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Impact of Psoriatic Disease on Quality of Life

Statement of Need

The persistence of psoriasis as a lifelong problem often translates to a frustrating condition for patients and clinicians. As awareness of the devastating impact psoriasis may have on patients' lives increases, healthcare professionals are becoming evermore sensitive to the emotional response associated with the condition. The focus on quality of life is an important part of the overall care of the patient, and its positive achievement should be a key therapeutic goal.

Effective treatment for psoriasis has been available for many years, and patients often respond well to medical intervention. In addition to the traditional agents, biologics provide several advantageous options. Long-term studies are generating data that indicate biologics are safe and effective for use over extended periods of time.

The relationship between psoriasis and co-morbid conditions is also a topic of great interest with new information continuing to come to the forefront of discussions on psoriatic disease. Prevalence rates of cardiovascular disease, obesity, diabetes mellitus, and lymphoma are higher among individuals with psoriasis than among those without the condition. The increased risk of these diseases suggests existence of an inflammatory process not restricted to the skin but also observed systemically with metabolic and vascular abnormalities. This speculation is further supported by the concurrent existence of psoriatic arthritis, colitis, or uveitis among many patients with psoriasis.

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Understanding both the pathophysiology of psoriasis and the proposed mechanisms of immune system modulation is necessary for appreciating the benefits observed with biologic agents. Utilizing strategies to inform practitioners about the latest data and why the biologics are advantageous in terms of efficacy and safety as they target the aberrant pathways involved in the disease process is an important component of continuing medical education.

Clinical trial data are published in several journals, and investigators present their latest information at national and international conferences; however, considering the hectic schedules of today's busy clinicians, it is often difficult for them to allot ample time to review pertinent materials. Nonetheless, dermatological experts have expressed a need for further education in the area of inflammatory dermatological disorders and the use of novel therapies. Evaluation of previous CME activities has demonstrated that evidence-based educational content that can be practically applied truly meets the learning needs of healthcare professionals because of the pragmatic nature of the case-based format. In addition, clinicians appreciate and profit from learning of the experiences of leaders in their field. An enduring material series designed to provide a national audience of dermatologists with a brief review of evidence-based clinical data and demonstrative practical case histories that illustrate appropriate uses of anti-TNF therapies exposes practitioners to the information they need in a format they can use.

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CASE 1

Management of a Patient with Mild Chronic Psoriasis and an Acute Flare



**Authored by
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He received his medical degree from the Texas

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Dr Jackson is a member of multiple professional societies, including the Medical Dermatology Society, American Academy of Dermatology, American Medical Association, and Dermatology Foundation. He was president of the Kentucky Dermatology Association for 2005-2006. He has

authored or co-authored numerous book chapters and articles appearing in such periodicals as *Journal of the American Academy of Dermatology*, *JAMA*, *Medicine*, and *Journal of Cutaneous Medicine and Surgery*, among others. Dr Jackson has also been a guest presenter at many meetings and symposia in the field of dermatology. Some of his research interests include systemic therapies for dermatology, cutaneous manifestations of internal diseases, contact dermatitis, and psoriasis.

Overview

The patient, a 23-year-old man with a 3-month history of guttate psoriasis, reports worsening skin lesions following a recent strep throat infection. The infection was successfully treated with amoxicillin, but his psoriasis continued to worsen.¹ Prior to this exacerbation, the patient had mild psoriasis of the elbows and knees for the past 3 years that was adequately controlled with topical therapy. No history of arthritis and no significant family history of psoriasis are reported.

Past medical history is negative for other medical problems. The patient admits to drinking alcohol on weekends regularly and, sometimes, heavily. He is on no other medications and reports no allergies.

He is frustrated by the continued worsening of his disease, severe itching, scaling, and his appearance.² He wants his skin to be clear for the summer. He also expresses embarrassment that women will not be interested in him if his skin continues to look bad.³

This treatment is chosen for its rapid onset of action in patients with previously limited psoriasis whose symptoms have recently worsened but whose disease is usually mild and easily controlled with topical therapy.

