Transcript Details

This is a transcript of a continuing medical education (CME) activity. Additional media formats for the activity and full activity details (including sponsor and supporter, disclosures, and instructions for claiming credit) are available by visiting:
https://reachmd.com/programs/cme/bridge-to-understanding-your-connection-to-advancements-in-psoriasis-and-psa-treatments/13521/

Released: 04/27/2022
Valid until: 04/27/2023
Time needed to complete: 45 Minutes

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Bridge to Understanding: Your Connection to Advancements in Psoriasis and PsA Treatments

Announcer:
Welcome to CME on ReachMD. This activity is a replay of a live broadcast titled: Bridge to Understanding, Your Connection to Advancements in Psoriasis and PsA Treatments, is provided by Forefront Collaborative, and supported by an educational grant from AbbVie. Here's your moderator, Dr. Jennifer Caudle.

Dr. Caudle:
To date, 16 biologics and novel small molecules are FDA approved for treatment of psoriasis and/or psoriatic arthritis. And many investigational drugs are in trials for both. This is an exciting time for the patients and medical community as complete skin clearance and prevention of arthritis disease progression becomes achievable goals for many patients. I am your host, Dr. Jennifer Caudle and joining me to share highlights from the 2022 American Academy of Dermatology Annual Meeting, plus their insights on treatment of psoriasis and psoriatic arthritis are doctors April Armstrong and Allan Gibofsky. Dr. Armstrong is a Professor of Dermatology, uh, at the Keck School of Medicine at USC. Dr. Gibofsky is a Professor of Medicine at Weill Cornell Medicine and a rheumatologist at the Hospital for Special Surgery. Doctors Armstrong and Dr. Gibofsky, welcome to the program.

Dr. Armstrong:
Thank you for having me here.

Dr. Gibofsky:
It's a pleasure Jennifer.

Dr. Caudle:
Well, we're excited that you're here. Uh, so, I would like to turn now, our attention to a few housekeeping notes before we get started today. To submit questions during the presentation, please type them into the chat control panel on the left side throughout the program or in your comment box through Facebook live. We'll try to answer as many questions as we can during the time allotted. We'll be asking you questions throughout the presentation, so please take out your phone and text ReachMD to 22333 to set up your phone. Alternatively, you can respond via your computer at pollev.com by entering ReachMD under username.

So, let's begin our program. Uh, let's start to – with our first question, uh, with research proceeding a pace inclusion of newer therapies into clinical guidelines really requires ongoing modification and updating. Dr. Armstrong let's start with you. What are the latest clinical practice guidelines to informed psoriasis treatment?

Dr. Armstrong:
Yes, Dr. Caudle, as you know that our psoriasis guidelines have been, uh, updated extensively since it was published more than 15 years ago. And our guidelines currently have really, uh, expanded the consideration of patients who would be suitable candidates for systemic therapies for psoriasis. For example, we typically think of patients who are candidates for systemic therapies such as biologics or oral
therapies, as those that are, number one, um, have moderate to severe disease and that is having around 10% or more greater surface - body surface area involvement for their plaque psoriasis.

But also importantly now, we consider patients who have psoriasis involving the special areas. For example, such as scalp, uh, intertriginous areas, this can get in skin folds, palms, and soles. Those patients have psoriasis in those sensitive areas that can have a disproportionate impact on their quality of life and therefore, we should also consider them as potential candidates for systemic therapy.

And then finally, the third category are patients who have failed topical therapies. Uh, they should also be considered for systemic therapy. So, as you can see, we've expanded our category and - and consideration of patients who would be appropriate for biological oral therapies.

In addition to that, we have also extensively updated our guidelines for checking baseline labs in our patients about to be, uh, put on a biologic as well as monitoring guidelines for those patients. And overall, those guidelines have really simplified compared to our previous, uh, guidelines. Specifically, for baseline evaluation, every patient, uh, should get a TB evaluation, uh, for those who are about to, uh, start a biologic and then also check, uh, CBC as well as CMP, hepatitis B and C. And now that's for, uh, everyone at baseline. And if you wanted to check more due to specific circumstances or the region that you're living in, that is okay as well.

For ongoing evaluation, tuberculosis evaluation is recommended for those who are on T- TNF inhibitors as well as those who may be at high risk for contracting TB. So those are some of the key, uh, guidelines in terms of some of the highlights on the updates.

Dr. Caudle:
Excellent. And Dr. Gibofsky, what could you say about the latest clinical guidelines for the treatment of psoriatic arthritis?

