QoliXane

Nab-paclitaxel/Gemcitabine First Line Therapy in Patients with Metastatic Pancreatic Carcinoma and High Bilirubin values - Data from the German QoliXane pancreatic cancer registry

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Introduction

Hyperbilirubinaemia is a common disease effect in patients (pts) with metastatic pancreatic cancer (mPC). As clinical trials often exclude them, data on management of these pts are rare. In the framework of a prospective German observational multicenter study (QoliXane), detailed quality of life and therapy data are currently being collected in pts with mPC receiving a combination of nab-paclitaxel and gemcitabine. This is an interim analysis on hyperbilirubinaemia management.

Methods

Pts were included to this analysis if they entered the trial with a bilirubin level ≥ 1.2 mg/dl and completed at least 2 cycles. Bilirubin levels were documented for up to 4 cycles and methods of hyperbilirubinaemia management have been assessed. A both descriptive and explorative analysis was performed using IBM SPSS V 23.

Results

25 of 294 pts (8.5%) were included. Mean bilirubin level was 2.96 mg/dl (range 1.2-12.3) at baseline and dropped considerably by the start of the 2nd cycle to 0.84 (range 0.29-3.9; p = 0.0001). Bilirubin levels decreased in 24 (96%) and increased in 1 (4%) pts upon treatment start. 18 (72%) pts started treatment with standard dosage, 7 (28%) with a reduced regime. 10 (40%) pts underwent additional intervention: either stenting (7 pts, 28%) or bile duct anastomosis (3 pts, 12%). Mean bilirubin values dropped from 4.59 to 1.09 in pts with and from 1.87 to 0.68 in pts without additional intervention. Grade 3/4 toxicity was seen in 60% of pts and most common 3/4 events were anemia, nausea, and fever.

Conclusions

Data show that bilirubin levels drop considerably after start of chemotherapy. The treatment with nab-paclitaxel and gemcitabine seems to be feasible in patients with hyperbilirubinaemia, although considerable frequencies of grade 3/4 toxicities were observed.

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