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

Case Consult: Adjuvant Therapy Following Localized Treatment for Stage III Melanoma

Announcer:
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Dr. Patel:
Hello. I'm Sapna Patel, a Medical Oncologist and the William Robinson Endowed Chair in Cancer Research at the University of Colorado. Thanks for joining me to talk about this patient case, which is adjuvant therapy following localized treatment for stage III melanoma.

So our case today is a 68-year-old woman. She has a history of hypertension, and she's diagnosed with what we call a primary superficial spreading or radial growth phase melanoma of the left leg. It measures 2.0 mm in depth without ulceration. She undergoes a wide local excision and sentinel lymph node biopsy, and this reveals one out of two positive lymph nodes in the same side groin. The BRAF testing was performed and it was negative. And her imaging reveals no evidence of metastasis. So she now comes to the medical oncology office with the really involved sister, and she wants to discuss her treatment options.

So when considering what to do in the now adjutant setting for this stage III patient, there's a few points. It's always helpful to talk about staging with these patients. So this woman had a 2.0-mm thickness, non-ulcerated, single sentinel lymph node-positive tumor. So this is a melanoma that's considered T2a, 2.0 mm. If it had been 2.1 or greater than 2.0, it would be a T3. So T2a, and then single sentinel lymph node positivity is N1a. T2a, N1a, M0 is stage IIIA using AJCC 8th edition.

Because there is adjuvant therapy using BRAF inhibitors, BRAF and MEK in combination in the stage III resected setting, it's important to make sure BRAF testing is completed; that way you know the full options available to you. In this case, this patient's BRAF testing was negative for any mutations.

Now in the BRAF negative setting for stage III and resected stage IV disease, we have a few pivotal trials, the CheckMate 238, KEYNOTE-054, COMBI-AD, and there's another trial, the SWOG S1404 that was also a registrational trial for adjuvant PD-1 versus investigator's choice.

Now, these trials all show the benefit of doing something versus doing observation. In CheckMate 238, it was doing something versus doing something else. So adjuvant nivolumab versus adjuvant IPI. And adjuvant nivolumab was superior in terms of recurrence-free survival. KEYNOTE-054 was adjuvant pembrolizumab versus placebo. And COMBI-AD, adjuvant BRAF/MEK, if the patient harbored a BRAF mutation.

It's important to note, however, these trials were very limited in the number of stage IIIA patients that were enrolled. IIIA carries a very low risk of melanoma recurrence at 5 years. It's about 7% recurrence at 5 years. And these therapies, in general, will reduce the risk of recurrence or death by about 50%, so taking that 7% recurrence risk down to about 3.5%.

Now, the risk of side effects should always be considered as well, because in many of these treatments, even with single agent anti-PD-1 therapy, the risk of side effects is in the 20 to 25% range, and these are serious grade 3 or 4 side effects. They could be lifelong. They might require hospitalization. They might require subspecialty services to help mitigate the toxicity. So this becomes financial toxicity, time toxicity, in addition to physical toxicity.

One of the tools that might be helpful when discussing this with a patient is talking about the number needed to treat versus the number needed to harm. So if you tell a patient, you know, for example, I need to treat X number of patients with your stage melanoma for 1 patient to derive the benefit, that may help contextualize it for them. In addition to giving them those same numbers, I need to treat X number of patients for 1 patient to develop a serious side effect.

So in summary, patients with resected stage III and IV melanoma still have a potential for recurrence or relapse despite definitive local therapy. And so we should consider treatment with both single agent anti-PD-1 therapy as well as BRAF/MEK targeted therapy for patients with a BRAF mutation. Both of these classes of treatments have been shown to improve recurrence-free survival when used as adjuvant treatment, but we're awaiting overall survival data in this setting. When using this treatment, it's important to also communicate the risk of these medications and involve patients in shared decision-making. Discuss, you know, whether the risk of side effects is worth it for the benefit in disease or death from melanoma. And also discuss what it means to manage those side effects; it might require hospitalization, referral to other specialties, and other management or monitoring plans.

So I'd like to thank the audience for their attention and participation in this activity.

Announcer:
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