

Abstract

Because of the poor results in stage III B carcinoma of the cervix with standard treatment using radiotherapy alone, we designed a randomized trial to determine whether administration of chemotherapy before pelvic irradiation would improve survival. Between May 1984 and August 1986, 107 patients with previously untreated squamous cell carcinoma were randomly assigned, after stratification by age (less than 50 v greater than 50 years), extent of parametrial involvement (unilateral v bilateral), and lymphangiographic findings (negative v positive) to pelvic radiotherapy (RT; arm A) or three cycles of chemotherapy (CT; bleomycin, vincristine, mitomycin, and cisplatin [BOMP]), followed by the same radiotherapy regimen (CT + RT; arm B). The groups were balanced by age, performance status, extent of parametrial involvement, bulkiness of cervical disease, nodal involvement, and presence of hydronephrosis. Minimal follow-up is 34 months. A complete local response was observed in 32.5% of the patients in arm A and in 47% of the patients in arm B ($P = .19$). Overall 5-year survival rates were 39% for the RT arm and 23% for the CT + RT approach ($P = .02$). Toxicity was severe in arm B and included fatal pulmonary toxicity in four patients. Locoregional and distant failures were similar in both groups. We conclude that, despite a satisfactory response rate, neoadjuvant BOMP chemotherapy adversely affects survival in stage III B cervical cancer and is associated with unacceptable toxicity.