Dr. Gibofsky:
Well, Dr. Caudle, we have three major guidelines that are in play in the clinical community. Uh, the first two are shown here, those are the EULAR, um, 20, uh, 19 guidelines and the, um, Combined American College of Rheumatology, uh, National Psoriasis Foundation guidelines, updated in 2018. And, uh, this is a stepwise progression of what therapeutic alternatives we have. In the next slide, you can see the, uh, the Research Group, so again, uh, Psoriatic Arthritis Treatment

Recommendations, perhaps the most, uh, new of the recommendations. And, uh, these tend to focus more on, um, the domains that are involved, the presence or absence of previous therapy, um, to a certain extent comorbidities that may, uh, alter the ability to give one or more drugs.

But I would say that all three of these guidelines, however used, do stress the notion of assessing disease activity, um, reassessing disease activity, uh, at least every three months once a therapeutic decision has been made. And, uh, looking at things like, um, uh, body surface area, looking at things like, uh, areas affected, looking at things like domains affected, comorbidities, and the presence or absence of, um, uh, other social factors that one has to take into account when treating patients as well. Uh, all of them tend to stress different ways of looking at the disease but all of them tend to seek the best outcome for the greatest number of patients, a logical adoption of a sequential and logical evidence-based approach to treatment.

Dr. Caudle:
Excellent. And Dr. Armstrong, could you elaborate on how the guidelines are being implemented in practice? You know, what are some of the learnings here?

Dr. Armstrong:
Yes, when we are thinking about these guidelines, and how they are really practicing in clinical setting, uh, first of all typically for a patient with plaque psoriasis who comes to dermatologist for example, the first decision point in that triage is really deciding whether the patient has psoriatic arthritis or not. This is very important because regardless of the amount of the skin psoriasis involvement, if the patient has active psoriatic arthritis, then our choice of therapy should be a systemic therapy that addresses both the joint as well as the skin signs and symptoms. Reason being that, uh, the joint signs and symptoms, especially the joint signs, er, uh, can be irreversible if untreated.

Now, if the patient does not have active psoriatic arthritis, then we focus on the extent of skin disease. If the patient has mild or localized, uh, skin disease, uh, then the typical therapies or topical therapies or targeted phototherapy. Now, topical therapy is used much more often than the latter. And then for patients with a more moderate to severe disease, then we think about concurrently, the use of biologics and/or oral therapies and/or phototherapy.

Also, I mentioned that two other cases where patient have psoriasis in the sensitive areas or if they have, uh, not responded to the conventional topical therapies, then we want to also consider the use of systemic therapy in those patients.

I think, uh, they're having a few studies looking at the use of systemic agents, uh, in the psoriasis population and what was interesting is that, uh, clinicians, who for example, have high volume of patients or who does not have, uh, much time that, uh – don't have the time luxury to spend as much time with the patients, oftentimes their patients are less likely to be recommended as systemic therapy. In

addition to that, are patients living in the rural regions oftentimes have lower access to systemic therapy as well.

Dr. Caudle:
Hmmm. Okay. And thank you for that. Um, staying with you Dr. Armstrong, when a therapy for a patient with moderate to severe plaque psoriasis and/or psoriatic arthritis doesn't work, how do you approach escalating therapy?

Dr. Armstrong:
Yes, so, when, an FDA approved, uh, standard dosing for, for example, biologic is not working, the first question I ask is whether this patient is someone who has never really responded to the initial therapy or someone we consider a primary failure versus someone who initially actually responded to therapy but then lost response over time. Someone we considered a secondary failure. So, in those patients who have never responded optimally to the initial biologic of choice, for
example, then the optimal next course is typically consider switching class all together. So, for example, if the patient has been on a - an IL-17 class of medication and we do want to try these patients for – in most patients for at least six months to see if they have any response. If they don't have any response, um, then we might want to consider switching that patient to an IL-23 class of medications, or vice versa.

Now for patients who have had a response to a medication initially, but then lost response, in those patients our options are more numerous, typically divided into, uh, these three categories: number one is that we could possibly increase the dose for that particular patient. And the strategy here is not increasing the dose per administration but rather oftentimes using the same dose but shorten the, uh, duration in between, uh, shots. And then number two is that we can consider even switching to another agent within that class. There are mechanistic differences, uh, among the different agents in the particular class and also dosing differences. So, potentially another agent from the same class could work. Uh, of course, the third option is that this patient can be switched to a whole different class of biologics to see if that might be a better option for this particular patient.

