Practical Considerations in the Treatment of Psoriasis with Biologics

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David M. Pariser, MD, Chair
Professor, Department of Dermatology
Eastern Virginia Medical School
Norfolk, Va.

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Craig L. Leonardi, MD
Associate Clinical Professor of Dermatology
St. Louis University Medical School and Central Dermatology
St. Louis, Mo.

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Associate Professor
Harvard Medical School, Massachusetts General and Brigham and Women’s Hospital
Boston, Mass.

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Jeffrey M. Sobell, MD
Assistant Professor of Dermatology
Tufts University School of Medicine
Boston, Mass.

TARGET AUDIENCE: This activity is designed for dermatologists and other healthcare providers who manage patients with psoriasis.

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Practical Considerations in the Treatment of Psoriasis with Biologics

NEEDS ASSESSMENT: Approximately 1.5 million people in the United States suffer with moderate to severe psoriasis. According to dermatology opinion leaders, all of these patients qualify for systemic therapy, yet only one third are being treated.* Although biologic therapies represent a significant safety advance over conventional systemic therapies, such as methotrexate and cyclosporine, most of the patients receiving systemic agents are not being treated with biologics; therefore, this patient population is greatly underserved.

Clinicians need to remain up-to-date on the most recent therapies for the patient with psoriasis. This multi-sponsored educational activity will review developments in the use of biologics in the treatment of psoriasis. It will provide dermatologists with practical clinical information that is immediately useful in the care of their patients.


EDUCATIONAL OBJECTIVES: After reading this supplement, clinicians should be able to:
• Discuss the basic science and real-world use of the biologic agents in the management of psoriasis
• Evaluate the long-term safety and efficacy of biologic agents in the treatment of psoriasis
• Describe to patients what expectations are realistic regarding biologic treatment of psoriasis
• Explain the role of screening for infectious diseases prior to initiation of certain biologic agents.

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Dr Kimball has received funding for clinical grants from and is a consultant to Amgen, Inc. Dr Korman has received funding for clinical grants from, is a consultant to, and has received honoraria from Abbott Laboratories, Amgen, Astellas, Centocor, and Genentech. He will discuss unlabeled use of adalimumab. Dr Leonard has received honoraria from and is a consultant to Abbott, Amgen, Bristol-Myers Squibb Company, Centocor, CombinatoRx, Genentech, and Warner Chilcott. He is also an investigator for 3M Pharmaceuticals, Abbott, Allergan, Altana, Amgen, Astellas, Centocor, Galderma Laboratories, Genentech, Novartis Pharmaceuticals, RTL, Schering-Plough Corporation, and Vitae. Dr Pariser has received funding for clinical grants from and is a consultant to and an investigator for Abbott, Amgen, Centocor, and Genentech. He will discuss the unlabeled use of adalimumab.

Dr Sobell has received funding for clinical grants from, is a consultant to, and has received honoraria from Abbott, Amgen, Centocor, and Genentech. Dr Strober has received funding for clinical grants and honoraria from Abbott, Amgen, Astellas, Centocor, and Genentech. He will discuss the unlabeled use of adalimumab.

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INTRODUCTION

David M. Pariser, MD, Chair

Approximately 1.5 million people in the United States have moderate to severe psoriasis. Only about one third of these patients who are eligible for systemic therapy are receiving such treatment. In addition, although biologic therapies have a significant advantage over conventional systemic therapies such as methotrexate and cyclosporine, most of the patients who do receive systemic agents are not being treated with biologics. As a result, this patient population is greatly underserved.

Dermatologists are in a unique position to treat patients with psoriasis, yet the biologics are not widely used by clinicians in this specialty. Instead, many patients with psoriasis receive their biologic therapy from rheumatologists.

In this supplement, five distinguished experts review developments in the use of biologics to treat psoriasis. Their presentations provide dermatologists with practical clinical information that is immediately useful in patient care.