Treatment options for this patient who is no longer controlled with topical therapy include acitretin, methotrexate, UVA/UVB, cyclosporine, a TNF- α inhibitor, and efalizumab.^{4,6} After discussing all of the available options and the different speed of clearance with each treatment with the patient, therapy is initiated with cyclosporine 300 mg/d (5 mg/kg dosing with 100 mg every morning and 200 mg every evening). This treatment is chosen for its rapid onset of action in patients with previously limited psoriasis whose symptoms have recently worsened but whose disease is usually mild and easily controlled with topical therapy. Baseline labs were performed prior to initiating therapy including a comprehensive chemistry panel, complete blood count, hepatitis panel, HIV testing, and a PPD. Results of all these screenings were unremarkable. In addition to discussion of the current treatment, the patient is given information on other, longer-term options for review.

After 1 month, the patient notes almost total clearing. He is then lost to follow-up until 4 months after presentation when he returns to the office with worsening psoriasis after running out of cyclosporine. Examination on this visit reveals 20% body surface area (BSA) psoriasis with no arthritis (*see Figures 1A-1C*).

The patient has reviewed information on all of the available agents provided by his dermatologist and now wants longer-term therapy to prevent return of the disease if he discontinues cyclosporine. Etanercept, infliximab, adalimumab, alefacept, and efalizumab are biologic agents approved by the FDA for the treatment of psoriasis.⁷⁻¹¹ He feels more

Learning Objectives

At the conclusion of this activity, participants should be able to:

- Interpret epidemiological information and recent data regarding psoriasis and psoriatic conditions
- Recognize the impact of psoriasis on patient quality of life
- Evaluate how scientific and clinical trial data impacts daily dermatology practice
- Determine management strategies to optimize therapeutic outcomes and quality of life

Target Audience

This CE/CME activity is designed for a nationwide audience of dermatologists, physician assistants, nurse practitioners, and other dermatology healthcare professionals who treat patients with dermatologic diseases and who are interested in enhancing their patient management strategies.

Accreditation Statements

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of CME Consultants and Educational Awareness Solutions®. CME Consultants is accredited by the ACCME to provide continuing medical education for physicians.



This program has been planned in accordance with AAPA's CME Standards for Enduring Material Programs and for Commercial Support of Enduring Material Programs.

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Credit Designation Statements

CME Consultants designates this educational activity for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This program has been reviewed and is approved for a maximum of one hour of AAPA Category 1 CME credit by the Physician Assistant Review Panel. Approval is valid for one year from the issue date of April 15, 2008. Participants may submit the Post-Test at any time during that period. Successful completion of the Post-Test is required to earn Category 1 CME credit. Successful completion is defined as a cumulative score of at least 70%.

This program has been approved for 1.0 contact hours of continuing education (which includes 0.50 hours of pharmacology) by the American Academy of Nurse Practitioners. Program ID 0801048.

Estimated Time to Complete

The estimated time to complete this activity, including the time to complete the post-test, is 1 hour.

Commercial Support

This activity is supported by an educational donation provided by Amgen and Wyeth Pharmaceuticals.

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Please note: Credits will only be awarded for Post-Test scores of 70% or greater. Post-Tests should be completed no later than April 15, 2009.

Disclosure Statement

In direct response to the September 2004 Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support, CME Consultants issued a conflict of interest policy dated January 2, 2005. The policy states that the disclosure of potential financial conflicts of interest within the last 12 months must be made and resolved prior to date of the CME/CE activity where commercial support grants are to be used to fund the activity. The following conflicts have been managed and resolved through the Independent Review Committee of CME Consultants. Our intent is to assist learners in assessing the potential for bias in information that is presented during the CME/CE activity.

The faculty is also aware that it is their responsibility to inform the audience if discussion of any non-FDA-approved uses of pharmaceuticals, medical equipment, prostheses, etc, will be included in their presentations.