Dr. Caudle:
Hmmm. That's very helpful. And Dr. Gibof, excuse me, Dr. Gibofsky, um, is the approach you use to treat patients with psoriatic arthritis who are not achieving the target outcomes similar to what Dr. Armstrong just explained, or are there any additional considerations?

Dr. Gibofsky:
Uh, they're – they're pretty similar. I - I think the only thing I would, uh, re-emphasize is that we tend to re-evaluate patients every three months rather than every six, but largely because of the fact that we are dealing with pain and prevention of bone erosion, um, the latter of which tends to be irreversible once
identified. So, our, uh, interval evaluations are, um, a little bit more frequent.

But we also use the same strategies of, um, switching within a class, switching between classes, depending upon where the patient is. It's a well-observed phenomenon that you can have two patients in your waiting room on the same medication and one swears by it, and one swears at it. So, this is where you have to practice the art of medicine as well as the science.

Uh, we have another consideration and that is related to the fact that you mentioned we have 16 biologic therapies, but we also have the conventional synthetics. And so, you can add a conventional synthetic to a biologic and then you can get multiple more therapies. Now, one would never add two biologics at the same time but the use of combination therapy versus monotherapy is something that is, uh, widely used, um, in our practices. But because of the observation that in some patients, um, the presence of both the biologic and the conventional synthetic, usually but not always methotrexate leads to greater efficacy. Indeed, uh, that is probably true for skin disease although it may be less so as we have seen in certain, uh, conditions or that certain drugs rather or combinations that are being used to treat joint disease. Uh, we consider the domains affected, we consider comorbidities, we consider disease activity and also as, um, Dr. Armstrong alluded, we can - we consider the presence of other medications that the patient may have received before coming to us as well as the medications that the patient has been on while under our observation.

So, um, all of these taken together are comprising the therapeutic approach that we use which is largely similar to what, um, Dr. Armstrong does but with the nuances that I mentioned.

Dr. Caudle:
It makes a lot of sense. Um, you know, uh, Dr. Gibofsky staying with you, how could you describe the evolving therapeutic landscape for the psoriatic, uh, disease?

Dr. Gibofsky:
Well, as you can see on the next side, we have, uh, multiple classes of medication and we have for the classes, um, multiple agents within most of the classes that you see. Uh, it's important to mention that some of the drugs that are approved for psoriasis are not approved for psoriatic arthritis. And some of the drugs that are approved for psoriatic arthritis are not approved for psoriasis. So, when

treating a patient, one has to be aware of what it is that you're treating and what the major domain that's affecting their quality of life is that they - they're seeking relief for.

Um, once we go through the, uh, the choice of agents as I mentioned a few moments ago and the different combinations that we have, we also think about, hmmm, what might be out there, hmmm, can we get this patient into a clinical trial perhaps, of one of the newer agents. But that tends to be the more refractory patient for whom, um, the agents that you see on this slide generally have not been particularly effective.

Dr. Caudle:
Hmmm. Thank you for that. And Dr. Armstrong, what are some of the promising novel systemic therapies in development for psoriasis?

Dr. Armstrong:
There are two systemic therapies that are in late phase development, one biologic called bimekizumab and another oral agent called deucravacitinib. So, I am gonna share some of the data from the American Academy of Dermatology that was, uh, unveiled recently. Looking at bimekizumab, which is a novel biologic that targets both IL-17A as well as IL-17F. It's currently being evaluated by the FDA at the time of this conversation that we're having, um, and its novel in that it's really helping us to understand the role of IL-17F in psoriasis, and that IL-17F is critical in addition to a - in terms of psoriasis pathogenesis.

So, when we look at the clinical trial results from bimekizumab, what we noted is that it has a quite deep response. So, what I mean by that is that, um, around 62% of the patients that were treated with bimekizumab achieved PASI 100, so complete clear, uh, clearance of skin disease at - at week 16. And very importantly, when we're thinking about complete clearance at two years' time, so these patients followed out for two years, what was seen is that over 80% of them are still completely clear at two years. So, this is something, uh, that is, uh, quite, uh, uh, unparalleled, uh, in terms of the, eh, the robust efficacy that, uh, that we've seen before. So, we're very excited as a field in terms of having another agent, uh, that have a deep, uh, therapeutic response for our patients.

Next, please.

And when we look at the safety of the, um, analysis of the Pool Data, what was also seen is that responders also had a robust response of terms of elimination of a lot of the symptoms that are psor - associated with psoriasis, probably not surprisingly. Uh, and those include, for example, itch, skin pain. So, bimekizumab has affects on all of those domains as well as on dermatology quality of life, uh, where we saw substantial improvement.

Next please.

