Employing a Patient-Centered Approach to Improve Clinical Outcomes in Patients With Moderate to Severe Psoriasis

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Activity Information

Activity Description and Educational Objectives
In this activity, a prominent expert in dermatology shares a personal story of the journey of a patient with moderate to severe psoriasis, highlighting important clinical considerations in the management of this disease.

Upon completion of this activity, participants should be better able to:
- Recognize conventional and novel treatment options for moderate to severe psoriasis in the context of mechanism of action, efficacy, safety, and clinical considerations for use
- Apply individualized therapy for patients with moderate to severe psoriasis, considering recent clinical trial data and patient-specific factors and preferences
- Employ accurate and appropriate counsel to patients with moderate to severe psoriasis, recognizing the impact of a strong clinician–patient relationship on improving medication adherence, as well as patient satisfaction and quality of life

Target Audience
This activity has been designed to meet the educational needs of dermatologists, primary care physicians, and other clinicians involved in the management of patients with psoriasis.

Requirements for Successful Completion
In order to receive credit, participants must view the activity and complete the post-test and evaluation form. A score of 70% or higher is needed to obtain CME credit. There are no pre-requisites and there is no fee to participate in this activity or to receive CME credit. Statements of Credit are awarded upon successful completion of the post-test and evaluation form.

Media: Enduring Material
Release and Expiration Dates: September 12, 2016 - September 11, 2017
Time to Complete: 30 minutes

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Jeff’s History: Unmet Needs in Psoriasis Management

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Los Angeles, California

Narrator: Welcome to this educational activity, where Dr. April Armstrong discusses a patient-centered approach to the management of moderate to severe psoriasis. After completing the activity, access the post-test and evaluation form by clicking the red "Get Certificate" button. We encourage you to download the slides, Practice Aids, and any other activity features that may interest you.

Patient Presentation: Jeff¹,a

Jeff is one of 7.5 million Americans living with psoriasis in the United States. He was working in sales for a company specializing in consumer goods, and in his spare time, he enjoyed walking his dog, Rudy.

When Jeff first came to me, he was 32 years old, and had already been living with psoriasis for 12 years. It had a significant, devastating impact on his life. At work, Jeff has always been bothered by how his psoriasis appeared to his colleagues and his customers, and he often wondered if it affected his career advancement. Personally, he has been reluctant to become intimate with anyone due to negative past experiences caused by his psoriasis.

I felt personally connected to this patient because I also enjoy spending time with my dogs, and it was something that we could always talk about during our visits. Importantly, I could see that he was a motivated and smart individual, but was held back by his psoriasis.

Let me tell you about Jeff’s journey with psoriasis before he saw me. In his early twenties, Jeff developed psoriasis and was living with it for about 6 and a half years before he even saw a doctor about it.

During that time he tried to self-medicate with over-the-counter treatments. He used salicylic acid cream for 2 and a half years, two to three times a week, even though he was completely unsatisfied with its effectiveness. He then started using tar shampoo for scalp psoriasis twice a week for 2 years.

While the tar shampoo only provided mild improvement, he found the smell to be quite unpleasant. He then started using tar shampoo for scalp psoriasis twice a week for 2 years.

Jeff decided to then see his family doctor about his psoriasis, who prescribed triamcinolone cream, 0.5%, to be applied daily for intermittent periods of time. He continued this treatment for about 2 years, and although it provided moderate improvement, the psoriasis still significantly impacted Jeff’s life.

He was reluctant to hang out with friends in fear of them asking him questions about his psoriasis. He went out on a few dates, and he was also very careful to cover up his psoriasis. He was afraid to tell his dates about his psoriasis or become intimate with them.

<table>
<thead>
<tr>
<th>Year</th>
<th>Treatment</th>
<th>Frequency</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>Salicylic acid</td>
<td>2-3 times per week</td>
<td>Unsatisfactory</td>
</tr>
<tr>
<td>2007</td>
<td>Tar shampoos</td>
<td>2 times per week</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>2010</td>
<td>Triamcinolone cream 0.5%</td>
<td>Daily intermittent periods of daily application</td>
<td>Moderate improvement</td>
</tr>
<tr>
<td>2011</td>
<td>Methotrexate</td>
<td>Max 20 mg/week with folic acid 1 mg/day on days when not taking methotrexate</td>
<td>Unsatisfactory</td>
</tr>
</tbody>
</table>

¹.iStock.com/Juanmonino,
Jeff’s family doctor then decided to refer him to a dermatologist. The dermatologist prescribed him another topical corticosteroid, which provided mild to moderate improvement over the course of a year. They then decided to add on a vitamin D analog, which only resulted in mild improvement in a year.

