Randomized multicenter phase II trial of cisplatin and ifosfamide with or without paclitaxel in recurrent or metastatic carcinoma of the uterine cervix: a Hellenic Cooperative Oncology Group (HeCOG) study.

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Source

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Abstract

BACKGROUND:

We undertook a randomized phase II trial to test whether the addition of paclitaxel (Taxol) to the cisplatin and ifosfamide (IP) combination could improve objective response (OR) rate, progression-free survival (PFS) and overall survival (OS) in patients with recurrent or metastatic cancer of the uterine cervix.

PATIENTS AND METHODS:

One hundred and fifty-three patients were randomly allocated to receive either the IP regimen (ifosfamide 1.5 g/m(2), daily, on days 1-3 and cisplatin 70 mg/m(2) on day 2) or the same combination with the addition of paclitaxel 175 mg/m(2) on day 1 [ifosfamide, paclitaxel and cisplatinum (ITP) regimen]. Cycles were administered every 4 weeks on an outpatient basis.

RESULTS:

A modest increase in neurotoxicity was observed with the triplet combination. OR rate was significantly higher in the ITP group (59% versus 33%, P = 0.002). Median PFS was 7.9 and 6.3 months for patients in the ITP and IP arms, respectively (P = 0.023). Median OS was 15.4 months and 13.2 months in the ITP and IP arms, respectively (P = 0.048). In multivariate analysis, the triplet yielded a hazard ratio of 0.70 for relapse or progression (P = 0.046) and 0.75 for death (P = 0.124) compared with the doublet.

CONCLUSION:

The ITP combination merits further investigation in randomized phase III studies.