Reviewer's report

Title: Cholangio-cellular carcinoma responding on Gemcitabine in combination with EGF-Receptor antibody (Cetuximab) - A Case Report

Version: 1 Date: 26 February 2006

Reviewer: Florian Eckel

Reviewer's report:

General
After introduction of gemcitabine case reports were published reporting partial response, increase in performance status and complete pain relief in patients with biliary tract cancer (Verderame F et al., Anticancer Drugs 2000; 11:707-8). Sprinzl et al. report on a case of a patient with biliary tract cancer treated with gemcitabine in combination with cetuximab. The authors observed partial response, improvement of performance status and intravenous alimentation could be discontinued. The authors argue, that the unusual gemcitabine schema of 1000 mg/m2 only every other week together with dose reductions due to severe gemcitabine toxicity may limit the possible effect of gemcitabine. Consequently the effects observed were interpreted as cetuximab effects.

Can we beleive this? Interestingly the treatment was started with gemcitabine alone for four cycles (eight weeks). After financial approval cetuximab was started together with the fith gemcitabine cycle. It would be interesting to know, if the clinical course changed after eighth weeks of gemcitabine alone. Any significant changes, e.g. tumor response with cetuximab after progression with gemcitabine alone, would strongly support cetuximab effects. However, the authors do not report any changes after introduction of cetuximab. The only information given is the course of tumor marker Ca 19-9. After four courses of gemcitabine alone Ca 19-9 decreased from about 200 U/ml to about 75 U/ml (decrease by more than 60%). Unfortunately CT-imaging was not performed after eight weeks of treatment with gemcitabine alone. After five more courses of gemcitabine, now in combination with cetuximab, Ca 19-9 decreased from about 75 U/ml to about 30 U/ml (decrease by about 60%). Does this at most constant decrease of Ca 19-9 support a significant effect of cetuximab? I do not think so. After 18 weeks CT-imaging was performed at least and showed partial response. However, as mentioned above, partial responses in biliary tract cancer have been reported with gemcitabine alone and published response rates range from 8 to 60%.

In conclusion, there is no significant information of any effect, which may be assigned to cetuximab. Therefore, all conclusions drawn are very speculative.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

What next?: Reject because scientifically unsound

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: No
Declaration of competing interests:
I declare that I have no competing interests