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FDA Disclosure

The contents of some CE/CME activities may contain discussions of nonapproved or off-label uses of some of the agents mentioned. Please consult the prescribing information for full disclosure of approved uses.

Impact of Psoriatic Disease on Quality of Life

The quantification of the impact of quality of life (QOL) in psoriasis patients has gained substantial credibility starting in the 1990s with the publication of seminal work such as Rapp et al.¹ Consistently, survey data since then using validated QOL instruments has shown substantial decrements on quality of life in psoriasis patients on par with those of other chronic diseases. Beyond the physical discomfort, effects include impact on work choices, formation of relationships, and socioeconomic status. In one study of psoriasis patients, most of whom had moderate to severe disease, nearly half of the patients would have

preferred to suffer from another serious medical condition such as hypertension or asthma than from psoriasis.² Moreover, in this same study, 46% of patients described themselves as chronically depressed, 83% avoided sports activities such as swimming, 35% felt that their sexual relationships were inhibited, and psoriasis had affected the careers of 23%.²

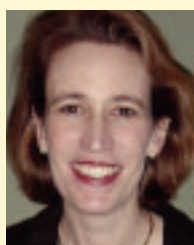
What has been somewhat surprising, however, is that although, in general, decrements in QOL increase with disease severity, there are patients who suffer profoundly in the setting of relatively mild disease. What leads to this differential coping? Likely, several factors mediate this experience, but data points to one that may predominate: stigmatization. In one paper that examined this phenomenon directly, psoriatic patients reported higher levels of episodes of stigmatization (EOSs) related to the disease compared with the comparison group. The authors' conclusions were that psoriasis patients experience higher levels of stigmatization than do other dermatological patients and that these EOSs mediate the

association between disease severity and patients' reported low levels of QOL.³ Related work has confirmed that the visibility of lesions is likely to contribute to the impact of psoriasis on the Dermatology Life Quality Index (DLQI).⁴

Other emerging data corroborating these findings show that the age at which one develops psoriasis affects one's experience. One study has shown that the health-related quality of life (HRQOL) impact of psoriasis decreases with time and that some of this change is due to declining concerns related to physical appearance.⁵ Surveys of young Americans (18-25 years old) without psoriasis confirm that appearance and fear of catching a contagious disease affect the romantic acceptability of people they would consider dating, highlighting the impact of a visible skin condition in people of this age group.⁶

This data raises the possibility that older psoriasis patients have learned to cope with their disease and set their life course while younger patients, especially those in their 20s, suffer disproportionately. As they enter the decade when they are choosing careers and forming lifelong attachments, younger patients may be hindered dramatically by their disease. Lastly, we know clearly from multiple recent studies that good therapy has a profound impact on QOL, and loss of disease control has substantial negatives. We also know that psoriasis patients are undertreated. Therefore, while the dermatologic paradigm has long been that we should "save our treatments" until our patients appear to really need them, it may well be that we can have greater impact if we employ them early in those we can most help.

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graduated Phi Beta Kappa from Princeton University and received her medical degree from Yale University School of Medicine, where she was inducted into Alpha Omega Alpha. Her postgraduate training includes Chief Resident in Dermatology at Stanford University Medical Center and Clinical Fellow in Dermatology at the National Institutes of Health in Bethesda, Maryland. She received her masters of public health degree from the Johns Hopkins School of Public Health, where she was inducted into Delta Omega Alpha.