And then, in terms of the, uh, health-related quality of life and whether if you're wondering, uh, if bimekizumab had a differential effect on those who have had biologics in the past or those who are bio naïve, what we showed is that the bimekizumab had a similar, uh, deep response in both of those populations. So, this was encouraging to see.

Next please.

There were also a number of head-to-head studies that were, uh, unveiled as well. Bimekizumab versus secukinumab, this particular study is special because it's our first IL-17 versus IL-17 inhibitor study. And here, we are able to see perhaps the additional inhibition in terms of IL-17F and what that does clinically. And what was shown was that patients who were treated with bimekizumab, uh, had superior clinical response compared to those patients who were treated with, uh, secukinumab. Uh, in terms of both the primary, uh, response in terms of a one-year, uh, period of time, but also more patients had earlier response with bimekizumab. Uh, in addition to that, patients who had been on secukinumab were then switched to bimekizumab. Those patients also achieved similar responses as those patients who had stayed on bimekizumab, uh, to begin with.

Next please.

In patients, uh, who were treated with bimekizumab, uh, with psoriatic arthritis, so here's a PsA study looking at bimekizumab, this is a Phase 2B study, uh, what was found is that those patients who had, uh, been treated with bimekizumab had a robust response in terms of their joint response but also, um, many of those patients had skin disease as well. So, we saw both, uh, good clearance in terms of both joint as well as skin disease.

In terms of safety, bimekizumab is overall well tolerated, um, there, uh, is a low rate of oral, uh, cutan – oral candidiasis that was seen in patients treated with bimekizumab but overall mild or moderate and was treated without, uh, discontinuation of bimekizumab.

Next please.

And then we're gonna go to deucravacitinib. Deucravacitinib has a unique mechanism of action, uh, in that it inhibits TYK2 which is an

enzyme that's very important in terms of psoriasis pathogenesis. It's central to mediating the pathways of IL-23 as well as IL-12, uh, as well as type 1 interferon. So, what we saw in the clinical trials with deucravacitinib is that we learned, number one, deucravacitinib, uh, appears to be superior to apremilast, uh, which is an approved oral agent for psoriasis as well as psor – psoriatic arthritis. And in addition to that, those patients who have failed apremilast, uh, seemed to have also responded to deucravacitinib. So, this speaks to some of the excitement around having a highly efficacious oral agent about to be introduced to our realm of tools for our patients with psoriasis.

Next please.

Studies was also done in terms of, uh, looking at deucravacitinib and its effects in ps - psoriatic arthritis. And what was seen is that deucravacitinib, eh, exhibited similar efficacy for the treatment in patients with PsA, uh, regardless of whether they had background, uh, uh, conventional DMARDs. So, this is, uh, also quite exciting. Here, we have another oral agent, uh, has a good tolerability and safety profile, uh, in that it had very little laboratory, uh, disturbances. Um, and I think this will be a good, uh, option for patients with not only psoriasis but also psoriatic arthritis as well.

Dr. Caudle:
Excellent. Excuse me. For those of you who are just joining us, this is a live CME broadcast on ReachMD. I'm your host, Dr. Jennifer Caudle and joining me to talk about advancements in psoriasis and psoriatic arthritis treatments are Dr. April Armstrong and Dr. Allan Gibofsky. As a quick reminder, you're able to submit questions for our Q&A session at the end of this program by typing them into the chat control panel on the left side of your screen or in your comment box through Facebook live. And additional - additionally, we will be asking polling questions during our case discussion. You can participate by texting ReachMD to 22333 or by going to pollev.com and entering ReachMD under username.

So, Dr. Armstrong, let's - let's go back to you for a moment. Uh, what other evidence was presented and discussed during the AAD meeting that you'd like to highlight?

Dr. Armstrong:
Yes, um, there were so many great posters and oral presentations that were presented at the AAD meeting and I'm gonna highlight some of the, especially in the systemic realm, I'm gonna highlight some of those.

So, first let's take a look at our IL-17 inhibitors. Uh, we learned about nail psoriasis with ixekizumab from the meeting. And what was shown is that patients who are treated with ixekizumab who had nail disease, many of them had pretty significant improvement. So, about 85% improvement in their nail disease out to about five years of time. And nearly half of them achieved complete nail clearance. So, this is something, uh, that's quite exciting and positive in terms, uh, of looking at one of our IL-17 agents and its eth - and its efficacy in nail psoriasis.

Next please.