THE PRACTICAL USE OF INFlixIMAB IN THE OFFICE: AS-observed DATA FROM ONE DERMATOLOGIST’S EXPERIENCE

Craig L. Leonardi, MD

Infliximab is a tumor necrosis factor (TNF) antagonist, binding soluble, membrane-bound, and receptor-bound TNF. The drug has been available since 1998, and, to date, more than 750,000 patients have been treated worldwide, representing 1.3 million patient-years of use. Infliximab has been approved by the US Food and Drug Administration (FDA) for a number of indications, including extensive and/or disabling plaque psoriasis in adults who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Infliximab should be administered only to patients who will be closely monitored and have regular follow-up visits with a physician.

Loss of Efficacy in Psoriasis

Despite its approval for psoriasis, few dermatologists have the facilities in their offices to administer this treatment. In practice, we instituted intravenous infusions because of our involvement in infliximab research.

At the FDA-approved dosage schedule, infliximab is administered by intravenous infusion of 5 mg/kg, with induction doses given at weeks 0, 2, and 6, and then administered every 8 weeks thereafter.

In the EXPRESS I study (the European Evaluation of Infliximab for Psoriasis (Remicade™) Efficacy and Safety Study I), Reich and colleagues demonstrated that by week 10—that is, the end of the initial study period—approximately 80% of patients treated with infliximab achieved at least a 75% improvement on the Psoriasis Area and Severity Index (PASI 75). However, the investigators saw a decline in efficacy over the subsequent 36 weeks.

All of the reasons for the loss of response to infliximab over time in the clinical trials may not have been established, but it is certain that some patients develop an immunologic response to the medication. The development of antibodies is associated with both infusion reactions and loss of efficacy, and antibodies enhance drug clearance. In addition, some patients metabolize drugs more quickly than others. The result, simply, is that if the drug is not present, the disease is not being treated. As the data from the EXPRESS II study demonstrate, the standard dosage regimen currently approved for infliximab is not effective in all patients.

Strategy for Overcoming Loss of Efficacy

Antibodies to infliximab are less likely to occur when infliximab levels are maintained between doses; patients reach a state of “immune tolerance.” The development of antibodies is most likely to be seen when the drug level falls to zero and the patient is then re-exposed. Several strategies may be useful to reduce antibody formation: increase the dose; increase the dosing frequency; add a medication. The development of antibodies is associated with both infusion reactions and loss of efficacy. As a result, this patient population is greatly underserved.

FIGURE. Infliximab In-Office Dosing Strategy

The timing of the next infusion is dictated by the response to therapy, according to my examination and assessment. If their skin is clear or almost clear (excellent response), their next infusion is scheduled in 7 weeks. Patients with a good response are scheduled for the next infusion in 6 weeks.

The algorithm becomes more complex for patients whose response is not adequate. First, I try shortening the interval between doses, infusing every 4 or 5 weeks. If the response is still inadequate, I try increasing the dose to 7.5 mg/kg—and, if necessary, up to 10 mg/kg—every 4 weeks (with prior approval of the patient’s insurance carrier). If a patient still does not respond, I consider discontinuing infliximab and trying another therapy.

I make treatment decisions at every point for every patient on the basis of skin response.

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ETANERCEPT: EFFICACY AND SAFETY OF TWICE-WEEKLY, 50-MG DOSING

Alexa Boer Kimball, MD, MPH

ETanercept has an excellent track record for both safety and efficacy in several immune-mediated inflammatory diseases, including psoriasis. The recommended dosage of etanercept for adult patients with plaque psoriasis is 50 mg twice weekly for 3 months, followed by a reduction to 50 mg/week for maintenance. Adding to our knowledge about how to use this medication, several recently completed studies have highlighted how to adjust dosage regimens as needed, combine etanercept with other therapies, and dose in special populations such as children. This excerpt will emphasize data supporting the use of etanercept at 50 mg twice weekly in the medium term.