Dr Kimball is currently conducting multiple trials, ranging from phase 1 through phase 4 studies. Her clinical trials experience includes topical and systemic agents for disorders such as psoriasis, atopic dermatitis, acne, superficial basal cell carcinoma, and epidermolysis bullosa, and she also has done extensive work in the area of anti-aging. She has been Medical Producer and Host of *On Call*, a weekly, 60-minute public access cable television program, and has served as a frequent interview source for over 50 media sources, including *Time*, *National Geographic*, *Vogue*, and *The New York Times*. Dr Kimball has presented her work at national and international medical and scientific symposia and has contributed significantly to the medical literature with articles and abstracts published in such journals as *Archives of Dermatology* and *Journal of the American Academy of Dermatology* and has published a book on psoriasis entitled *100 Q & A About Psoriasis* for the lay public.

comfortable with the addition of etanercept than with the other options as he feels etanercept has more history of long-term therapy in psoriasis. The patient is comfortable with the autoinjector syringe and opts to proceed with therapy with etanercept 50 mg SQ injection twice weekly for more rapid control.⁷

After 1 month of etanercept therapy, the patient notes marked improvement with good tolerability and efficacy and opts to continue with therapy. At 3 months, the patient is almost clear and able to reduce his etanercept dose to 50 mg SQ weekly. He maintains efficacy on one 50-mg injection every 7-10 days with topical therapy for localized control.

The first concern is how to manage patients with mild chronic disease that flares acutely and what to do if the flare persists on a more chronic basis.

Discussion

This case highlights a few issues which apply to many psoriasis patients. The first concern is how to manage patients with mild chronic disease that flares acutely and what to do if the flare persists on a more chronic basis.

Cyclosporine was initiated in this patient for its quick control, but it is not best for long-term administration.¹² Many patients respond to a 4-6-month course of cyclosporine and are able to control their disease afterwards with local therapy only, but some patients need longer-term control. This patient ultimately chose the long-term treatment option as there was a history of psoriasis prior to the flare.

Other agents to consider for this type of patient and the reasons they were not suitable options in this case are as follows:

- Acitretin: too slow for current patient but good side effect profile

- Methotrexate: not a good option with patient's alcohol history
- UVA/UVB: good option, but patient's schedule prohibits this regimen and insurance copays for light are too high
- TNF- α inhibitors: etanercept, infliximab, and adalimumab are all good options for patients with psoriasis, and are well-tolerated, and long-term data on their use have demonstrated excellent safety profiles^{5,13,14}; but with no previous use of systemic therapies, self-administration and insurance issues make these agents difficult to prescribe initially^{4,6,8}
- Efalizumab: good option for this patient with rapidly worsening psoriasis, but same issues as with TNF- α inhibitors

Figure 1A.



Figure 1B.



Figure 1C.



If the patient does not have psoriatic arthritis, we, as dermatologists, are able to detect recurrence visually, allowing us to taper medications to effect; however, if arthritis is present, one must wait for pain and/or joint symptoms to occur in order to titrate the dose.

The second issue that this case raises is what to do with a psoriasis patient who clears on therapy. Should you continue the current dosing regimen or begin tapering the dosing interval? If the patient does not have psoriatic arthritis, we, as dermatologists, are able to detect recurrence visually, allowing us to taper medications to effect; however, if arthritis is present, one must wait for pain and/or joint symptoms to occur in order to titrate the dose. It has been documented that pain is not an indicator of joint inflammation, and in many patients, by the time pain is manifest, joint destruction has already occurred.¹⁵ This patient only had findings of psoriasis which allow for tapering the dose or increasing the interval between injections.

Changing the interval of dosing of TNF- α inhibitors should be performed slowly over 3-6 months as many of the effects of therapy persist for up to 90 days after the last dose. I recommend that patients increase the time between injections by 1 day every 4-6 weeks in order to maintain disease control while utilizing fewer injections. The other obvious option is to continue the standard dosing regimen even when the patient is clear.