Uh, when we look at ixekizumab long-term safety, these days, it's all about long- term safety for our approved medications. What we saw is that the five-year long-term safety, uh, looks quite reassuring for ixekizumab. No new safety signals, the main thing we will continue to remind ourselves in terms of IR- or IL-17 inhibitors is to avoid use in patients with inflammatory bowel disease and, uh, we can also treat low rates of oral candidiasis when it occurs.

Next please.

We also looked at brodalumab, which is one of our IL-17 inhibitors that has a very unique mechanism of action in that it's not a cytokine inhibitor, it's a receptor inhibitor. And what we saw is that with brodalumab, uh, it is often used as
perhaps not the first-line agent, but, uh, or, uh, but perhaps a second- or third-line agent, is that many of the patients go to brodalumab after they have failed other biologics. And even in this difficult to treat population, about 44% of them still achieved complete clearance at week 26. And I think that speaks to the robustness of brodalumab in terms of its, uh, clinical efficacy but also speaks to the unique mechanism of action and how patients who may have failed other biologics could still respond well with brodalumab.

Next please.

Now we are gonna to talk about secukinumab, uh, the first, uh, IL-17 agent that was approved for plaque psoriasis. And what was known is that, uh, with the long-term safety, uh, which saw similar to ixekizumab is that we did not see any new safety signals, uh, it - with secukinumab. So - so no news is good news here, uh, and, uh, we can continue to, uh, inform our patients of these, uh, reassuring long-term, uh, safety results.

Next please.

Uh, there was an interesting study that looked at ustekinumab failures. And so, patients who had not responded to ustekinumab and, uh, then they randomized those patients to either getting secukinumab or getting guselkumab. We know that ustekinumab's main mechanism of action is through IL, uh, 23 inhibition. So here, we're looking at these patients, if you, um, randomize them into then an IL-17 agent or another IL-23 agent, whether you will see any differences.

Now, mind us that this is a small study, only 40 patients were included but what was found was that 60% of the patients who were randomized to the secukinumab group had achieved clear or almost clear at week 16 compared to 40% in the guselkumab group. This was not statistically significant, probably likely due to the small sample size, uh, however, it was helpful and instructive in terms of, uh, looking at some of the mechanistic differences and how, when we think about that in terms of, uh, treating patients who have failed to one particular class of medications.

Next please.

And then going on to our IL-23 inhibitors, guselkumab, as we know, uh, many of our patients have benefitted greatly from guselkumab. And what we learned is that patients who had been a responder tend to respond in long-term, uh, uh in, uh, terms, uh, to guselkumab. And what was also seen is that almost regardless of their baseline, uh, disease activity, they could be moderate, or they could be quite severe, uh, guselkumab's clinical response seemed to be equally effective in both of those groups. In addition to that, it doesn't seem matter if the patient had, uh, experienced biologics in the past or biologic naïve, uh, guselkumab also had equal, uh, penetration in terms of the depth of response in both of those, uh, patient populations. So, that is, uh, something I think we are continuously seeing with our advanced therapies in biologics and their deep response in our patients.

Next please.

And then, uh, finally looking at the guselkumab safety data. Uh, the good news there is that, uh, we do not see any, uh, new signals, uh, with our IL-23 class of medications, so quite reassuring in that we can continue to reassure our patients who are on these medications of the safety record of our IL-23 class of medications.

Next please.

Just kind of rounding out on our 23 – IL 23 class of medications, tildrakizumab, uh, which, uh, also targets IL-23, what was seen is that, uh, for patients who responded well to tildrakizumab, they also tend to maintain that response over time. So, as you can see, over 80% of the patients on tildrakizumab 100-milligram group have PASI score of less than 3, so this is absolutely PASI score of less than 3, which is clinically meaningful in most of their visits. In addition to that, uh, the medication continues to appear safe and well tolerated among our patients.

Next please.

Going to our, uh, last IL-23 inhibitor, uh, risankizumab. Risankizumab as we know from it, uh, clinical studies, parent studies, has a really high response rate for patients. And when the patients are followed out to 4.5 years, uh, as we can see or 50% of the patients, uh, maintain clearance at 5 years which is quite encouraging.

Next please.

And, uh, we cannot forget about, uh, risankizumab in our patients with, uh, psoriatic arthritis through the KEEPsAKE 1 and 2 Study. And what was seen here is that significantly greater proportion of patients, um, have achieved clinically meaningful endpoints in terms of ACR20, um, and minimal disease activity and – as well as a number of other, uh, index - indices for psoriatic arthritis compared to those with a placebo, therefore gaining its approval in psoriatic arthritis last year.

Next please.

