PD – 004 Baseline characteristics and second-line treatment for metastatic pancreatic adenocarcinoma (mPAC) patients receiving first-line FOLFIRINOX, gemcitabine+nab-paclitaxel or gemcitabine-monotherapy in routine clinical practice across Europe

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Introduction: Both FOLFIRINOX and gemcitabine+nab-paclitaxel have shown superior overall survival over gemcitabine-monotherapy in fitter and younger first-line mPAC patients, but with increased toxicity. No randomized phase III data comparing FOLFIRINOX and gemcitabine+nab-paclitaxel are available to help clinical decision making. Furthermore, data on systemic treatment choices in first-line mPAC and outcomes outside clinical trials are scarce. The goal of this large pan-European project was to generate data on diagnosis, treatment patterns and outcomes from the records of patients who completed first-line mPAC treatment across Europe.

Methods: In this observational chart review, physicians completed retrospective electronic records from initial diagnosis onwards for patients with the following minimal inclusion criteria: completed first-line mPAC treatment between 07/2014-01/2016 and ≥18 years. In each country, respondents were recruited across different regions and settings (university and general hospitals, cancer and reference centers, office-based specialists) to ensure a balanced selection. Physicians were encouraged to enter as many second-line metastatic patients as possible. We report here on baseline characteristics and subsequent second-line treatment of patients receiving (m)FOLFIRINOX/gemcitabine+nab-paclitaxel/gemcitabine-monotherapy as first-line mPAC treatment, including variations across countries. All data are descriptive.

Results: A total of 2,565 online patient records were completed by 225 physicians (9 countries; n = 500-504 for France/Germany/Italy/Spain/UK). At start of first-line treatment, median age was 64 years, 57.7% was male and median CA19-9/albumin/bilirubin levels were 457U×ml-1/32.0g×L-1/1.30mg×dL-1. WHO performance status was grade 0/1/2/3/4 in 14.3%/55.5%/26.9%/2.6%/0.2%. Although substantial variations was noted in countries, (m)FOLFIRINOX/gemcitabine+nab-paclitaxel/gemcitabine-monotherapy were most frequently used first-line treatments and accounted for 35.6%/25.7%/20.5% of patients across Europe. Patients treated with (m)FOLFIRINOX versus gemcitabine+nab-paclitaxel versus other gemcitabine-combinations versus gemcitabine-monotherapy had a better performance status, were more often ≤65 years of age, were more often male, had lower median CA19-9 and bilirubin levels and higher median albumin levels. WHO performance status grade 0/1/2/3/4 for patients receiving (m)FOLFIRINOX/gemcitabine+nab-paclitaxel/gemcitabine-monotherapy was 22.5%/64.7%/11.1%/1.0%/0.1%, 13.6%/62.9%/21.8%/1.7%/0.0%, and 4.2%/35.0%/55.3%/4.6%/0.4%, respectively. 70.1%/50.6%/26.8% of patients were 65 years or younger, and 63.7%/56.8%/51.3% of patients were male. Median CA19-9/albumin/bilirubin levels were 456/480/593U×mL-1, 34.0/33.0/31.0g×L-1, and 1.18/1.30/1.42mg×dL-1, respectively. Similar trends were seen in individual countries, although percentages and values differed and differences were sometimes less outspoken. Overall, no substantial differences between FOLFIRINOX full and modified dose at start were noted. Of the patients who had received (m)FOLFIRINOX/gemcitabine+nab-paclitaxel/gemcitabine-monotherapy, 12.2%/9.8%/78.1%, 23.2%/9.4%/67.4%, and 54.8%/4.8%/40.5% patients were not scheduled for further treatment/were waiting to receive further treatment/had started second-line treatment, respectively. For patients who had received (m)FOLFIRINOX as first-line treatment, most frequent second-line treatments were gemcitabine-monotherapy/gemcitabine+nab-paclitaxel/other gemcitabine-combinations with 45.9%/33.1%/10.5%. For gemcitabine+nab-paclitaxel, most frequent second-line treatments were 5FU+oxaliplatin/5FU-monotherapy/5FU+irinotecan/FOLFIRINOX/gemcitabine-monotherapy/other gemcitabine-combinations in 39.1%/23.4%/10.8%/9.0%/7.6%/7.4%. For gemcitabine-monotherapy, most frequent second-line treatments were 5FU-monotherapy/5FU+oxaliplatin/5FU+irinotecan/gemcitabine+nab-paclitaxel in 42.7%/28.2%/8.0%/8.0%. Substantial variation across countries was noted.

Conclusion: Overall, mPAC first-line treatment application across Europe is in line with ESMO recommendations. (m)FOLFIRINOX/gemcitabine+nab-paclitaxel/gemcitabine-monotherapy were applied most often and choice appears to be strongly related to the patient's overall condition: performance status/age/CA19-9/bilirubin/albumin and gender. Second-line treatment choice was dependent on first-line as well and varied to some degree between countries. Insights into use and efficacy of treatments in real-world may help developing treatment plans and improve outcomes of mPAC patients.