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https://reachmd.com/programs/cme/navigating-adjuvant-ici-treatment-in-stage-ii-melanoma-a-patient-case-presentation/24379/

Released: 04/26/2024
Valid until: 04/26/2025
Time needed to complete: 47m

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Navigating Adjuvant ICI Treatment in Stage II Melanoma: A Patient Case Presentation

Announcer:
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Dr. Patel:
Hello, everybody. I'm Sapna Patel, a William Robinson Endowed Chair in Cancer Research at the University of Colorado Cancer Center. Today, we're going to talk about navigating adjuvant immune checkpoint inhibitor treatment in stage II melanoma, and we'll do it in the form of a case.

We have a 61-year-old man with no prior past medical history who's diagnosed with a primary nodular melanoma of the right upper back. It measures 2.5 mm depth with ulceration, and this is treated with standard wide local excision and sentinel lymph node biopsy, which was negative in one lymph node. And post-operative imaging says no distant metastasis. So now he presents to the office for a discussion of treatment options.

So of course, the first thing to discuss with this patient is his final staging. This is T3b, N0, M0, which is a stage IIB melanoma. The BRAF testing would not be indicated in this setting, as there are no BRAF targeted therapy options for stage II disease. And you would talk about adjuvant treatment options in the context of two approved anti-PD-1 therapies. This is based off of the KEYNOTE-716, trial and the CheckMate 76K trial, so it's adjuvant anti-PD-1 versus placebo.

Now you could also discuss the role of active surveillance, or what is sometimes called watchful waiting, which means no therapy, but they maintain a surveillance schedule.

When thinking about adjuvant anti-PD-1 therapy, of course, you'd want to discuss with the patient the potential for side effects, including lifelong side effects, reversible side effects, possible hospitalization from high-grade side effects, and how those side effects might be treated.

And then, in the context of their melanoma, by taking this adjuvant therapy, what would be their reduction in the risk of recurrence, distant metastasis, or death, ideally, death from melanoma. That sometimes can be pretty meaty to discuss with the patient in terms of hazard ratio. So one way that you can describe as to a patient is in the form of number needed to treat and number needed to harm. So, for example, these are not exact numbers for these treatment scenarios, but if the number needed to treat is 25, you explain to a patient that I would have to treat 25 patients with your exact stage of melanoma with this treatment in order for 1 patient to have the benefit and risk of recurrence, distant metastasis, or death. And then they can decide for themselves, if the, you know, that number needed to treat, if they would be willing to be part of that large number needed to treat. Often, the number needed to harm is smaller, so it takes fewer patients to develop a high-grade side effect in these earlier settings. So you also want to make sure to describe, you know, it's, for example, not specific for these treatments. If the number needed to harm is 5, we would treat 5 patients, and 1 is likely to develop a high-grade side effect, which could lead to lifelong treatment for that side effect, it could be irreversible, it could also lead to

hospitalization. So these are important things to consider.

I think it's also important to consider what happens if you start adjuvant treatment in this patient and they develop an immune mediated toxicity. So does that lead to cessation of therapy? Do you want to use steroids which would blunt an anti-melanoma immune surveillance? What about using the other anti-toxicity regimens, such as IL-6 or TNF alpha? It's also important to consider we have limited data on the efficacy of adjuvant PD-1 in mucosal melanoma, so those may be scenarios where we just don't know if this treatment works as well, and it may be better for these patients with low-grade mucosal melanoma to be observed and have the full treatment arsenal in the advanced setting, should their melanoma recur. And what does happen if you use adjuvant anti-PD-1 in the adjuvant setting, as I said, and the melanoma still recurs? We have limited data on the efficacy of PD-1 use despite the use of adjuvant therapy.

So the bottom line is, you know, these patients with stage IIB/IIC melanoma do have a significant risk of relapse with local therapy alone, but it's still low. It's still, you know, the minority of these patients that are recurring. So whether all patients need to be treated or you need to personalize this discussion, that's an important consideration. And these adjuvant anti-PD-1 immune checkpoint inhibitors do improve recurrence-free survival as well as distant metastasis-free survival, but you do have to weigh the benefits of the treatment against the risk of these side effects.

So thanks for attending this discussion today.

Announcer:
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