And emphasizing the safety of our IL-23 class, uh, also long-term safety data for risankizumab is also quite reassuring. And I think one thing I would just want to emphasize is that our IL-23 class of medications, uh, you don't have to inject these medications very frequently. It's an infrequent injection, so typically once every 8 weeks or every 12 weeks, which can be quite convenient for our patients.

Dr. Caudle:
Great, thank you so much for that. Janus kinase, or JAK, inhibitors belong to a new class of oral targeted therapies in the therapeutic landscape for immune-mediated diseases. Recently, uh, the FDA expanded safety warnings and restricted use of the approved JAK inhibitors. So, what does it mean for treating psoriatic disease? It - and is there any new evidence about the safety of JAK inhibitors?

Dr. Gibofsky:

Um, well, first I have to point out that when we talk about psoriatic disease, uh, we have to differentiate in this instance with - for this therapy between psoriasis and psoriatic arthritis. There are three approved, um, JAK inhibitors in the United States, tofacitinib, baricitinib, and upadacitinib. And none of them are approved for the treatment of psoriasis, and only two of them, tofacitinib and, uh, upadacitinib are approved for the treatment of psoriatic arthritis. So, that would be the first thing.

Now, what you can see on this slide is that when tofacitinib, which was the first agent in the class to be approved a number of years ago, uh, was approved, the FDA required that the manufacturer do a long-term observational study comparing tofacitinib at two doses, one of which is approved, the 5-milligram dose and one of which was investigational but patients were allowed to continue on it though it was not approved at the 10 milligram dose. They were required to do a long-term study, comparing the tofacitinib doses to the standard of TNF therapy, adalimumab.

And what they found in this study, this long-term extension study, was that there appeared to be an increased risk of heart attack, of stroke, uh, numerical increases were seen, a moment of malignancy in the JAK inhibitor, tofacitinib treated patients as compared to the TNF inhibitor treated adalimumab, uh, population.

Um, this led to a risk - uh, this led to a, uh, the agency taking two actions: The first is a class label, whereby all of the three agents that I've mentioned were given a warning about the potential for major adverse cardiovascular events, DVT, and malignancy, even though it was only demonstrated in the tofacitinib study that I have shown you. Um, in addition, the FDA also restricted the use of a JAK inhibitor following a TNF inhibitor, so that the JAK inhibitors could not be a first-line therapy anymore, unlike the other agents that we've been discussing.

And, I'll just conclude by showing the next slide, um, which is the, um, numerical increase of malignancy that was seen in the tofacitinib patients as compared to the adalimumab treated patients, uh, in the next slide.

Dr. Caudle:
Excellent. And Dr. Gibofsky, staying with you, uh, what information about different characteristics of systemic therapies is important to discuss with your patients when developing a treatment plan?

Dr. Gibofsky:
Well, uh, obviously patients do want to know about, uh, the frequency of injection or whether it's an infusion, whether one can take an oral molecule route of administration is certainly important, uh, as well as frequency. Uh, but, um, one also needs to do more than just give informed consent as we understand it, which is the risks, benefits, and alternatives. Um, I like to go into the process which I refer to as shared decision-making which is an interactive two-way process between the patient and me, um, trying to give them this information and assessing their health literacy, assessing their understanding, in a supportive atmosphere of mutual respect. I need to create this atmosphere, classify their concerns, um, I need to identify all of the information that they're seeking for, both on this slide and the next. And then allow them the opportunity to make an informed decision based on their values and preferences. Um, merely giving a patient a brochure to read and saying come back when you make up your mind is not the way to do it, uh, because numerous studies in all fields of medicine demonstrated that the more involved the patient is, in, uh – as a partner in their own care, the better the outcome is going to be.

Dr. Caudle:
And so those are very excellent points. And Dr. Armstrong, do you have anything to add to that?

Dr. Armstrong:
Yes, uh, adding on to, uh, what Dr. Gibofsky already said, um, I would just like to add oftentimes I do, uh, watch out for patients' body language. Um, and, uh, the reason for this is that sometimes they can have concerns, or they may not agree with what we recommend and oftentimes they may not bring it out explicitly. So, if I see if there is any hesitance, um, or if they're frowning, I typically would actually stop and ask them, uh, if they have any questions or if they have concerns, um, thereby, really listen to what their particular concern is. And, if I can address their concern first, then I can help really increase some of the treatment adherence, uh, that we'll - that we will see in the long-term.

Dr. Caudle:
Also, quite excellent points. Thank you for that.