A third issue is the impact of psoriasis on quality of life.^{2,16} The impact of psoriasis on quality of life is a well-appreciated reality and a concern that clinicians should discuss with their patients and consider when selecting therapeutic intervention. This patient is a single male in his early twenties. Dating and feeling embarrassed that he will not be attractive to women is a great motivator for seeking treatment for visible

lesions. This patient also was impacted as his coworkers noted the involvement of his arms and wondered if he was contagious. These factors should play a role in what the clinician decides to utilize for therapy in patients with psoriasis. This patient's state of mind improved dramatically with his initial clearance and then worsened again when the disease returned. He was obviously in need of long-term control for both his skin findings as well as his mental state. The rapid onset of improvement with cyclosporine was critical in the initial choice of therapies. Once the patient had shown the need for longer-term treatments, other options were available. Of the available options given to the patient, etanercept was chosen based on its long-term safety and efficacy data in psoriasis as well as for the fact that it is safer than the traditional therapies available in a less-than-compliant patient.

Case 1 Editorial Commentary: Alexa B Kimball, MD, MPH

This case scenario raises several areas for consideration. It describes a young man who is in need of sophisticated medical care in an era when many treatment options are available to him. Moreover, because of his age, he will likely need to be treated for decades to come. Setting expectations about efficacy, persistence of improvements, side effects, and adherence are critical components of his care at this early stage. This case also highlights a major gap in our current knowledge about the effect of therapy on QOL in psoriasis patients. Although we clearly know that a good therapeutic response is associated with QOL improvements, we do not yet understand how the relationship changes when patients who are clear or almost clear lose their response. Anecdotally, many clinicians describe the anxiety that patients express about losing control of their disease, but we have yet to quantify this effect in a meaningful way.

It has been documented that pain is not an indicator of joint inflammation, and in many patients, by the time pain is manifest, joint destruction has already occurred.

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CASE 2

Treatment of a Female Patient with Psoriasis: Quality of Life Issues and Pregnancy



Authored by
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Dr Kristine Jane Kucera is a Physician Assistant with Texas Dermatology Associates at the Baylor Research Institute in Dallas where she is

clinically involved with the evaluation, diagnosis,

and treatment of general dermatologic patients as well as the diagnosis, monitoring, and therapy of individuals with skin cancer, psoriasis, and other relevant disorders. Dr Kucera is also a sub-investigator in multiple drug study clinical trials.

She earned her Bachelor of Science and Master of Science degrees in Physician Assistant Studies at Galveston's University of Texas Medical Branch and Omaha's University of Nebraska College of

Medicine, respectively. Her Doctorate of Health Science was awarded in mid-2006 at Nova Southeastern University in Ft Lauderdale, Florida.

Dr Kucera has made dozens of presentations on such topics as TNF-alpha inhibitors, psoriasis/psoriatic arthritis, eczema, acne vulgaris, geriatric dermatology, skin cancer, and more. She has also done extensive research on such drugs as tazarotene, etanercept, and clindamycin and all of the biologic drugs.

Overview

RG is a 28-year-old woman referred to the dermatology clinic for management of her skin lesions. She first noticed raised red areas with dry, flaky scales on her elbows 6 months ago. Her primary care physician treated her with several different topical corticosteroids but never had a good response. The lesions have now spread to her face, scalp, trunk, and knees, and she complains of itchy, flaky scalp. She is otherwise in good health. Her past medical history is unremarkable with no history of chronic illnesses.

Family history is positive for psoriasis (father) and skin cancer (mother and maternal grandmother, type unknown). RG is married and has no children, but she wishes to start a family within 1-2 years. She currently takes oral contraceptives but no other medications. RG works as an attorney, does not smoke, and drinks 2-3 glasses of wine per week. During her evaluation, she states that she is very embarrassed about the lesions on her face and does not like her husband to see her without clothing. In addition, she avoids wearing dark suits to work because she is embarrassed by dandruff-like flaking.

On physical examination, red plaques with dry, silvery-white scales are observed on RG's face, scalp, trunk, elbows, and knees with a body surface area (BSA) of 12% affected. A few discrete pits are noted on the fingernails. There are no other signs of illness and no signs of psoriatic joint tenderness or swelling.

