Author's response to reviews

Title: Phase II Trial of Weekly 24-Hour Infusion of Gemcitabine in Patients with Advanced Gallbladder and Biliary Tract Carcinoma

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Author's response to reviews:

Dear referees, dear editors,

thank you for your comments. I have revised my manuscript accordingly:

2. "In terms of response RECIST criteria [9] were applied, since in most cases of these tumors interpretation of bi-dimensional measurements is complicated by associated inflammation and/or necrosis, as well as anatomical structures in the vicinity." inserted in paragraph "Patient Evaluation"

3. Because of the low incidence of Cholangiocarcinomas no upper limit for age was defined. 5 patients were older than 75 years on time of inclusion (3x 77, 1x 80 and 1x 83 years). Nevertheless Performance status (WHO) was acceptable and comparable to younger participants of the study (ECOG: 3x 2 and 2x 3).

Table 1 Resection changed to previous surgical resection.

Table 1 Pre-treatment and because of obstructive jaundice inserted in the row of requiring stent or percutaneous transhepatic drainage.

Table 1 4 rows inserted with sites of metastasis.

As AP is the main parameter in most phase II studies, I chose to report on this lab value. Unfortunately as GGT is our preferred parameter for cholestasis at our center, AP was evaluated in only 9 patients, mostly patients with stent therapy and/or hepatic metastasis. GGT was evaluated in all 19 patients, so I replaced AP with GGT in table 1. There is still a 2,5x elevation probably due to high rate of patients with stent therapy (and bile duct irritation) and patients with hepatic metastasis (and small bile duct obstruction).

"Patients and methods" are revised.

4. Dose of gemcitabine inserted in paragraph "Treatment Plan"

7. Table 3 inserted

Point-to-point response to Dr. Gebbia

Thank you very much for your clear comments.
Negative outcome is emphasised in discussion ans conclusion.

Subgroup analyses are deleted.

Thank you very much.

I wish you all a nice Pentecost.

With kind regards,

Stefan von Delius