

Addition of trastuzumab to chemotherapy for stomach cancer extends survival by nearly 3 months

August 19 2010

An Article published Online First by The *Lancet* says that for patients with HER2-positive advanced gastric cancer, addition of trastuzumab to standard cisplatinum/fluoropyrimidine chemotherapy results in a median survival of 13.8 months, compared with 11.1 months with chemotherapy alone. This corresponds to a 26% reduction in the death rate for patients in the trastuzumab group. Thus trastuzumab combined with standard chemotherapy could be considered a new standard option for patients with this condition. However, an accompanying Comment questions the cost effectiveness of the treatment. The Article is by Professor Yung-Jue Bang, Seoul National University College of Medicine, Seoul, South Korea, and Dr Eric van Cutsem, University Hospital Gathuisberg, Leuven, Belgium, and colleagues.

Trastuzumab is a drug which acts against human [epidermal growth factor receptor 2](#) (HER2), and is already a standard treatment in many settings for breast cancers that are HER2 positive. There is growing evidence that HER2 is an important biomarker and key driver of tumour growth in [gastric cancer](#), with studies showing amplification or overexpression of HER2 in around one fifth of tumours. The authors investigated trastuzumab in combination with [chemotherapy](#) for first-line treatment of HER2-positive advanced gastric or gastro-oesophageal junction [cancer](#).

This randomised controlled phase 3 trial took place in 122 centres in 24

countries. Patients with gastric or gastro-oesophageal junction cancer were eligible for inclusion if their tumours showed overexpression or amplification of HER2. Participants were randomly assigned in a 1:1 ratio to receive a chemotherapy regimen consisting of capecitabine plus [cisplatin](#) or fluorouracil plus cisplatin given every 3 weeks for six cycles or chemotherapy in combination with intravenous trastuzumab every 3 weeks until disease progression.

A total of 584 patients were included in the primary analysis (294 trastuzumab group, 290 chemotherapy only). Median overall survival was 13.8 months in the trastuzumab group and 11.1 months in the chemotherapy only group, a difference of 2.7 months (and a 26% reduction in the death rate for those given trastuzumab). In patients with high levels of HER2, the median survival was 16.0 months in the trastuzumab group and 11.8 months in the chemotherapy only group, a 35% reduction in the risk of death. Rates of adverse events, including those that were serious or heart-related, were similar in both groups.

The authors conclude: "Addition of trastuzumab to chemotherapy improved survival in patients with advanced gastric or gastro-oesophageal junction cancer compared with chemotherapy alone; this improvement was mainly the result of the survival advantage conferred to patients with high expression of HER2 protein. On the basis of these findings, trastuzumab can be considered as a new standard option for patients with HER2-positive advanced gastric or gastro-oesophageal junction cancer when combined with a chemotherapy regimen consisting of capecitabine plus cisplatin or fluorouracil plus cisplatin."

In the linked Comment, Professor Alastair J Munro and Dr Paddy G Niblock, Department of Surgery and Molecular Oncology, Ninewells Hospital and Medical School, University of Dundee, UK, say: "If we presuppose that only randomised trials produce evidence of sufficient quality to support decisions about the allocation of scarce resources,

there is a problem. There is a lot of evidence on the effects of adding expensive new drugs to conventional therapies, but little evidence for when older, less expensive interventions are combined. The evidence we have might not be the evidence we need, and the evidence that we need may never become available."

They add: "There are also problems with affordability. Patients in the ToGA study were treated with trastuzumab every 3 weeks until disease progression. The median time to progression was 6-7 months. When we use the cost estimates of trastuzumab therapy calculated by the UK's National Institute for Health and Clinical Excellence (NICE), this equals an average cost of £13 857 per patient . Cost per life-year gained will therefore be around £55 000. In the 24 countries that contributed to the study, yearly health expenditure per citizen varies from \$40 to \$5500 (2007 US dollars), which reiterates the important moral question—what is the justification for introducing a treatment that might enable one individual to live a few months longer but, which will consume for each person treated, the total yearly health expenditure for scores of their fellow citizens?"

Provided by Lancet

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