Treatment options and individual treatment goals are discussed with the patient. PUVA is initially considered, but RG has fair skin and a positive family history for skin cancer. She is fearful of developing skin cancer and does not want to increase her risk by treating her psoriasis with ultraviolet light. Moreover, PUVA is impractical for RG because of the frequency of required visits to the dermatology clinic. A decision is made to start biologic therapy, and options are reviewed. Not wanting to come to the office for an infusion and feeling confident in her ability to give herself an injection, it is agreed that she will start a course of etanercept.

Over the next 6 months, RG does very well with therapy; however, at her follow-up visit, she states that she is 8 weeks pregnant. A consultation with her obstetrician has reassured her that she can continue on etanercept therapy. Still, RG remains concerned about continuing the medication and decides to stop treatment. As a backup plan should her psoriasis worsen while she is pregnant, RG is to contact the office to start Ultraviolet Light B therapy.

Update:

Light therapy did not become necessary, and following an uneventful pregnancy, RG gave birth to a healthy baby boy.

Discussion

Psoriasis not only affects the patient's skin but is associated with significant psychosocial morbidity and a decrease in quality of life. It is important that clinicians view psoriasis as a serious disease and resist the tendency to underestimate its impact on overall patient well-being.¹ The management of psoriasis, like that of other immune-mediated conditions, is complex. The extent of skin involvement, impact on a patient's daily life and functioning, patient age, patient gender, presence of co-morbid disease, pregnancy consideration, and therapy risks versus benefits may all influence the choice of treatment. To assist in considering an agent for use in pregnant patients, the FDA has defined pregnancy categories (*see Appendix A*).

Consensus guidelines on psoriasis treatment as well as diagnostic algorithms have been published to assist in determining if a patient is a candidate for systemic treatment. According to these guidelines and algorithms, important factors to consider are whether or not patients' psoriasis affects more than 5% of BSA, whether or not they are disabled by their psoriasis, and whether or not their psoriasis has a significant impact on quality of life. If any of these conditions apply, then the patient is considered to be a candidate for systemic therapy.²

Traditional systemic therapies such as methotrexate, cyclosporine, and acitretin are widely used but have well-known associations with toxicity. Methotrexate, developed in 1951, was the first systemic drug to control psoriasis. The most serious long-term adverse event associated with methotrexate is hepatotoxicity; it is also rated Pregnancy Category X by the FDA.³ Cyclosporine is a potent immunosuppressant and was first shown to be effective in the treatment of psoriasis in 1979. The main adverse event of cyclosporine is nephrotoxicity, and hypertension is common as well. In addition, this agent has many drug interactions and is rated Pregnancy Category C by the FDA, with premature labor and lower birthweight babies being noted.⁴ Acitretin is an oral retinoid that is effective as monotherapy for treating pustular psoriasis and is used as an adjunct therapy in treating guttate and plaque psoriasis. However, acitretin is highly teratogenic, has a pregnancy rating of X by the FDA,⁵ and must not be used by women who wish to become pregnant within 3 years of stopping therapy.⁶

The newer, targeted immune therapies, known as the biologics, have shown promise in treating moderate to severe psoriasis more safely than the traditional therapies. Etanercept, infliximab, adalimumab, alefacept, and efalizumab are biologic agents approved by the FDA for the treatment of psoriasis.⁷⁻¹¹ Etanercept, infliximab, and adalimumab inhibit tumor necrosis factor-alpha (TNF- α), a proinflammatory cytokine implicated in the pathogenesis of psoriasis. The anti-TNF agents are well-tolerated, and long-term data on their use have demonstrated excellent

The newer, targeted immune therapies, known as the biologics, have shown promise in treating moderate to severe psoriasis more safely than the traditional therapies.

safety profiles.¹²⁻¹⁴ Etanercept and adalimumab are subcutaneous injections that the patient may self-administer at home; infliximab is an intravenous infusion that must be given at the doctor's office or at an infusion center.