Efficacy at Higher Doses

In a landmark study, Leonardi et al.1,2 compared a dosage of 50 mg twice weekly to two other dosage regimens of etanercept over a period of 24 weeks: 25 mg once weekly and 25 mg twice weekly. Similar to other studies, at week 12, 4% of the patients who received placebo achieved a 75% improvement in the Psoriasis Area and Severity Score (PASI 75). In comparison, 14% of those in the group that received 25 mg once weekly achieved PASI 75 (P = 0.0006), 34% of patients who received 50 mg/week (two 25-mg doses) reached PASI 75, and 49% of those who received 50 mg twice weekly reached that end point. However, by week 24, the group maintained on etanercept 50 mg twice a week continued to improve, with 59% achieving PASI 75, compared to 44% in the group who received 50 mg once weekly.

More recently, a phase III, randomized, double-blind trial3 was conducted in which 618 adults with moderate to severe plaque psoriasis were assigned—in a 1:1 ratio—to receive either etanercept (50 mg twice weekly) or placebo for 12 weeks. At the end of that 12-week period, 591 subjects in the original cohort participated in an 84-week, open-label extension of the study; in this portion of the study, all patients received etanercept 50-mg twice weekly.

High response levels in several standard psoriasis measures were observed over the total study period (both blinded and open-label phases) for patients in the etanercept-only group. At week 24, after 12 weeks of receiving etanercept in the open-label phase of the study, patients in the original placebo group had clinical benefits similar to those seen in the patients who had received etanercept since the beginning of the study. The Figure shows the PASI 75 responses for both groups at weeks 12, 24, 48, and 96.

Safety of Higher Etanercept Dosage

If a dosage of 50 mg twice weekly is planned, what safety issues should be considered? Safety data from the 96-week study discussed above were evaluated and recently published by Tyring and colleagues.3 Over 900 patient-years of etanercept exposure occurred over the 96-week study period. The exposure-adjusted safety profile of etanercept, 50 mg twice weekly is very similar to the accumulated 50 once weekly data: an overview is shown in the Table.

Neutralizing antibodies were not present in any patients. Non-neutralizing antibodies at one or more time points occurred in 18.3% of subjects and in 5.7% of individuals at three or more time points. A comparison between patients who tested positive and those who tested negative for anti-etanercept antibodies revealed similar mean PASI score improvements. In addition, safety was not influenced by the presence of nonneutralizing, anti-etanercept antibodies.

Finally, an important update was made to the “warnings” section in the labeling of all of the anti–tumor necrosis factor biologic drugs regarding hepatitis B reactivation. A small number of cases of hepatitis B reactivation have been reported in North America in patients receiving these agents, so screening for hepatitis B is now recommended prior to starting treatment.

Conclusion

In the 5 years since etanercept was approved for psoriatic disease, additional studies and clinical observation of this agent have provided valuable practical information about optimum use that can be used to guide clinician and patient expectations and decision making.

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adalimumab, a monoclonal antibody that binds tumor necrosis factor (TNF), has been approved by the US Food and Drug Administration (FDA) for the treatment of psoriatic arthritis (PsA). Phase III trials have been completed using adalimumab in patients with plaque psoriasis, and FDA approval is pending. Although adalimumab is not currently indicated for psoriasis, almost all patients with PsA also have some degree of psoriatic skin disease.

**Data on Efficacy in Psoriasis**

The 16-week, phase III pivotal trial of adalimumab in psoriasis involved a total of 1,212 patients with moderate to severe plaque psoriasis who were randomized 2:1 to receive monotherapy with either adalimumab (n=814) or placebo (n=398).

In the first week of the initial 16-week period of the trial, an 80-mg loading dose was given, followed by a 40-mg dose in week 2, then 40 mg every other week. By week 4, 18.9% of patients in the adalimumab group had achieved a 75% improvement in the Psoriasis Area and Severity Index (PASI 75), compared to 1.3% in the placebo group. No cases of lymphoma, nonmelanoma skin cancer occurred, but seven cases of tuberculosis (TB) among the patients in the placebo group; however, one patient developed reactivated TB. (This patient entered the study with known latent TB and, as per protocol, was treated with isoniazid in addition to adalimumab. The patient could not tolerate the isoniazid and discontinued the drug without telling the investigator.)

