Initiative for Quality in Psoriasis and Psoriatic Arthritis

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ABSTRACT. Psoriasis is a common and severe skin disease. Up to 30% of psoriasis patients develop psoriatic arthritis (PsA), another severe disease that contributes significantly to the burden of psoriatic disease in patients. The treatment of patients with both psoriasis and PsA is particularly challenging, because different strategies are often followed, and considerable resources are needed for these chronic inflammatory diseases. Of note, psoriasis patients tend to be undertreated. Efforts to improve the management of psoriasis and PsA are urgently needed, to incorporate improvement of patient outcomes by promotion of best practice from both the medical and the pharmacoeconomic perspective. These are the goals of the Quality Movement in the USA and of quality management in general. The need for evidence-based guidance on safety, efficacy, overall outcome, and cost-effectiveness is being addressed by numerous initiatives striving to generate practice guidelines, control costs, and optimize cost-effectiveness of treatments. The 2007 Group for Research and Assessment of Psoriasis and Psoriatic Arthritis's (GRAPPA) Initiative for Quality aims to secure and improve management of psoriasis and PsA, elaborating on these evidence-based guidelines by defining major domains of quality and creating a checklist that identifies physicians who can administer state-of-the-art medical services to patients who need their services. (J Rheumatol 2008;35:1431–3)

Key Indexing Terms:
PSORIATIC ARTHRITIS PSORIASIS

Management of Psoriasis and Psoriatic Arthritis: Medical Challenges

Psoriasis is a common and severe skin disease known to be associated with numerous other diseases such as obesity, diabetes, or hypertension[1]. Increasing evidence, e.g., elevated serum levels of C-reactive protein[2] or higher levels of platelet activation[3], points toward the systemic nature of the psoriatic inflammation. Further, inflammation-triggered insulin resistance may substantially contribute to the comorbidity seen in psoriatic patients in general and to an increased risk for cardiovascular morbidity and mortality in particular[4-6]. Between 25% and 30% of psoriasis patients develop psoriatic arthritis (PsA)[7], a severe disease that contributes significantly to the burden and severity of disease in psoriatic patients[8].

The treatment of patients with both psoriasis and PsA is particularly challenging because different strategies are often followed. Despite the above-mentioned pathogenetic considerations, psoriasis is still considered a chronic-recurrent disease and is primarily treated intermittently to control actual rashes, using topical therapies in most cases. In contrast, the chronic-progressive course of PsA demands continuous and systemic treatment, predominantly comprising drugs used for patients with rheumatoid arthritis (RA). In contrast to RA, however, PsA management must consider the potential adverse effects of these drugs to the skin condition of psoriasis (Table 1). This is particularly true for systemic steroids, which may cause a rebound of psoriasis, and for nonsteroidal antiinflammatory drugs, which may worsen psoriasis. Although several drugs are used in the treatment of both psoriasis and PsA, numerous drugs such as cyclosporin A are not approved for treating PsA in some countries, and other drugs such as leflunomide have limited effects on the skin.

Another treatment complexity is the fact that skin and joint disease quite often diverge in terms of disease activity as assessed by the Psoriasis Area and Severity Index (PASI) and American College of Rheumatology (ACR) joint counts, as well as by patient and physician perception of disease[9]. Therefore, considerable expertise is needed to meet the challenge of treating patients with both psoriasis and PsA.

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Supported by an unrestricted financial grant from Abbott, Centocor, Wyeth, Amgen, and UCB Pharma.

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Table 1. Summary of drugs used to treat psoriatic arthritis and their effects on psoriasis.

Drug	Approval	Effect on Skin	Evidence for Efficacy in PsA
NSAID	No	No (worsening)	No
Steroids	No	Yes (rebound)	No*
Gold	Yes	No	No
Sulfasalazine	No	No	(Yes)†
Cyclosporin A	No	Yes	No
Methotrexate	Yes	Yes	Yes (n = 1)
Leflunomide	Yes	Yes	Yes
Adalimumab	Yes	Yes	Yes
Etanercept	Yes	Yes	Yes
Infliximab	Yes	Yes	Yes

NSAID: nonsteroidal antiinflammatory drugs; * Injection of steroids in single affected joints is effective; † Sulfasalazine is considered only moderately effective in PsA.

Management of Psoriasis and Psoriatic Arthritis: Economic Challenges

Considerable resources must be allocated to the care of patients with chronic inflammatory diseases. This, along with their effects on patients' functional abilities, makes them costly. The recent approval of a number of biologic agents for the treatment of psoriasis and/or PsA has improved therapeutic options. Given their efficacy and safety profile, these drugs should be considered in patients who need photo or systemic therapies. However, only the US Food and Drug Administration has approved these drugs. In contrast, the European regulatory body, the European Medicines Evaluation Agency, has approved biologics only as last-line therapy for psoriasis. This decision was due in part to much higher yearly direct treatment costs, which may easily exceed US$20,000, compared to less than US$1,000 for methotrexate, a widely accepted, commonly used alternative therapy.

Moreover, many countries have introduced additional regulatory mechanisms. Some healthcare systems (e.g., Spain and Italy) restrict prescriptions of biologics for psoriasis to defined clinics. In other countries (e.g., Norway), a central body of experts reviews applications individually for each patient to be treated with a biologic. In Germany, current legislation will require physicians to seek a second opinion from a predefined expert before initiating biologic treatment in their psoriasis patients. Finally, numerous countries (e.g., Venezuela) severely limit the number of approved biologics for psoriasis.