They then discussed phototherapy, which is one of the treatments for patients with moderate to severe psoriasis, but the phototherapy hours in clinic conflicted with Jeff’s work schedule. So finally, they added methotrexate.

After a year on this regimen, the response to methotrexate was overall unsatisfactory, and Jeff experienced occasional nausea.

Jeff’s Examination

At this point, Jeff was extremely frustrated, having had to live with his psoriasis for so long and continuously trying out all these various treatments. He wanted a second opinion from another dermatologist, and that’s when I first met Jeff.

When I first saw Jeff, he seemed depressed and almost had given up. I felt terrible for how his psoriasis was not able to be under good control, and I wanted to see what I could do to help him.

When I examined Jeff, I saw well-demarcated, erythematous, scaly plaques on his chest, abdomen, back, and extremities, which are very characteristic of plaque psoriasis.

Jeff’s Assessment: Comorbidities

All in all, Jeff’s clinical presentation was consistent with moderate to severe psoriasis.

Jeff had psoriasis covering about 15% of his body surface area, which qualifies him as having severe psoriasis. His PASI score, 13.3, was in the realm of moderate to severe psoriasis, which is usually a PASI score greater than 10. His physician global assessment score, or PGA, which was a score of 3, characterizes the appearance of the plaques, and his appearance of the plaques was graded as moderate severity.

I also screened Jeff for signs of psoriasis affecting the joints, which is important to do, as the presence of psoriatic arthritis influences treatment options. I found no evidence of psoriatic arthritis, and I also noted that he had no family history of psoriasis. However, the assessment of a patient with psoriasis oftentimes needs to go beyond the physical component. As we have seen with Jeff, psoriasis can substantially impact a person’s life and negatively affect their lifestyle, emotional well-being, social life, and the ability to work.

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Screening patients with psoriasis for comorbidities is another important aspect of the assessment. Upon further questioning Jeff and examining his medical records, I discovered that Jeff also has had depression for the past few years. He has gradually lost interest in things that he used to enjoy, and he was becoming more socially isolated. He had also started drinking alcohol more frequently, which was not recommended, given that he had been taking methotrexate.

Psoriasis: Unmet Needs

- Many patients will self-treat with over-the-counter agents without seeing a doctor, a practice that typically leads to prolonged suffering from the disease\(^1\)
- Given the extent of Jeff's psoriasis and its devastating impact on his life, he should have received treatment with a systemic agent much sooner in the process\(^2\)


Jeff's experience with psoriasis highlights many unmet needs in the treatment of this disease. For example, many patients will self-medicate with over-the-counter agents without seeing a doctor, and this often results in prolonged suffering from the disease.

Additionally, given the extent of Jeff's psoriasis and the devastating impact it had on his life, he probably should have received treatments with a systemic agent much sooner in the process.

When psoriasis involves 10% or more of the body surface area, as it did for Jeff, a topical treatment alone is really not enough. These patients definitely need to be evaluated for phototherapy or a systemic agent.
Dr. Armstrong: In psoriasis patients with no psoriatic arthritis, phototherapy is among the recommended treatment options, if available. Depending on how psoriasis plaques are distributed, phototherapy—and typically we talk about narrow-band UVB phototherapy—is delivered to large surface areas of the body, or sometimes to smaller and more specific areas.

Broadly, systemic therapies can be divided into oral systemic agents or biologic agents, which are typically injectable treatments. So what are the oral systemic agents for psoriasis? Conventional oral systemic agents include methotrexate, which Jeff has already tried and had not been satisfied with. Other conventional oral agents include cyclosporine and oral retinoids such as acitretin. We also have a newer oral treatment, apremilast, which is a specific phosphodiesterase 4, or PDE4, inhibitor.

