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Titel des Beitrags: Randomized phase III trial of sequential adjuvant chemoradiotherapy with or without erythropoietin Alfa in patients with high-risk cervical cancer: results of the NOGGO-AGO intergroup study.

Abstract: This open-label, randomized phase III study was designed to investigate the effects of erythropoietin alfa (EPO) in addition to adjuvant chemotherapy and pelvic radiotherapy (CRT) in patients with stage IB to II cervical cancer who had undergone radical hysterectomy. Two hundred fifty-seven patients were randomly assigned to four cycles of carboplatin/ifosfamide chemotherapy followed by external-beam pelvic radiotherapy (CRT group) or four cycles of carboplatin/ifosfamide chemotherapy and EPO followed by pelvic radiotherapy and EPO (CRT + EPO group). The primary end point was recurrence-free survival (RFS). Secondary end points included overall survival (OS), change in hemoglobin levels, and safety, including thromboembolic events. The estimated 5-year RFS rates were 78% for patients receiving CRT + EPO and 70% for patients receiving CRT. There was no statistically significant difference in RFS, although a trend favoring patients treated with CRT + EPO was observed (hazard ratio [HR], 0.66; 95% CI, 0.39 to 1.12; log-rank P = .06). Exploratory analyses suggest a benefit with CRT + EPO for patients with stage IB to IIA disease (HR, 0.39;
95% CI, 0.18 to 0.85; P = .014) or patients with complete resection (HR, 0.55; 95% CI, 0.31 to 0.98; P = .039). OS was similar in both groups (HR, 0.88; 95% CI, 0.51 to 1.50; log-rank P = .63). Patients treated with EPO maintained higher hemoglobin levels throughout CRT. No significant differences in safety profiles were observed between the two groups. Incidence of thrombovascular events was low (2%) and comparable between both groups. This study confirms that EPO can be added safely to CRT in patients with cervical cancer, but it failed to demonstrate a significant benefit in RFS and OS.