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Session L. Gastrointestinal (noncolorectal) cancer

L41 Phase II study of Gemcitabine and Curcumin (Meriva®) as first line treatment for locally advanced or metastatic pancreatic cancer: preliminary results

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Background: Gemcitabine (GEM) was the first drug to demonstrate survival advantage and improvement in quality of life (QoL) in advanced pancreatic cancer (PC). Improvement in response rate (RR), progression free survival (PFS) and survival were obtained with newer combination treatments but at the expense of increased toxicities. Thus, GEM still represents one of the standard treatment for PC. Curcumin has demonstrated antinflammatory, antioxidant and potential antitumor properties in different solid tumors. Therefore, we evaluated the possibile synergistic activity of curcumin extract coniugated with phospholipids (MERIVA®) to enhance bioavailability, and GEM in advanced PC.

Patients and methods: This was a single center, single arm prospective phase II trial. Inclusion criteria were: previously untreated patients with histologically confirmed metastatic or locally advanced PC, ECOG performance status of 0-2, adequate organ function and written informed consent. The patients received GEM (1000 mg/mq in 100 minutes on day 1,8,15 every 28 days) and Meriva® (2000 mg/die, continuously) until progression, unacceptable toxicities or patients refusal. Primary endpoint was RR (according to RECIST criteria version 1.1), secondary endpoints were PFS, OS, tollerability and QoL. Serum samples collection for inflammatory biomarkers was also performed.

Results: Between October 2012 and February 2015 a total of 57 consecutive patients were enrolled. Forty patients (14 females and 26 males; 14 patients locally advanced disease and 26 metastatic) are at present suitable for primary endpoint evaluation. Median age was 66 years (range 42-87); all patients except one had ECOG performance status 0-1. The median number of treatment cycle was 4 (range 1-14). The overall RR was 27,5% (all partial responses), stable disease (SD) was reported in 32,5% of cases with a disease control rate (RR + SD) of 60%. Grade 3/4 hematological toxicities included neutropenia (40%, but no febrile neutropenia were observed) and anemia (7,5%). No grade 3/4 non-hematological toxicities nor treatment-related deaths were reported.

Conclusions: The addition of Meriva® to GEM was safe and translate in good disease control rate in first line therapy of advanced PC. Treatment was well tolerated, but we observed a higher than expected rate of hematological toxicities. No treatment-related deaths were observed. Biomarker analyses are ongoing to identify potential patients whi canc get more benefit with this combination.