One patient receiving adalimumab developed mucocutaneous candidiasis; also in that group was a case of congestive heart failure (CHF), although the diagnosis was questionable since it involved leg edema with no other signs or symptoms suggestive of CHF, and the patient did not require hospitalization. Seven cases of nonmelanoma skin cancer occurred, but the incidence was not enriched in the adalimumab group when compared to the placebo group. No cases of lymphoma, lupus-like syndrome, or demyelinating syndrome were seen in this study.

**Adalimumab Therapy: Practical Considerations**

As with the other TNF inhibitors (infliximab and etanercept), there are several important potential adverse events that must be addressed. The risk for TB has made pre-screening the standard of care with all three drugs in this class. Any patient with latent TB must be treated prior to starting anti-TNF therapy. In addition, patients should be monitored for infections, particularly skin infections such as furunculosis and cellulitis. Opportunistic and fungal infections are seen rarely, as are demyelinating conditions, CNF, hepatitis B reactivation, and aplastic anemia.

My experience with adalimumab in real-world practice reflects the results reported in the phase III pivotal trial. I treat patients with adalimumab 40 mg every other week. I find that this regimen provides good control of joint and skin signs and symptoms in patients with PsA and cutaneous plaques. I have had good results with adalimumab as monotherapy, but I often use it in combination with low-dose methotrexate or, much less commonly, cyclosporine or acitretin. The practice of using low-dose methotrexate in combination with adalimumab derives from evidence that immunomodulators seem to augment and perpetuate the efficacy of the TNF blockers.

I also have found that adalimumab combined with a short course of therapy with cyclosporine can provide rapid and predictable control of mild flares of psoriasis. Patients with severe PsA and skin disease often are treated with etanercept 50 mg twice weekly, which can establish excellent control of both joint and skin disease. With step-down of the dosage, however, control of the dermatologic signs and symptoms can wane, while arthritis control is maintained. If this occurs, the patient and clinician must decide whether to continue etanercept and add methotrexate or acitretin or to combine etanercept with phototherapy. Another option is to resume a twice-weekly dosage schedule of etanercept monotherapy (if the patient’s insurance covers this strategy).

A third possibility is to switch to another TNF blocker (adalimumab or infliximab) or to one of the other biologics (alefacept or efalizumab) if there is no PsA. For example, I often see patients who do well on etanercept 50 mg twice-weekly, who lose therapeutic response at 50 mg once weekly, and who derive a good response on adalimumab 40 mg every other week. In patients who are appropriate candidates for methotrexate, I may add low doses of this drug—7.5 to 10 mg weekly—to the adalimumab regimen. Another choice for combination therapy with a biologic is mycophenolate mofetil at a low dosage (500 mg/day).

For patients who experience periodic mild flares of skin disease after achieving a good response, topical therapy with a
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cellular response. One potential safety concern with T-cell inhibitors is whether a reduced CD4 cell count may result in an increased risk for infections as a result of immune system compromise. So far, no such association has been reported. Nevertheless, clinicians should adhere to the recommendations regarding baseline CD4 counts and ongoing monitoring throughout treatment.

Safety Data

The accumulated safety data on the TNF inhibitors are extensive compared to those available for T-cell agents (alefacept and efalizumab). The TNF inhibitors were initially approved for the treatment of diseases other than psoriasis and have been used worldwide for a number of years. In contrast, the experience with T-cell agents—developed for the treatment of psoriasis—is much more recent.

One potential safety concern with T-cell inhibitors is whether a reduced CD4 cell count may result in an increased risk for infections as a result of immune system compromise. So far, no such association has been reported. Nevertheless, clinicians should adhere to the recommendations regarding baseline CD4 counts and ongoing monitoring throughout treatment.

Strategies for Improving Efficacy

In general, treatment with the TNF inhibitors has yielded higher response rates compared to treatment with alefacept, raising the issue of how to augment patient response to the T-cell biologic. In a small, randomized study involving 20 patients with chronic plaque psoriasis, Gribetz and coworkers treated subjects with alefacept, 15 mg/week for either 12 weeks followed by placebo for 4 weeks, or for 16 weeks without interruption. The patients who received the full 16 weeks of alefacept treatment had a significantly better response. This study suggests that a longer course of treatment may yield a better response, a conclusion that would have to be confirmed by a larger, controlled trial.