Aside from the oral treatments, another category of systemic treatments is the biologic therapies. Biologic therapies target cytokines and other molecules that are implicated in the immunogenesis of psoriasis. Most biologic agents are monoclonal antibodies. One class of biologic therapies used to treat psoriasis is TNF inhibitors, and these include etanercept, adalimumab, and infliximab. A second class constitutes an inhibitor to the IL-12 molecule as well as the IL-23 molecule, which is ustekinumab. A third class of biologics used to treat psoriasis is inhibitors to IL-17A, which include secukinumab and ixekizumab.

Now with all of these treatment options, how do we decide what to use? A historical approach had been to use a stepwise approach, starting with a topical, then to a phototherapy option, then to conventional systemic medications, and then finally to biologics.

However, we have evolved towards an approach where, for patients with moderate to severe psoriasis, we consider phototherapy or oral systemic therapy, or biologic agents simultaneously. The ultimate treatment decision will need to be individualized, and depends on patients’ comorbidities and their preferences.

So, successful psoriasis care is a long-term, collaborative effort, and it requires commitment from both the provider as well as the patient. Discussing treatment efficacy and safety data together with the patient can enhance patient-centered treatment strategies. This can in turn lead to more informed choices, improved medication adherence, greater patient satisfaction, and optimal clinical outcomes.

So when I sat down with Jeff, I went over his past treatment history with him, his dissatisfaction with methotrexate, and what the potential next steps could be.
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Conventional Treatment Options: Efficacy and Safety

- **Side Effects**
  - Methotrexate and cyclosporine associated with significant side effects (eg, birth defects, malignancy, effects on kidney and liver)
  - Acitretin is teratogenic

- **Efficacy**
  - Methotrexate and cyclosporine effective
  - Acitretin only effective when combined with phototherapy


I explained that while conventional treatments can be effective, they can also be associated with both short-term and long-term serious adverse events. I then talked to Jeff about the biologic therapies and how they have transformed psoriasis treatment.

Biologic Treatment Options: Efficacy and Safety

- **Side Effects**
- **Efficacy**


I explained that the currently approved biologics offered robust efficacy in clearing psoriasis, and they have a favorable safety profile. I also explained that most biologics require injections into the subcutaneous tissue, and some monitoring would be required.

Psoriasis Treatment: Selecting a Biologic

- **PASI 75 Response**
  - **Greatest**
    - Infliximab
    - Ustekinumab
    - Adalimumab
  - **Least**
    - Etanercept


After taking in everything I had explained to him, Jeff decided that he was willing to take injections with a biologic if it increased his chance of alleviating his psoriasis.

The next question, of course, is then, which biologic? The options that were available at the time were adalimumab, etanercept, infliximab, and ustekinumab. I showed him some comparative efficacy data on these treatments, explaining that, in head-to-head trials, ustekinumab was superior to etanercept in the short term. While infliximab had very robust efficacy rates, it is an infusion that requires him to come to an infusion facility.

I also explained that both adalimumab and ustekinumab had very good and comparable efficacies based on indirect comparisons. While ustekinumab required fewer injections, adalimumab had longer-term safety data at the time than ustekinumab.

Jeff had some questions about tuberculosis. He had a BCG vaccination as a child and had positive PPD test results with a negative chest x-ray or TB symptoms. With the availability of QuantiFERON-TB Gold test, he tested negative later on, and he had a negative chest x-ray, and also no symptoms of TB. Upon consultation with infectious disease specialists, it was deemed that his previous PPD positivity was due to the BCG vaccination.

Jeff found this to be reassuring and was willing to try a TNF inhibitor. We determined that getting infliximab infusions would not be convenient for him. We decided to go with adalimumab, as we believed that it had the best balance of efficacy and long-term safety that was appropriate for Jeff.

Jeff liked that adalimumab has been used in many patients with great results and it also has a longer safety track record than ustekinumab. I also prescribed topical corticosteroids and vitamin D analog for Jeff to use as an adjunctive treatment. Prior to treatment, I also screened for HIV, hepatitis B, and hepatitis C, for which he was negative.

I also cautioned Jeff to avoid receiving any live vaccinations, such as intranasal flu vaccine.

