Adding Pembrolizumab to Chemotherapy Extends Survival in Advanced Cervical Cancer

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For patients facing persistent, recurrent, or metastatic cervical cancer, treatment options have historically been limited. Recent research has explored strategies to enhance the efficacy of established chemotherapy regimens. A pivotal Phase 3 study, KEYNOTE-826, investigated the impact of incorporating pembrolizumab into standard treatment protocols, offering new insights into managing advanced cervical cancer.

KEY TAKEAWAYS

- The Pivot: Pembrolizumab, an immune checkpoint inhibitor, significantly improves survival outcomes when added to chemotherapy for advanced cervical cancer.
- The Data: In the intention-to-treat population, pembrolizumab extended median progression-free survival by 2.2 months and increased 24-month overall survival by 10 percentage points.
- The Action: Clinicians should consider pembrolizumab in combination with platinum-based chemotherapy, with or without bevacizumab, for patients with persistent, recurrent, or metastatic cervical cancer.

Context for Advanced Cervical Cancer Treatment

Cervical cancer, when persistent, recurrent, or metastatic, presents a significant clinical challenge with limited long-term survival rates. Standard treatment often involves platinum-based chemotherapy. The addition of bevacizumab, a vascular endothelial growth factor (VEGF) inhibitor, has previously demonstrated an improvement in overall survival for these patients when combined with chemotherapy 2. However, there remains an unmet need for further advancements to improve patient outcomes.

Pembrolizumab, a programmed death receptor-1 (PD-1) blocking antibody, has shown efficacy in PD-L1-positive metastatic or unresectable cervical cancer that has progressed during chemotherapy 1. This established activity provided a rationale for investigating its role earlier in the treatment sequence, specifically in combination with first-line chemotherapy, with or without bevacizumab.

Study Design and Patient Cohort

The KEYNOTE-826 study was a double-blind, phase 3, randomized trial designed to assess the benefit of adding pembrolizumab to chemotherapy, with or without bevacizumab, in patients with persistent, recurrent, or metastatic cervical cancer 1. Patients were randomly assigned in a 1:1 ratio to receive either pembrolizumab (200 mg) or placebo every 3 weeks for up to 35 cycles. Both groups also received platinum-based chemotherapy, and bevacizumab was administered at the investigator's discretion.

The study enrolled 617 patients in the intention-to-treat (ITT) population. Subgroup analyses were performed based on

PD-L1 combined positive score (CPS), with primary endpoints evaluated in patients with a CPS of 1 or more (n=548) and a CPS of 10 or more (n=317). The combined positive score is calculated as the number of PD-L1-staining cells divided by the total number of viable tumor cells, multiplied by 100 1.

Improved Progression-Free Survival with Pembrolizumab

The addition of pembrolizumab significantly improved progression-free survival (PFS) across all evaluated populations 1. In patients with a PD-L1 CPS of 1 or more, the median PFS was 10.4 months in the pembrolizumab group compared to 8.2 months in the placebo group (hazard ratio [HR] for disease progression or death, 0.62; 95% confidence interval [CI], 0.50 to 0.77; PAmong patients with a PD-L1 CPS of 10 or more, the median PFS was 10.4 months in the pembrolizumab group and 8.1 months in the placebo group (HR, 0.58; 95% CI, 0.44 to 0.77; P<0.001). These findings indicate a consistent benefit of pembrolizumab in delaying disease progression, irrespective of PD-L1 expression level, although the magnitude of benefit was numerically greater in the higher PD-L1 expression subgroup.

Enhanced Overall Survival and Safety Profile

Beyond progression-free survival, pembrolizumab also demonstrated a significant improvement in overall survival (OS) 1. At 24 months, the OS rate was 53.0% in the pembrolizumab group compared to 41.7% in the placebo group for patients with a PD-L1 CPS of 1 or more (HR for death, 0.64; 95% CI, 0.50 to 0.81; PFor patients with a PD-L1 CPS of 10 or more, the 24-month OS rates were 54.4% with pembrolizumab and 44.6% with placebo (HR, 0.61; 95% CI, 0.44 to 0.84; P=0.001). These results highlight a clinically meaningful extension of life for patients receiving pembrolizumab in combination with chemotherapy.

Regarding safety, the most common grade 3 to 5 adverse events were anemia (30.3% in the pembrolizumab group vs. 26.9% in the placebo group) and neutropenia (12.4% vs. 9.7%) 1. While the addition of pembrolizumab was associated with an increase in some adverse events, the overall safety profile was considered manageable and consistent with the known safety profiles of the individual agents.

Clinical Implications and Future Directions

The KEYNOTE-826 study provides compelling evidence that adding pembrolizumab to platinum-based chemotherapy, with or without bevacizumab, significantly improves both progression-free and overall survival for patients with persistent, recurrent, or metastatic cervical cancer 1. This represents a substantial advancement in the management of this challenging disease, offering a new standard of care.

Why this matters for clinical practice today: For clinicians managing patients with advanced cervical cancer, these findings underscore the importance of considering pembrolizumab as part of the initial treatment strategy. The observed survival benefits, particularly in the overall survival endpoint, are significant and warrant a shift in current practice. While PD-L1 testing can help identify patients who may derive greater benefit, the positive outcomes across the intention-to-treat population suggest a broad applicability. Integrating pembrolizumab into treatment plans for eligible patients could lead to improved long-term outcomes and quality of life.

It is important to note that while the study included bevacizumab as an optional component, its established benefit in this setting 2, combined with the new data on pembrolizumab, suggests that a triplet or quadruplet regimen may be considered for appropriate patients. Further research, such as the innovaTV 205 study, is exploring other novel combinations, including tisotumab vedotin with carboplatin or pembrolizumab, which have also shown promising activity and

encouraging long-term overall survival in recurrent or metastatic cervical cancer 3. These ongoing investigations will continue to refine treatment algorithms and expand therapeutic options for patients with advanced cervical cancer.

Limitations and Next Steps

The results presented are from the protocol-specified first interim analysis, meaning longer-term follow-up data may provide additional insights into the durability of response and potential late-onset adverse events 1. While the study demonstrated clear benefits, the optimal sequencing and combination strategies with other emerging therapies, such as antibody-drug conjugates, warrant further investigation 3. Additionally, identifying specific biomarkers beyond PD-L1 CPS that can predict response to pembrolizumab could help personalize treatment approaches further.

Future research should also focus on understanding the long-term impact on quality of life and exploring strategies to mitigate treatment-related toxicities while maintaining efficacy. The role of pembrolizumab in earlier stages of cervical cancer or in combination with other modalities like radiation therapy also represents an important area for future study.

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