Following several initiatives to investigate the cost-effectiveness of certain biologics for treating psoriasis, criteria have been established in 2 healthcare systems: the British public health services and Germany. Both have concluded that the biologics analyzed may be used cost-effectively if psoriasis is sufficiently severe. For example, the cutoff point for cost-effectiveness of treating psoriasis with etanercept in Germany is a PASI score > 15 and a Dermatology Life Quality Index score > 15[10].

Similar analyses for the use of tumor necrosis factor-α-blocking biologics exist for PsA. In a recent Italian multicenter project, the costs per quality-adjusted life-year (QALY) gained were €40,383 for the National Health Service and €37,096 for the society. Cost-effectiveness ratios were therefore within the threshold of €50,000 commonly accepted in the European Union[11].

The Quality Movement

In light of the above considerations, it comes as no surprise that psoriasis patients tend to be undertreated. A recent survey among German dermatologists in private practice documented that about 50% of patients with a PASI score > 10 were receiving systemic therapy, and < 50% with PsA (verified by a rheumatologist) received systemic therapies[12]. This standard meets neither the criteria cited in textbooks nor those of evidence-based treatment guidelines[13]. Indeed, psoriasis and PsA patient advocacy groups such as Arthritis Care in the United Kingdom and the Canadian Arthritis Patient Alliance are actively pursuing higher standards of care from healthcare providers[14]. Therefore, efforts to improve the management of psoriasis and PsA are urgently needed and must not only incorporate improvement of patient outcomes by identification and promotion of best practice from a purely medical point of view, but also consider the pharmacoeconomic perspective. These are the goals of the Quality Movement in the US and of quality management in general. Among the respective tools are Quality Performance Indicators (QPI), processes of measure used to assess the quality of care, which are based upon best scientific evidence and expert opinion that will benefit patients (outcomes), physicians (efficiency), and the health system (safety and productivity).

In the US, the payers are currently most active when it comes to defining these QPI, as reflected by initiatives from Medicare and Medicaid services. On July 1, 2007, Medicare launched the Physician Quality Reporting Initiative, in which physicians choosing to report quality data receive a bonus equalling 1.5% of the total Medicare billing. Currently, 74 items eligible for reporting have been defined (http:/www.cms.hhs.gov/pqri). Similar initiatives include disease management programs, such as for diabetes in Germany, where a predefined maximum HgbA1C value must be met.

The GRAPPA Initiative for Quality

There is a major need for evidence-based guidance on safety, efficacy, overall outcome, and last but not least, cost-effectiveness. To meet this demand, numerous initiatives to generate evidence-based treatment guidelines are under way, complemented by the above-mentioned activities on controlling costs and optimizing cost-effectiveness of such

treatments. Although the former accurately summarize valid scientific data, and the latter apply management tools to influence the cost aspects of care, they both fall short of providing practical guidance to secure and improve disease management. The GRAPPA Initiative for Quality aims to close this gap for the management of psoriasis and PsA and to address all 3 major aspects of quality: structure/formal aspects, quality of the processes, and quality of results. At this time, the GRAPPA Initiative for Quality has reached consensus on the following items:

- If a patient has psoriasis and/or PsA, the healthcare provider should consider all of the following individual aspects of disease and to what extent disease is active in these different areas[15]: peripheral arthritis; psoriasis, including nail involvement; axial disease; dactylitis; enthesitis; and other comorbidities, e.g., iritis, vasculitis, cardiac disease, and risk factors.
- The evaluation of all these aspects should be done using appropriate tools, which are currently being defined by the GRAPPA subcommittee on screening and assessment tools[16]. The tools applied must appropriately reflect the perspectives of the physician, patient, and payor.
- Based on this assessment, patients will be stratified as having mild, moderate, or severe disease (see the grid of GRAPPA treatment recommendations)[17].
- Depending upon the level of disease activity and severity, an evidence-based treatment regimen will be followed. Where the respective national guidelines are lacking, it is suggested that GRAPPA's evidence-based treatment recommendations be followed[17].
- A dialogue between rheumatologist and dermatologist is potentially beneficial in the longterm management of PsA patients.
- The overall goals of treatment are to minimize pain, maximize function, avoid toxicity from treatment, and prevent disease progression. Defining benchmarks for these outcomes is an important part of the GRAPPA research agenda.

Summary and Perspective

GRAPPA's Initiative for Quality intends to secure and improve management of psoriasis and PsA and may serve as an extension to evidence-based guidelines on the treatment of these diseases. The major domains defining quality are currently being addressed in an attempt to create a checklist that helps physicians to provide state-of-the-art medical services and may also provide patients a means of identifying those doctors who can administer these state-of-the-art services. Currently, an attempt to reach consensus on feasible treatment goals in psoriasis and PsA is under way, building on recently published suggestions[18]. To the extent that it can be accomplished, GRAPPA will attempt to work with patient advocacy groups and with professional societies in rheumatology (e.g., ACR, European League Against Rheumatism) and dermatology (e.g., American Academy of Dermatology and European Academy for Dermatology and Venereology) to develop, promote, and implement these quality indicators for patients with psoriasis and PsA.

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