Addressing the patient’s psychosocial issues is another important aspect of psoriasis treatment. So I encouraged Jeff to talk about...
how psoriasis is affecting him at a personal level, and we discussed the possibility of him also working with a counselor or a mental health professional.

At the time, Jeff said that he wasn’t ready to see someone for his depression yet, but he was willing to make efforts to be more connected to his family and his friends. Finally, I provided Jeff with a list of online resources, such as the National Psoriasis Foundation, where he could get more information on psoriasis and its treatments.

Jeff: Treatment Outcomes

<table>
<thead>
<tr>
<th>3 months</th>
<th>3 years</th>
</tr>
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<tbody>
<tr>
<td>• BSA: 15%</td>
<td>• BSA: 10%</td>
</tr>
<tr>
<td>• PGA: 3</td>
<td>• PGA: 3</td>
</tr>
<tr>
<td>• PASI: 13.3</td>
<td>• PASI: 11</td>
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</tbody>
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Approximately 3 months following the initiation of treatment with adalimumab, Jeff’s psoriasis had significantly improved. His BSA decreased to 1.5%, his PGA score to 1, and PASI score decreased to 1.2, which was about 90% improvement.

Another important point I make to my patients at times like this is that, currently, there is no cure for psoriasis, and if they stop taking the treatment, it could come back. This helps with setting expectations with regards to treatment and can help maintain medication adherence.

I recall that, during adalimumab initiation, Jeff told me that he had some redness around the injection site during his second injection, which I assessed to be an injection site reaction. I had advised him to rotate injection sites, and he had not experienced this since.

Overall, Jeff was very happy with these results, and he also enthusiastically noted he is more confident at work because he no longer worries about having embarrassing flakes shedding from his scalp onto his clothing or his work area. Jeff seemed to be in a much better mood, and I was happy for him, and this response was maintained for the next several years.

Jeff: Treatment Outcomes (Cont’d)

Three years after the treatment, however, Jeff started to experience a return of his psoriasis. During a follow-up visit, I noticed that his psoriasis had significantly worsened. His BSA was up to 10%, PGA score increased to 3, and PASI score increased to 11. Jeff was again returning to the realm of moderate to severe psoriasis.

There are a number of reasons why patients may lose response to treatment: [lack of] medication adherence, interruption in therapy, and possibly a biological rationale for this loss of response.

In talking with Jeff, I found out that he had been quite busy dealing with clients at work as well as matters at home, and he had missed occasional doses of adalimumab. I emphasized that it is important to maintain a certain drug level in the body in order to achieve efficacy, and therefore medication adherence is very important.

In other patients who are adherent, a loss of efficacy could indicate the potential development of anti-drug antibodies, among many other factors, that could affect drug level and therefore response to a biologic. And this can happen with any biologic.

To reduce the possibility of anti-drug antibody development, we usually advise patients to avoid practicing having drug holidays or decreasing the dose below what is recommended. In my experience, the majority of patients who are on biologics who have had excellent medication adherence and who have had excellent response initially to the biologic tend to have sustained efficacy over a number of years.

In Jeff’s case, while he did not have perfect medication adherence, other factors may be in play that have led to the recurrence of his psoriasis. So what we did was that we increased the dose for adalimumab from 40 mg every other week for his maintenance therapy to 40 mg weekly for the next 6 months. Unfortunately, his psoriasis did not improve significantly. So, we decided to think about some other treatment options.
Modification of Jeff’s Management Plan: New Treatment Options for Psoriasis

Dr. Armstrong: I informed Jeff that, in the 3 years since he started treatment with adalimumab, two new treatments had become available for moderate to severe psoriasis. Apremilast, an oral phosphodiesterase inhibitor, was approved in 2014. Secukinumab, an injectable biologic that inhibits IL-17A ligand, was approved in 2015.

I also brought up that it was an oral agent. However, there is a small possibility of apremilast worsening depression in certain individuals.

I then educated him about secukinumab. I told him that in phase 3 studies [ERASURE and FIXTURE], secukinumab [300 mg] resulted in at least 75% improvement in psoriasis severity in about 77% to 82% of patients within 3 months of initiating the treatment.

I also pointed out that several head-to-head studies showed that secukinumab was superior to etanercept and that it was superior to ustekinumab. Specifically, greater proportions of patients on secukinumab were able to achieve PASI 100, or complete clearance of their psoriasis.