Another possible strategy for augmenting the benefit of alefacept is combination treatment with ultraviolet light. Ortonne and colleagues conducted a small study using alefacept alone or with 6 or 12 weeks of broadband ultraviolet B light (UVB) therapy. Both groups of patients who also received UVB had a faster response; there were no differences between the 6- and 12-week UVB groups.

Patient Selection

Both clinicians and patients must be aware of and accept the fact that alefacept works slowly, and results may not be seen until the end of a 12-week course of treatment. Therefore, this drug is not the optimum choice for individuals who cannot tolerate waiting for a response. However, for several groups of patients, alefacept therapy may be ideal.

Individuals for whom the possibility of treatment-free disease remission is very important probably will be satisfied as well as patient with the process. In addition, alefacept is a good option for patients in whom TNF inhibitors are contraindicated, particularly those who also have mild psoriatic arthritis; there is evidence that alefacept may be effective against this form of the disease. This drug is also a good choice for women who would like to plan a pregnancy; if the patient achieves remission, this is an excellent opportunity to attempt conception.

Conclusion

All of the available data have demonstrated that the optimum treatment of psoriasis with a biologic is not a matter of identifying the “best drug,” but in establishing the best match between agent and patient. Alefacept has an excellent safety profile and is a good choice for several subgroups of patients. Accelerating the drug’s slow onset of action with UVB phototherapy or combination treatment with other systemic agents may make it more acceptable to patients who are not likely to tolerate a delay in therapeutic response.

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lefacept, the first biologic drug approved for the treatment of psoriasis, works principally by targeting T lymphocytes, preventing their activation and subsequent production of a number of inflammatory cytokines, including tumor necrosis factor (TNF). Alefacept also has a role in apoptosis (ie, programmed cell death) of T lymphocytes. The drug is administered by intramuscular injection once weekly for 12 weeks.

Clinical Efficacy

In a phase III study, Krueger and colleagues found that 28% of patients achieved a 75% improvement in the Psoriasis Area and Severity Index (PASI 75) during 12 weeks of treatment with alefacept, or within the 12-week follow-up period following their last dose of the drug. Forty percent of patients who received two courses of treatment with alefacept achieved PASI 75. In contrast, 8% of patients in the placebo group achieved the PASI 75 benchmark.

The effect of this drug on T lymphocytes may be seen during treatment, but the maximal effect does not occur until after the course of therapy is complete. Thus, the anytime analysis more accurately reflects the number of patients who responded to the drug.

It is also important to recognize that alefacept may produce remission (Figure). In the phase III study, the median duration of response was 3.5 months among patients who achieved PASI 75 with one course of therapy (vs 1 month in the placebo group). When the subjects received a second course of alefacept therapy, a subset of responders were crossed over to placebo; those patients maintained a 50% or greater reduction in PASI for a median of 7 months.

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One potential safety concern with T-cell inhibitors is whether a reduced CD4 cell count may result in an increased risk for infections as a result of immune system compromise. So far, no such association has been reported. Nevertheless, clinicians should adhere to the recommendations regarding baseline CD4 counts and ongoing monitoring throughout treatment.

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Efalizumab is a humanized monoclonal antibody with activity against T cells. It is a first-line biologics choice approved to treat adult patients with moderate to severe plaque psoriasis who are candidates for systemic treatment and phototherapy. In addition, my experience is that this drug is helpful for other subpopulations of patients with psoriasis, including those who weigh ≥91 kg (=200 lb or more), individuals with hand and/or foot psoriasis, and patients who have not responded adequately to prior therapy with tumor necrosis factor (TNF) antagonists.

