Background: QOL parameters may be predictive of treatment efficacy in PDAC.

Methods: Eligible consenting patients (pts) received n-P/Gem or Gem in standard regimens. CO was possible at progression. Monthly EORTC QLQ-C30 v3.0 QOL questionnaires were used. Deterioration-free rate of global health status (GHS) at 3 months (mths) was the primary endpoint. Safety, efficacy and molecular studies on blood were secondary endpoints.

Results: One hundred forty-six pts (125 metastatic), median age 65, were included in 17 hospitals of the Belgian Group of Digestive Oncology network between May 2014 and Nov 2015 and randomized to n-P/Gem (72) or Gem (74). 37 crossed-over. Median duration on treatment was 5 mths (0-28). Ninety-nine pts (68%) experienced at least one serious adverse event; 6 events had fatal outcome, one was possibly related to Gem (sepsis). Gastrointestinal toxicity and infections were frequent. Hemolytic uraemic syndrome occurred in 5 pts. Overall, 1,465 QOL questionnaires were completed. 85% of pts responded to a series of at least three. Deterioration-free rate of GHS at 3 mths was 83% (60/72) with n-P/Gem, 60% (28/47) with Gem alone and 96% (26/27) after CO. Median times to definitive deterioration were 12.8, 8.9 and 12.3 mths respectively. Baseline GHS scores correlated at 0.05 significance level with survival time in the n-P/Gem group. Other QOL indicators showed equivalent patterns. Tumour response was locally assessed in 43% of pts (95%CI 31-55) with n-P/Gem, 19% (95%CI 6-32) with Gem and 24% (95%CI 10-39) in the CO group (p = 0.006) with 2 pts in complete response. Median PFS was 6.8 mths (95%CI 3.5-8.1) in all pts, with 7.4 in n-P/Gem, 7.2 in Gem and 5.4 mths in CO (1st progression). Median PFS for 2nd progression in CO was 10.8 mths. Overall survival was 11.9 mths (95%CI 10-14) with 10.7, 8.8 and 13 mths in the three groups.

Conclusions: Survival was long and response rates significantly higher in pts receiving the combination. Pts receiving n-P/Gem reported better quality of life scores for longer duration compared to pts on Gem alone. QOL analyses and translational studies will be presented at the congress. Academic study with support from Celgene.


Legal entity responsible for the study: Academic study governed by the Belgian Group of Digestive Oncology network. Sponsored and coordinated by University Hospitals Leuven.

Funding: Celgene.

Disclosure: I. Borbath: Research grants: Celgene. E. Van Cutsem: Grants, Research support: Amgen, Bayer, Boehringer, Celgene, Ipsen, Lilly, MSD, Merck, Novartis, Roche, Servier; Honoraria, Consultation fees: Bayer, Celgene, Lilly, Novartis, Servier. All other authors have declared no conflicts of interest.