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

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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.

Materials 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 or unacceptable toxicities or patients refusal.
Primary endpoint was RR (according to RECIST criteria version 1.1), secondary endpoints were PFS, OS, tolerability and QoL. Serum samples collection for inflammatory biomarkers was also performed.

Results

Between October 2012 and February 2015 a total of 55 consecutive patients were enrolled. Thirty-nine patients (14 females and 25 males; 14 patients locally advanced disease and 25 metastatic) are at present suitable for primary endpoint evaluation. Median age was 66 years (range 42-80); 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 28,2% (all partial responses), stable disease (SD) was reported in 33,3% of cases with a disease control rate (RR+SD) of 61,5%. Grade 3/4 hematological toxicities included neutropenia (41%, but no febrile neutropenia were observed) and anemia (7,7%). No grade 3/4 non-hematological toxicities nor treatment-related deaths were reported.

Patients' characteristics

N. of patients		
Enrolled		55
Evaluable at present		39
Sex	Male	25
	Female	14
Disease status	Locally advanced	14
	Metastatic	25
ECOG PS	0-1	38
	2	1
Median age	66 (range 42-80)	

Results

Best response	
Complete response	0%
Partial response	28.2%
Stable disease	33.3%
Progression	38.5%
Disease control rate	61.5%

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 hematological toxicities. No treatment-related deaths were observed. Biomarker analyses are ongoing to identify potential patients who can get more benefit with this combination.

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