**Efficacy Data**

In an efficacy study of efalizumab after 3 and 6 months of treatment, Menter and colleagues found that 27% of the patients in the 3-month group achieved a 75% improvement in the Psoriasis Area and Severity Index (PASI 75) and that 44% of those in the 6-month treatment group achieved this level of response (Figure). Subsequently, Gottlieb and coworkers conducted a 3-year, open-label study of efalizumab. They reported that, in the as-treated analysis, response rates at 3-month intervals were maintained at PASI 75 or better in approximately 70% to 75% of patients who remained in the study at those points in time. In the intent-to-treat analysis (that is, considering all 339 patients enrolled in the trial, including dropouts), the response rates were 45.4% for PASI 75 and 24.5% for PASI 90. In real-world practice, the response is likely to be somewhere between the two extremes of as-treated and intent-to-treat rates.

**Subpopulations**

**Obesity.** Among patients with psoriasis, obesity has a twofold greater prevalence than among individuals in the general population. In addition, patients who weigh ≥91 kg (=200 lb or more), seem to be more resistant to treatment. Pooled data from several preapproval trials showed that there were no significant differences in achievement of PASI reductions between patients who weighed less than 91 kg (“nonheavy”) and those who weighed 91 kg or more (“heavy”) in both short-term (12- and 24-week) and long-term (3-year) treatment regimens.

**Hand and Foot Psoriasis.** Psoriasis affecting the hands and/or feet is challenging to treat, yet effective therapy can be crucial to the maintenance or restoration of function for some patients. A total of seven case reports have appeared in the literature, including one report on 17 patients, suggesting that efalizumab may be a good choice for the treatment of hand and/or foot psoriasis.

Our group has conducted a phase IV double-blind, placebo-controlled trial, now close to completion, looking at efalizumab for patients with moderate-to-severe hand and/or foot psoriasis. Eighty patients who had not previously used efalizumab were randomized 2:1 to receive 12 weeks of either the active drug or placebo. The primary efficacy end point was the percentage of patients whose psoriasis had cleared, had almost cleared, or was mild after 12 weeks of therapy, as determined by a physician’s global assessment scale. (Mild psoriasis was defined as slight erythema, minimal scale, with or without pustules.)

Not surprisingly, almost all of the patients had a history of recalcitrant disease. More than half of the patients had a history of prior phototherapy or systemic therapy (including 14 patients who had received treatment with a biologic agent).

The data from this study are pending publication and cannot be detailed here, but the patients in the active treatment group had significant improvement compared to those in the placebo group. The responses to treatment were encouraging after only 12 weeks of therapy, but clinical experience suggests that the improvements would have been even greater with a longer treatment time.

**Inadequate Response to Current Anti-TNF Treatment.** Inadequate responses may be seen with all of the TNF inhibitors. Several case studies have suggested that efalizumab may be effective in patients who have shown inadequate response to TNF inhibitors. A clinical trial currently is under way that addresses the question of efalizumab efficacy in nonresponders.

**Safety Update**

To date, the most common side effects reported with the use of efalizumab during the first 12 weeks of therapy are mild and transient flu-like symptoms that tend to occur very early, usually after the first one or two injections.

The adverse events data from the efalizumab 3-year trial showed no evidence of a trend toward an increase in the incidence of psoriatic adverse events with long-term therapy. In addition, there seems to be no evidence of cumulative immunosuppression with continued use of efalizumab, and no cases of significant infections or reactivation of tuberculosis have been reported. The number of new malignancies—the majority of which were nonmelanoma skin cancers—did not increase with long-term use. Finally, no new adverse events have been seen with long-term use of efalizumab, and there is no evidence of cumulative or end-organ toxicity.

**Conclusion**

Patients who respond to efalizumab tend to maintain that benefit with continued therapy over time. Efficacy seems to be consistent regardless of weight, making efalizumab a good option for patients who weigh 91 kg or more. The efficacy of this agent in the treatment of hand and foot psoriasis affecting the hands and/or feet is challenging to treat, yet effective therapy can be crucial to the maintenance or restoration of function for some patients. A total of seven case reports have appeared in the literature, including one report on 17 patients, suggesting that efalizumab may be a good choice for the treatment of hand and/or foot psoriasis.