The two FDA-approved biologics that affect the T cell are efalizumab and alefacept. Efalizumab is a humanized monoclonal antibody, and alefacept is a fusion protein. Efalizumab works to inhibit T-cell activation; alefacept disrupts T-cell activation and induces selective apoptosis of memory T cells.^{9,10}

Many available agents support pregnancy exposure registries. The Organization of Teratology Information Specialists (OTIS) maintains an ongoing registry designed to evaluate the safety of autoimmune medicines, including adalimumab and etanercept, for maternal and fetal outcomes when used in pregnancy (*see Appendix B*). At press time, both of these agents are defined by the FDA as Pregnancy Category B.^{7,11} When using these agents in patients who are or may become pregnant, it is important to explain the meaning of a Category B classification and recommend that the patient consult her obstetrician.

Finally, pregnancy can affect skin diseases due to the immunologic, endocrine, metabolic, and vascular changes that are taking place within the body. The most common type of psoriasis to develop or worsen during pregnancy is chronic plaque psoriasis. Studies report that 40-60% of women with psoriasis improve during pregnancy, but 14% worsen. During pregnancy, women have high levels of a specific cytokine, interleukin 10, which has a positive effect on the course of psoriasis. If a patient's psoriasis does worsen, UVB has been proven a safe alternative during pregnancy with a good long-term side effect profile.^{15,16}

It is important that clinicians view psoriasis as a serious disease and resist the tendency to underestimate its impact on overall patient well-being.

Case 2 Editorial Commentary:

Alexa B Kimball, MD, MPH

One of the interesting things that emerges from a review of data from available pregnancy registries for women with psoriasis is how few pregnancies are actually reported. This finding leads to some key questions. Is the lack of data due to there not being any pregnancies in this group of women on systemic therapy because we tend to treat women

of childbearing potential differently from other psoriasis patients or are there cases that are not being reported? Both factors could, of course, be playing a role. Young women with moderate to severe disease might have a lower chance of getting married or forming long-term relationships. Physicians might be very cautious about prescribing systemic medication in this demographic group, and women planning a pregnancy might strongly avoid being treated systemically. Lastly, dermatologists might not be aware of how to report pregnancies. Further research in this area could lead to some useful findings about this demographic group. Regardless of the small number of cases, it is critical to collect this data in order to counsel women who cannot realistically be off therapy during their pregnancies.

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Appendix A

The United States FDA has the following definitions for the pregnancy categories:

Category A: Adequate, well-controlled studies in pregnant women have not shown an increased risk of fetal abnormalities to the fetus in any trimester of pregnancy.

Category B: Animal studies have revealed no evidence of harm to the fetus, but there are no adequate and well-controlled studies in pregnant women; or animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.

Category C: Animal studies have shown an adverse effect, and there are no adequate and well-controlled studies in pregnant women; or no animal studies have been conducted, and there are no adequate and well-controlled studies in pregnant women.

Category D: Studies, adequate well-controlled or observational, in pregnant women have demonstrated a risk to the fetus. However, the benefits of therapy may outweigh the potential risk.

Category X: Adequate well-controlled or observational studies in animals or pregnant women have demonstrated positive evidence of fetal abnormalities or risks. The use of medications in this category are contraindicated in women who are or may become pregnant.

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Appendix B

Pregnancy Exposure Registry Information

Medical Conditions	Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and psoriasis
Medical Products Studied	Autoimmune medicines – Adalimumab – Etanercept
Registry Name	OTIS Autoimmune Diseases Study
Contact Information	Organization of Teratology Information Specialists Phone: 1-677-311-6972 (toll free) Web: http://otispregnancy.org/otis_study_ra.asp

CME Post-Test

Please circle your best answer for each of the following questions on the Answer Grid found on the Evaluation/Certificate Request Form on the next page and **return along with your completed Evaluation/Certificate Request Form** to CME Consultants. Or to complete this activity online, please visit www.psoriasisHQ.org. Successful completion of the post-test is required to earn Category 1 CME credit. Successful completion is defined as a cumulative score of at least 70% correct.