I also let Jeff know that the side effects associated with secukinumab included nasopharyngitis, upper respiratory infections, headache, and oral candidiasis. As with other biologics, there is a risk of infections, but it has been unclear whether these were due to the treatment itself.

I also explained that he would still need to be monitored for signs of tuberculosis, as he was when taking adalimumab, and he would also need to be monitored for signs of inflammatory bowel disease and hypersensitivity reactions.

So after hearing all these, Jeff decided that he would like to try secukinumab. After all, he wanted something that would give him the best odds of clearing his psoriasis.

Jeff seemed interested in learning more about these new treatments, so I sat down with him and gave him more information. I explained to him that, while apremilast did have a lower efficacy rate than biologics, it had an excellent safety profile and did not require him to obtain routine blood work.
Psoriasis Treatment: New Options (Cont'd)\(^1,2\)

\[\text{UNCOVER-2} \quad \text{UNCOVER-3} \quad \text{Ixekizumab > Etanercept}\]

While I was talking with Jeff, I couldn’t help but to think about how we are discussing treatment expectations with patients in terms of new therapies. In the past, we used to focus on PASI 75, or at least 75% improvement in psoriasis as measured by the PASI score. But with newer treatments, we can now talk about PASI 90, or 90% improvement, and even PASI 100, or complete clearing.

In fact, even since I had this conversation with Jeff, another antibody against interleukin-17A, ixekizumab, has become available. Ixekizumab was approved in March 2016 for the treatment of moderate to severe plaque psoriasis in adults.

Ixekizumab has also been demonstrated to be superior to etanercept and placebo over 12 weeks. The side effect profile of ixekizumab is acceptable and similar to that of secukinumab.

There are also several emerging treatments under development for psoriasis, such as brodalumab, an antibody against the IL-17 receptor. This treatment is currently under FDA review. There is also certolizumab, a TNF blocker already approved for psoriatic arthritis. This agent is being investigated for psoriasis.

Tofacitinib, a JAK inhibitor, is also being looked at for psoriatic diseases. There are also several anti--IL-23 agents in development for psoriasis, including tildrakizumab, guselkumab, and risankizumab.

So, in the future, we may have even more treatment options, with more convenient dosing schedules for our patients.

Emerging Treatments for Psoriasis\(^1,6\)

\[\begin{align*}
\text{Brodalumab} & \rightarrow \text{IL-17R} \\
\text{Certolizumab} & \rightarrow \text{Anti-TNF} \\
\text{Tofacitinib} & \rightarrow \text{JAK} \\
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So, getting back to Jeff, we switched him from adalimumab 40 mg weekly to secukinumab 300 mg every month. His psoriasis is currently well controlled, with BSA less than 1%. He is happy with the treatment response thus far, and he says that clearer skin can help him focus on what’s really important to him, his family and his work.

I continue to remind Jeff that, while his psoriasis is not cured, we can keep it under control with continued treatment and continued monitoring for potential development of side effects. Jeff and I have both agreed that our goal is to stay on top of his psoriasis and keep it under control.

1. iStock.com/Juanmonino.
Employing a Patient-Centered Approach to Improve Clinical Outcomes in Patients With Moderate to Severe Psoriasis

Conclusions

- Psoriasis has a detrimental effect on the lives of patients, and there are many unmet needs in the treatment of this disease.

- Biologics have changed the landscape of the management of psoriasis, and newer treatment options provide a greater chance for complete clearance.

- Management decisions must be made in conjunction with the patient; shared decision making can result in more informed choices, more satisfied patients, improved medication adherence, and optimal clinical outcomes.

In conclusion, psoriasis has a detrimental effect on the lives of our patients, and there are many unmet needs in the treatment of this particular disease. Biologics have changed the landscape of management for psoriasis, and newer treatment options provide a greater chance for complete clearance.

Management decisions must be made in conjunction with the patient. Shared decision making can result in more informed choices, more satisfied patients, improved medication adherence, and optimal clinical outcomes.

Thank you very much for listening to my story about Jeff. I hope you have found this to be informative and can apply what you have learned when caring for your own patients with psoriasis.
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