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Clinical Data Prompting Guideline Updates for Subcutaneous ICIs in Melanoma

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Dr. Patel:
This is CME on ReachMD, and I'm Dr. Sapna Patel. Here with me today is Dr. Hussein Tawbi.

Dr. Tawbi, I'm going to give you a stumper today. What clinical data prompted guideline updates for subcutaneous immune checkpoint inhibitors, specifically in melanoma?

Dr. Tawbi:
Yeah, no, that's a really interesting development in our field. I mean, we've spent a lot of time trying to get drugs FDA-approved and just newer agents FDA-approved. And we love our immunotherapy because it offers cures for our patients. And now we're actually greedy enough to start thinking about how to make it easier for our patients to get treatment. And so the idea of using subcutaneous administration has already been used a lot in other cancers and obviously in hematologic malignancies as well. And it's really great to see this development for our patients with metastatic solid tumors, especially metastatic melanoma.

So when you think about treating with immunotherapy or checkpoint inhibitors, I would say maybe ipilimumab is the one agent in which the dose is very directly related to both activity and to toxicity. In the case of single-agent PD-1, or now we're going to be seeing with PD-1/LAG-3 combinations, really activity has been seen since the phase 1 trial from doses as low as 0.1 mg/kg all the way to 10 mg/kg given even every 2 weeks. So we've kind of explored the whole dose range, and we see very similar activity and efficacy.

And so when you think about how you could induce the right PKs and the right pharmacokinetics and the right pharmacodynamics, the fact that we have that range of doses really makes it very comfortable to think about different methods of administration. And so the idea of being able to do a subq injection for nivolumab has been really great to see come through. I think similarly for atezolizumab.

So subq administration works just as well in terms of being able to affect the same pharmacokinetics and pharmacodynamics you would expect from IV. I mean, maybe slightly different pharmacokinetics, just obviously, because it takes kind of a little while for things to kind of get into the bloodstream. But in terms of impact on efficacy for treatment, it looks almost identical.

So while the studies were not necessarily done in melanoma, I think, from my perspective, the idea that you could get the same receptor occupancy and the same efficacy and toxicity, means that we should very easily be able to switch to subq.

Now, to be honest, I'm not sure how often it's going to happen, because the patients can't get it still at home. They still have to show up in your office. So it's probably more relevant in terms of the time. Obviously, a quick injection is different than getting an IV started and spending 30 minutes in a chair. And also, I think especially in places where there's resource issues, or in rural places, I think there's going to be a really major impact on having a subq administration.

The other thing that you should take into account is, at this moment in time, the studies were done with single-agent PD-1, so it is still not studied properly in combination with ipilimumab. And since we use ipilimumab and nivolumab frequently, in the setting when you're doing the induction, as we call it, I would stick with the intravenous formulation. But then, obviously, when you go to maintenance nivolumab, then you could do single-agent subq at that point.

And I will probably close this part by saying that nivolumab and relatlimab is now being studied in a subq administration as well. The study, to my knowledge, is fully enrolled, and we should be seeing some data kind of, hopefully, in the next year or two, so that we could really get to that combination as well, which I think would be important for practice.

Dr. Patel:
And that's specific to melanoma population, which will be very helpful.

And I think you make some strong points about subcutaneous nivolumab use here. It really is just for a monotherapy use so maintenance phase of a nivo/ipi regimen, a monotherapy standalone regimen, then subcutaneous nivolumab makes sense.

I think things for practices to consider are whether that still is chair time in their infusion center for a 5-minute slow IV push. Or is that clinic nurse injection time, where the nurse is doing that there and not using up the chair time. To this day, it remains nurse administered. This will not be a patient-administered medication. But to your point, maybe we'll get there one day. And convenience, even in shortening the time, is something. It is important for patients.

So I think this is great. I think our time is up talking about subq nivolumab though. So thanks everybody for listening, and thanks, Dr. Tawbi, for your expertise.

Announcer:
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