- 1. What factor(s) should influence choice of psoriasis treatment?**
 - a. Extent of skin involvement
 - b. Impact on daily life and functioning
 - c. Presence of co-morbid disease
 - d. All of the above
- 2. According to consensus guidelines on psoriasis treatment, which of the following factors should be considered to determine if a patient is a candidate for systemic therapy?**
 - a. Gender
 - b. Age
 - c. Impact on quality of life
 - d. None of the above
- 3. Which medication is rated Pregnancy Category C by the FDA?**
 - a. Cyclosporine
 - b. Methotrexate
 - c. Acitretin
 - d. Adalimumab
- 4. Which is the most common type of psoriasis to develop or worsen during pregnancy?**
 - a. Guttate
 - b. Plaque
 - c. Palmar-plantar
 - d. Seborrheic
- 5. According to survey data using validated QOL instruments, what area(s) of patients' lives are negatively impacted by psoriasis?**
 - a. Work choice
 - b. Relationships
 - c. Socioeconomic status
 - d. All of the above
- 6. In one psoriasis study, what percentage of patients described themselves as chronically depressed?**
 - a. 5%
 - b. 26%
 - c. 46%
 - d. 59%
- 7. Episodes of stigmatization mediate the association between disease severity and patients' reported low levels of quality of life.**
 - a. True
 - b. False
- 8. Which of the following statements regarding psoriasis and quality of life is false?**
 - a. Younger patients, particularly those in their 20s, suffer a great deal as a result of their psoriasis
 - b. Saving treatments until patients appear to truly need them is a recommended management strategy for psoriasis
 - c. Effective psoriasis intervention profoundly impacts patient quality of life
 - d. When it comes to dating/romantic acceptability, appearance is a big issue for individuals aged 18 to 25
- 9. If a patient with psoriasis but no evidence of psoriatic arthritis clears with anti-TNF therapy, what is a recommended strategy for maintaining the patient's status?**
 - a. Taper the anti-TNF dose to effect
 - b. Stop the medication and schedule a follow-up visit
 - c. Increase the interval between injections
 - d. A and C
 - e. All of the above
- 10. Which is not an anti-TNF agent?**
 - a. Etanercept
 - b. Efalizumab
 - c. Infliximab
 - d. Adalimumab

Practice With the Experts: Impact of Psoriatic Disease on Quality of Life Evaluation/Certificate Request Form—Volume 2, Issue 1

Date of Original Release: April 15, 2008; material expires one year from release date: April 15, 2009

Please complete the Evaluation/Certificate Request Form and return to CME Consultants, 94 Main Street, Wakefield, RI 02879 or fax to (401) 789-4366. Answers should be submitted no later than April 15, 2009. Please read the instructions below.

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This program has been reviewed and is approved for a maximum of one hour of AAPA Category 1 CME credit by the Physician Assistant Review Panel.

This activity is designated for a maximum of 1.0 *AMA PRA Category 1 Credit(s)*[™]. In order to receive your CME/CE credits, you are requested to review the material in full and take the Post-Test. Once you have completed the Post-Test, please note in the space provided on the Certificate Request Form the amount of time it took you to complete the entire activity, including the Post-Test. **Please note:** Credits will **only be awarded** for Post-Test scores of 70% or greater.

Thank you for completing the Evaluation Form. Your evaluation of the activity and comments are important to us and will remain confidential.

Please rate how effectively you are able to:

	Poor	Fair	Satisfactory	Good	Excellent
Interpret epidemiological information and recent data regarding psoriasis and psoriatic conditions	1	2	3	4	5
Recognize the impact of psoriasis on patient quality of life	1	2	3	4	5
Evaluate how scientific and clinical trial data impacts daily dermatology practice	1	2	3	4	5
Determine management strategies to optimize therapeutic outcomes and quality of life	1	2	3	4	5

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