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The Evidence Base: Key Trials and Emerging Data

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Dr. Oliva:
Welcome to CE with GLC. I'm Dr. Marc Oliva, and here with me today is Dr. Christophe Le Tourneau. So I have a question for you. Dr. Le Tourneau. What does the evidence show for perioperative immune checkpoint inhibitors in locally advanced head and neck squamous cell carcinoma?

Dr. Le Tourneau:
So we have been very lucky to have 2 trials presented in 2025 at major congresses, the KEYNOTE-689 and the NIVOPOSTOP trial.

So let's start with the KEYNOTE-689. That study was a randomized phase 3 clinical trial evaluating standard of care with surgery followed by radiotherapy plus or minus chemotherapy for patients with stage III or IVA locally advanced head and neck cancer versus 2 injections of neoadjuvant pembrolizumab, followed by surgery, followed by radiation plus or minus cisplatin, but pembrolizumab as well, followed by maintenance with pembrolizumab.

And actually, that clinical trial was positive in terms of event-free survival, and some patients actually had a major pathological response of around 10% to 13%, and some of them had the pathological complete response, so in 3% to 4% of patients. So despite this quite low pathological complete response rate, I mean the trial was positive in terms of event-free survival, so of meaning that less patients actually had distant metastasis in the experimental arm as compared to the standard of care arm.

The other study that was presented in 2025 was the NIVOPOSTOP trial, which was also a randomized phase 3 trial, but with a completely different design. In that study, patients had to have undergone surgery first and have a pathological stage III or IV disease but also have high-risk pathological features, including either extracapsular extension or invaded margins or 4 or more invaded lymph nodes.

In that study, patients were randomized between chemoradiation, which is the standard of care in the adjuvant setting, versus 1 injection of nivolumab followed by chemoradiation plus nivolumab, followed by nivolumab for 6 injections. And again, that study was positive in terms of disease-free survival.

So these are exactly two randomized phase 3 trials that were presented last year that demonstrated the added value of immunotherapy for locally advanced head and neck squamous cell carcinoma, one with the perioperative approach, the KEYNOTE-689, and the other

one with a strictly adjuvant approach for patients with very high-risk features on the pathological specimen.

In terms of safety, I have to say that nothing unexpected happened. Patients in the experimental arms of these 2 trials experienced some immune adverse events, but this was expected, and overall the immunotherapy was well tolerated by the patients in both trials.

Dr. Oliva:
Well, I think these are exciting times, right, for head and neck cancer in the resectable space with these 2 positive studies. I think we are also expecting to see, hopefully, a benefit in overall survival in the long term, although the results were still immature at the time of the presentation of these results. And definitely, that will imply certain changes in how we diagnose, we manage, and we decide the treatment in the tumor boards across the different countries and regions and institutions. So definitely a lot of work to do, but really happy to have new options for these patients and to have increased those curative rates.

So I think with that, I think we nailed it. So thank you so much for listening, and we'll see you next time.

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