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Background. The combination of bevacizumab and erlotinib has shown promising clinical outcomes as the first-line treatment for patients with advanced hepatocellular carcinoma (HCC). We aimed to assess the efficacy and safety of using the combination as a second-line treatment for patients with advanced HCC who had failed first-line sorafenib treatment.

Methods. Eligible patients with advanced HCC and documented radiological evidence of disease progression with sorafenib treatment were recruited. All patients received bevacizumab at 10 mg/kg every 2 weeks with erlotinib at 150 mg daily for a maximum of six cycles. Response assessments using both Response Evaluation Criteria in Solid Tumours (RECIST) and modified RECIST criteria were done after every 6 weeks. The primary end-point was the rate of clinical benefit and the major secondary end-points were response rate, time-to-progression (TTP), and overall survival (OS).

Findings. The trial was stopped during the first stage according to the pre-set statistical criteria with 10 patients recruited. The median age was 47 years (range 28–61) and all patients had Eastern Cooperative Oncology Group (ECOG) performance status 1. Eighty per cent of patients were chronic hepatitis B carriers and all patients had Child A cirrhosis. None of the 10 enroled patients achieved response or stable disease. The median TTP was 1.81 months (95% confidence interval [CI], 1.08–1.74) and OS was 4.37 months (95% CI, 1.08–11.66). Rash (70%), diarrhoea (50%), and malaise (40%) were the most common toxicities.

Interpretation. The combination of bevacizumab and erlotinib was well tolerated but had no activity in an unselected sorafenib-refractory population of patients with advanced HCC.

The authors declared no conflicts of interest.

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AOSOP4 COMPARISON OF VOLUMETRIC EVALUATION FOR TUMOUR RESPONSE WITH RECIST IN METASTATIC COLORECTAL CANCER WITH LIVER METASTASES ONLY

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Background. Response Evaluation Criteria in Solid Tumours (RECIST) is the most widely acceptable assessment tool for assessing tumour response. However, volumetric evaluation (VE) was shown to be even more accurate than was RECIST in recent studies.

Methods. VE of liver metastases from patients with metastatic colorectal cancer (mCRC) was performed by manual contouring of all liver metastases on computed tomography (CT) images of 5 mm slice thickness on the Eclipse Treatment Planning System at baseline and after chemotherapy with FOLFOX4 ($n = 18$) with or without cetuximab ($n = 14$) on 41 pairs of CT images in 32 patients treated at the Queen Mary Hospital from January 2008 to December 2010. The aggregate tumour volumes were then compared with the baseline for tumour response. Best objective response (OR) by use of VE (PD, >73% compared with nadir; SD, between PD and PR; PR <65% compared with nadir; CR, complete disappearance) was defined according to previous reports. Cohen kappa was used to compare OR based on VE, RECIST, and Independent Radiologist Review Committee (IRRC). Pearson correlation was calculated for association between VE and RECIST after cubic root transformation of the aggregate tumour volumes. Logistic regression was done for any clinical and radiological factors, accounting for the difference in OR between VE and RECIST.

Findings. OR by VE did not match with that by use of RECIST in six pairs of comparisons. However, VE showed good agreement with RECIST ($\kappa = 0.755$) and also better agreement with IRRC than did RECIST ($\kappa = 0.547$ and $\kappa = 0.462$, respectively). Pearson correlation showed an excellent correlation between VE and RECIST ($r^2 = 0.968$, $p < 0.001$). Subgroup analysis showed better agreement for enlarging lesions than for shrinking lesions ($r^2 = 0.974$ and $r^2 = 0.887$, respectively). No factor was predictive of the difference in OR between VE and RECIST.

Interpretation. VE showed good agreement with RECIST in OR evaluation. It might be a better method than RECIST when evaluating conglomerate matted liver metastases.

The authors declared no conflicts of interest.

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AOSOP5 BIRTH RATES AMONG MALE CANCER SURVIVORS: A POPULATION-BASED COHORT STUDY

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Background. With early diagnosis, improvements in treatment of cancer, and better survival rates, more men of reproductive age are long-term survivors. The trends in birth rates among male cancer survivors were assessed in this study.

Methods. From the Swedish Multi-generation Register and the Cancer Register we identified 67,740 men aged 70 years or younger with a history of cancer, for whom we calculated birth rates relative to the background population (standardised birth rates, SBRs). Independent factors associated with reduced birth rates among cancer survivors were estimated by use of Poisson modelling.

Findings. Overall 7.3% of men with a history of cancer had partners who gave birth after their diagnosis. These men were 23% less likely to father a child than were those in the background population. Men with breast, skin, and thoracic cancers had SBRs similar to the background population, whereas those with prostate, brain and eye, reproductive, and haemopoietic cancers were the most affected, having low SBRs. Nulliparous men were significantly more likely to father a child (SBR 0.80, 95% confidence interval (CI) 0.78–0.82) than were those who were parous (SBR 0.69, 95% CI 0.66–0.72), and at seven of 12 sites nulliparous men had birth rates similar to men in the background population. Cancer site (prostate), age at onset of cancer (<12 years), parity status (parous), current age (>40 years), and a recent diagnosis were significant and independent predictors of a reduced probability of fathering a child after diagnosis.

Interpretation. Male cancer survivors are less likely to father a child than are men in the background population. Fertility is affected by the cancer site, age of onset, and parity status at diagnosis.

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