no charge.[9] A score of > 4 indicates unacceptable PsA control and a score of ≤ 4 indicates acceptable control. Patients with PsO with either a rheumatologist-confirmed diagnosis of PsA or who score ≥ 3 on the PEST instrument should be administered the PsAID-12. If the PsAID-12 score is > 4, it is likely that the patient is not adequately controlled and a change in treatment strategy and/or comanagement with a rheumatologist should be considered. Both the PEST and PsAID-12 can be performed by the patient even before seeing the HCP.

At the Mount Sinai Hospital system in New York, both the PEST and PsAID-12 are being integrated into EPIC, our electronic medical record (EMR) system. A patient with PsO (defined as having ≥ 1 PsO codes in the problem list) fills out the PEST and, if applicable, the PsAID-12, at home or in the waiting room through the EPIC patient portal or a tablet. Data are electronically entered into EPIC and scores for the PEST and PsAID-12 are calculated within EPIC. When the HCP opens the chart, dropdown menus will report the scores of the PEST and PsAID-12 with a recommendation on subsequent steps.

We plan to study the effectiveness of this program over an 18-month time period. Initially, we will determine the prevalence of PsA in the PsO population over the past 2 years before the beginning of the study (baseline). We will assess if we have improved detection of PsA in our patients with PsO over the 18-month time period, and whether the control of PsA symptoms improved.

Bath Ankylosing Spondylitis Disease Activity Index and RAPID-3 work in PsO and PsA, by Dr. Alexis Ogdie. Whereas there are numerous PROs for measurement of symptoms in PsA, there are only a handful attempting to measure the overall disease at a given point in time.[10] These include a PGA of disease, the PsAID questionnaire, the RAPID-3, and the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).[9,11,12] Whereas RAPID-3 was developed for rheumatoid arthritis and BASDAI was developed for ankylosing spondylitis, they both work well in PsA overall.

During the workshop, we reviewed the latter 3 instruments (PsAID, RAPID-3, BASDAI), first taking a look at the types of questions included. The content included within the 3 instruments differs quite a bit. The RAPID-3 includes a patient pain assessment, a PGA, and 10 questions about function (ie, ability to do certain activities such as get dressed, get in and out of bed or a car, walk, lift a cup, bend down, and turn faucets). The PsAID has 12 items focused on individual symptoms that can be ascribed to PsA. In fact, each item ends with "due to your PsA" to encourage thinking about the symptoms in that context. The symptoms include pain, fatigue, skin problems, work/leisure, functional capacity, discomfort, sleep disturbance, coping, anxiety, embarrassment, social participation, and depression. Finally, the BASDAI is a 6-item questionnaire that includes fatigue; neck, back or hip pain; pain or swelling in the joints; areas of tenderness; and 2 items about morning stiffness. Note that the BASDAI has only 1 item specific to axial disease. From a content perspective, the PsAID has greater face validity because it was constructed for PsA, but all 3 questionnaires do assess important components of PsA symptoms.

Next, we reviewed the association between the 3 measures using data from the Psoriatic Arthritis Research Consortium (PARC), a US-based cohort study. At baseline, there was strong correlation between the 3 instruments: PsAID vs RAPID-3 ($\rho = 0.90$), BASDAI vs RAPID-3 ($\rho = 0.88$), and PsAID vs BASDAI ($\rho = 0.87$).[13] Additionally, there was strong correlation between each questionnaire and patient pain and global assessments ($\rho > 0.81$). Thus, at baseline, all 3 questionnaires appear to measure similar aspects of the disease despite having different questions. Next, within PARC, we examined responsiveness of the measures. All 3 measures had similar responsiveness as well, and this did not differ significantly based on whether or not the patient had axial disease.[14,15] However, the standard response mean for BASDAI was slightly greater than PsAID, and PsAID was slightly greater than RAPID-3.[15]

Additional considerations in selecting a tool to measure PsA symptoms among patients with PsO will include determining

how much the PsO severity affects these disease scores (ie, severe PsO can be associated with more pain and limited function, and it remains unclear whether this differentially affects these 3 instruments). There is also a need to implement these questionnaires in a PsO population to determine whether the responsiveness and construct validity are similar in this population. These measurement properties can differ between the clinical practice population with PsA and PsO enrolled in clinical trials because, in general, the level of disease activity is lower in the clinical population. The overall disease activity is likely to be even lower in the PsO population and thus the responsiveness of the questionnaires may likewise be lower.

Conclusion

At the GRAPPA 2021 annual meeting, IDEOM and its respective working groups presented a summary of their works in progress related to improving patient-centered outcomes in patients with dermatologic and rheumatologic diseases. The Treatment Satisfaction working group created a 7-question treatment satisfaction instrument to improve patient-related outcome measures for use in PsO clinical trials. Currently, the instrument is being tested for its validity, consistency, and reliability. The MSK Symptoms working group presented its development of screening measures for use in predicting the presence of MSK symptoms in patients with PsO in response to the core domain set established by IDEOM for PsA symptoms. Discussions of these screening tools addressed challenges and have been crafted to best capture relevant MSK symptoms for accurate diagnosis. The working group also reviewed the content and correlation between several instruments for measurement of PROs in PsA. In addition, the progress of integrating screening instruments in the EMR for the prevalence of PsA was discussed. At the 2021 virtual IDEOM annual meeting, the respective working groups shared their progress and updates.

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