Uh, so, now as we transition to our case study, just a reminder that during registration for this live program, we asked all users to let us know which case study interested them the most. For this time slot, it seems that the majority of our viewers wanted to learn more about case number three. A 30 - 30, excuse me, a 33-year-old, Black woman with low back pain and a two-year history of mild psoriasis. I'll now pass it over to Dr. Gibofsky to tell us more about his case.

Dr. Gibofsky:
Um, so, this is a, uh, as you indicated, a – a young, um, Black woman who presented with, um, psoriatic arthritis. I think there is a – um, um, and, uh, presented indicating that she really had back pain as her primary presentation. Um, she was, um, um, she had a normal physical examination. Um, she, uh, had no active medical problems. She did have a two-year history of mild psoriasis which was limited to the scalp and controlled with topical shampoos, actively employed. Um, she predominantly had back pain as I mentioned, difficulty while doing light cleaning in the house and, uh taking care of her - her children. Um, the pain began about four months ago, intermittent, worse in the mornings and there was no history of trauma. She was a runner in college and still likes to jog but finds it more difficult to do this, uh, because of wear and tear. She denied fever or any other pain in her joints or worsening of her scalp psoriasis.

Next slide please.

As I mentioned, her physical exam is normal, her joint exam was normal. She had, um, limitation of forward flexion and mild tenderness to percussion over her lower back. And, um, she understands. She's an extremely intelligent woman who understands that she's at risk for psoriatic arthritis even though she had no joint swelling and was surprised by this. And her scalp psoriasis and the - the activity of it really hasn't changed. And she has not experienced any worsening or, um, any additional skin rash. So, we began to talk about a phenotype of psoriatic arthritis, namely the axial phenotype and how difficult that could be to diagnose. And, uh, x-rays do show that she had sacroiliitis and early ankylosis of two lumbar vertebrae.

Next slide please.

Um, what you see here are the CASPAR Criteria designed to help identify homogenous groups of patients for clinical studies. But, are also used diagnostically as well, to try and get at whether a patient with a known diagnosis of psoriasis, who then develops joint pain, in fact, has psoriatic arthritis or some other etiology of joint pain. Not all joint pain in patients with psoriasis is psoriatic arthritis. Hence, the need to use these classification criteria to hone down whether one is dealing with a true inflammatory arthritis or a mechanical arthritis.

Next side please.

And I've alluded to the radiographic findings that, um, Ms. Smith had in her lower back. Um, patients with psoriatic arthritis can also have destruction of cartilage and bone in other areas as well, uh, if they have a peripheral form of arthritis, you would see joint erosions and they may very well see the so-called pencil-in-cup deformity when there is joint space flaring and joint erosion on the other side as a result of new bone formation, periostitis, ankylosis, emphysitis, and numerous other things. And, as I have mentioned, uh, axial psoriatic arthritis may have fusion of - of the sacroiliitis of various grades 1 to 4, and, uh, syndesmophyte formation as well as, uh, disc destruction.

Next slide please.

An obvious, uh, problem is that one can't use the laboratory very much because it's what the patient doesn't have that often helps you make the diagnosis.

Now, in this instance, Joan was on nonsteroidals, um, that she was taking as well as a prescribed, uh, definite course. And she had no response to therapy. So, what would be the recommended treatment be in a patient with, um, no response to therapy?

And wow, um, initially everyone said abatacept and then there was a change, uh, so that now we're equally split, but, we're still equally split but the third choice, um, but not no, the TNF inhibitors are in the lead and, uh, let me give you another five-second count down, five, four, three, two, one. Oh, you're changing your minds. You should always go with your first impression. Okay, let's go to the answer.

So, the group appeared to be evenly split, um, between a TNF inhibitor and abatacept with a respectable minority, um, giving apremilast that I recall. And it's a little bit of a trick because all of those agents are indicated for the treatment of psoriatic arthritis. But as I mentioned before, one has to be concerned with the phenotype of the disease, axial versus peripheral and the domains affected. And with 2021 GRAPPA recommendations do suggest that in a patient with axial disease and no peripheral involvement, that has failed to respond to a course of ster - to nonsteroidals, the best choice would be a TNF inhibitor. There are five agents in that class and any of them can be used in this patient.

Next slide please.

So, um, you confirm with her the axial phenotype of psoriac – uh, psoriatic arthritis and now the question is what you are gonna treat her with and how are you going to deal with any questions you have. So, you bring her back into your consulting room and you tell the staff that you don't want to be disturbed as you're with her. The likelihood of not being disturbed is low, but you want the patient to hear that you don't want to be disturbed as a prelude to letting the patient understand that you are now going to focus your attention on her and not be distracted by other things going on around you.

