Ann Oncol. 2012 Nov 7. [Epub ahead of print]

Prospective, open-label, randomized, phase III study of two dose-dense regimens MVAC versus gemcitabine/cisplatin in patients with inoperable, metastatic or relapsed urothelial cancer: a Hellenic Cooperative Oncology Group study (HE 16/03).

Bamias A, Dafni U, Karadimou A, Timotheadou E, Aravantinos G, Psyrri A, Xanthakis I, Tsiatas M, Koutoulidis V, Constantinidis C, Hatzimouratidis C, Samantas E, Visvikis A, Chrisophos M, Stravodimos K, Deliveliotis C, Eleftheraki A, Pectasides D, Fountzilas G, Dimopoulos MA.

Source

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Abstract

BackgroundThe combinations of methotrexate, vinblastine, Adriamycin, cisplatin (Pharmanell, Athens, Greece) (MVAC) or gemcitabine, cisplatin (GC) represent the standard treatment of advanced urothelial cancer (UC). Dose-dense (DD)-MVAC has achieved longer progression-free survival (PFS) than the conventional MVAC. However, the role of GC intensification has not been studied. We conducted a randomized, phase III study comparing a DD-GC regimen with DD-MVAC in advanced UC.Patients and methodsOne hundred and thirty patients were randomly assigned between DD-MVAC: 66 (M 30 mg/m(2), V 3 mg/m(2), A 30 mg/m(2), C 70 mg/m(2) q 2 weeks) and DD-GC 64 (G 2500 mg/m(2), C 70 mg/m(2) q 2 weeks). The median follow-up was 52.1 months (89 events).ResultsThe median overall survival (OS) and PFS were 19 and 8.5 months for DD-MVAC and 18 and 7.8 months for DD-GC (P = 0.98 and 0.36, respectively). Neutropenic infections were less frequent for DD-GC than for DD-MVAC (0% versus 8%). More patients on DD-GC received at least six cycles of treatment (85% versus 63%, P = 0.011) and the discontinuation rate was lower for DD-GC (3% versus 13%).ConclusionsAlthough DD-GC was not superior to DD-MVAC, it was better tolerated. DD-GC could be considered as a reasonable therapeutic option for further study in this patient population.Clinical Trial NumberACTRN12610000845033, www.anzctr.org.au.