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THE PRACTICAL USE OF INFILXIMAB IN THE OFFICE
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In-Office Infliximab Use:
One Practitioner’s Experience

Since January 2005, 119 patients have been treated in our office according to this strategy, for a total of more than 1,300 infusions. About 8% of these patients were on concomitant medications (7 on methotrexate, 1 on cyclosporine, and 1 on azathioprine). Most of them would be classified as “difficult to treat,” having been on other systemic treatments (on average, two or three agents) before starting infliximab therapy.

Among the patients who have had at least four infusions to date (n=79), 30% are clear, and 75% are either clear or almost clear. Ninety percent of the patients in this group receive infusions every 6 to 8 weeks, with 70% at a dose of 5 mg/kg and 30% at a dose of 7.5 mg/kg.

Among the entire group treated to date (n=119), 11 discontinued treatment for reasons related to efficacy. In a small number of good response, 4 patients; inadequate response, 4 patients; and flare of psoriatic arthritis, 3 patients). Adverse events caused discontinuation in 6 patients (2 serious and 2 moderate infusion reactions, 1 bacterial infection, and 1 case of ovarian cancer, cause unknown). The rest of the treatment dropouts were attributable to administrative causes (pregnancy, physician preference, patient preference, or problems related to insurance coverage).

Conclusion

The results discussed in this article are not based on a research trial, but are presented as a post hoc, as-observed data analysis. Variables were not controlled and included factors such as concomitant medication use and health insurance carrier decisions. What this experience does show is that dermatologists can and should incorporate the use of biologic therapy as an option for appropriately selected patients with psoriasis.

ADALIMUMAB
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mid- to high-potency corticosteroid can be considered.

Conclusion

Biologic agents are valuable additions to the roster of treatment options for patients with moderate to severe psoriasis, and dermatologists who do not already use these agents in their practices should consider incorporating them. In carefully selected patients and with attention to the recommended precautions (for example, screening patients for TB), these drugs are safe as well as effective. Adalimumab is an excellent choice of therapy for patients with PsA who also have skin disease.

EFALIZUMAB
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psoriasis has been the subject of several case reports, but formal data supporting this observation will be available soon in the literature. The safety data accumulated to date on efalizumab demonstrate that this drug is generally safe and well tolerated.

Dr Pariser’s Reference


Dr Leonardi’s References


Dr Kimball’s References


Dr Strober’s Reference


Dr Korman’s References


Dr Sobell’s References

Practical Considerations in the Treatment of Psoriasis with Biologics

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INSTRUCTIONS: For each question or incomplete statement, choose the answer or completion that is correct. Circle the most appropriate.

1. In the EXPRESS I study of infliximab in psoriasis, Reich and colleagues found that, by week 10 of therapy, more than _____ of patients had achieved at least a 75% improvement on the Psoriasis Area and Severity Index (PASI 75).
   a. 50%
   b. 60%
   c. 70%
   d. 80%

2. Etanercept’s mechanism of action involves:
   a. Binding of tumor necrosis factor
   b. Enhancing of cytokine production
   c. Increasing the production of T cells
   d. Preventing the activation of T lymphocytes

3. Which one of the following statements concerning adalimumab is true?
   a. Concomitant use with immunomodulators tends to decrease efficacy.
   b. Concomitant use with immunomodulators tends to shorten the duration of disease control.
   c. The drug is a T-cell inhibitor.
   d. The drug is a tumor necrosis factor inhibitor.

4. Alefacept should be considered a good treatment option in all of the following categories of patients except one. The exception is patients who:
   a. Are not candidates for treatment with tumor necrosis factor inhibitors
   b. Are planning a pregnancy
   c. Prefer a treatment that allows for the possibility of treatment-free disease remission
   d. Want a rapid response after starting therapy

5. Data have demonstrated that patients with psoriasis who weigh ≥91 kg (≈200 lb or more):
   a. Are less likely to have severe disease
   b. Are significantly less likely to respond to efalizumab treatment
   c. Respond as well to efalizumab as patients who weigh less than 91 kg
   d. Respond more readily to therapy with biologic agents

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