You go through the issues of, um, the routes of administration of all the agents available, the frequency of administration, the risks, benefits, and alternatives. You attempt to ascertain after each discussion what she understands and whether she has any questions and, um, she then tells you she would prefer self-injection as infrequently as possible versus infusion. You then arrange for your office administrator to check what you can get for her based on her coverage and, um, she's very grateful to you as she leaves to learn about her diagnosis and her options.

Can we have the next slide please?

So, your interaction with Joan best exemplifies what? And you've got five choices to make. But everyone is quickly going for shared decision-making. But I'll give you the chance to change your mind if you want to. Uh, this is a democracy, but the right answer isn't gonna be done by the numerical choice. Except in this instance. Go with your first gut.

Shared decision-making. This is not precision medicine. You've not done anything to, uh, uh, determine her genotype. You've not determined anything to determine specific genetic risk factors. Um, you did fulfill the elements of informed consent. As I've mentioned, shared decision-making does include informed consent, but you went beyond that. You gave her the information she needed. You gave her a supportive environment. You did not impose a decision. You did all you could to support her, and this is a good example of shared decision-making. So, this is the best answer of - of the alternatives that were presented.

Dr. Caudle:
Excellent. Thank you so much for that, um, interesting and, uh, informative case, Dr. Gibofsky. Um, this has been a – a wonderful program and I'd like to transition now to our question and answer to make sure that we can at least get one question in before our time, uh, runs out.

Um, and this question is going to be directed towards Dr. Armstrong. The question is what should be the first treatment in a patient with mild to moderate psoriasis who failed topicals and phytotherapy, excuse me, phototherapy?

Dr. Armstrong:
Great. Some - sometimes plant therapies can work, uh, at certain times but, um, the, uh, so yes, great question. Um, so, when they have mild to moderate, uh, psoriasis and they failed topical or phototherapy, we can think about systemic therapies. In fact, one of our oral agents, apremilast, uh, recently the indications have expanded, uh to include psoriasis, uh, of - of essentially all severity. Um, so they - a patient may have mild to moderate but if they don't respond to the topical, uh, modalities, uh, apremilast is actually FDA approved to, uh, to be, uh, uh, treated – uh, to treat these patients.

I would say that, uh, that being said, uh, many of our biologics these days are – we're starting to investigate their efficacy in patients with mild to moderate, uh, severity of psoriasis. Now, none of them are approved for mild, uh, psoriasis, uh, but the key thing, I think, uh, where the field is going is that if the safety profile looks good, uh, then, uh, what are some, the, uh, then we want to consider the – the benefit-risk profile and, uh, is there a rationale not to treat our patients who have not responded to topical therapies with, uh, potentially, uh, biologic therapies if they have mild to moderate disease. So, I think, uh, stay tuned, for some of the, uh, clinical, uh, data on that. Uh, but certainly I think the field is starting to move in that direction.

Dr. Gibofsky:
If I can just comment, Dr. Caudle.

Dr. Caudle:
Yes.

Dr. Gibofsky:
Um, many of the patients that are referred to me in situations just like this, in fact, do come on apremilast, because apremilast does not require laboratory monitoring as all of the other agents do. And so, it's relatively easy to take and relatively easy to monitor the patient clinically for response or non, without inconveniencing the patient to have to come in for repeated blood draws and - and urinalyses. So apremilast would be an excellent option for that patient. As I indicated, many of the patients that are referred to me in that situation generally do come in on apremilast.

Dr. Caudle:
Hmm. Thank you so much for adding that, Dr. Gibofsky, and thank you, Dr. Armstrong, for your answer. I wish we had more time for questions but, um, this was excellent and I - I really cannot thank you enough for this wonderful program. Um, thank you doctors April Armstrong and Dr. Allan Gibofsky. We - you've really helped us better understand the advancements in the treatment of psoriatic disease. I - I do wanna say very quickly before we close, um, there are two other cases, uh, that we've prepared for you as well so if you would like to see those and review those, please download them at, um, uh, the website,

ReachMD.com/psoriaticdisease. Uh, Dr. Armstrong and Dr. Gibofsky, it was great working with you today.

Dr. Armstrong:
Thank you for having me.

Dr. Gibofsky:
Same, thank you Dr. Caudle.

Dr. Caudle:
Thank you.

Announcer:
Thank you for listening. To receive your free CME credit and to download resources, go to ReachMD.com/psoriaticdisease, and keep an eye out for our follow-up survey next month. This is CME on ReachMD. Be part of the knowledge.