Real World Evidence for FOLFIRINOX vs. Gemcitabine/Nab-paclitaxel in 1st Line Metastatic Pancreatic Cancer

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OBJECTIVE

To demonstrate the validity of our analysis techniques utilizing real-world data to assess and compare the effectiveness of two chemotherapy regimens that have not been directly compared in randomized clinical trials: FOLFIRINOX (combined leucovorin calcium, fluorouracil, irinotecan and oxaliplatin) and gemcitabine plus nab-paclitaxel as for first line metastatic pancreatic cancer.

COHORT

Initial cohort of 32k diagnosed with pancreatic cancer

Sub cohort of 17k pancreatic cancer patients treated either with FOLFIRINOX or gemcitabine/nab-paclitaxel as first line therapy in the last 5 years

Target cohort of 2439 metastatic patients aged 50+ at the time of the first line starting date, who completed first line treatment prior to December 31st, 2021.

Treatment	Male	Female
FOLFIRINOX	628	438
Nab-Paclitaxel Gemcitabine	705	668

METHOD

Clinical Patient Journey:

- Source data – open claims data.
- Statistical and Medical data validation:
  - Longitudinal patient data stability
  - Medical procedures and oral products
- A regimen detection algorithm capable of detecting treatment pattern directly on claims.
- Kaplan-Meier method to perform Overall Survival (OS) analysis
- Cox Proportional Hazard Model to evaluate interaction and confounding

Intercurrent Events	
Direct Death Event	non-observable
Death Surrogate Event	termination of the data for the patient in the claims database
Observation End	30st June 2022
Progression	first week of the next treatment line

Clinical Patient Journey features :

- Identifying potential clinical trials sites based on real world treatments.
- Informing protocol design and study feasibility.
- Identifying treatment paradigm shifts over time across lines of treatment.
- Comparing real world overall survival in target populations versus interventional clinical trials.
- Answering some trial questions with a greater statistical power than traditional observational trials (e.g., lengths of treatments, timing of critical interventions)

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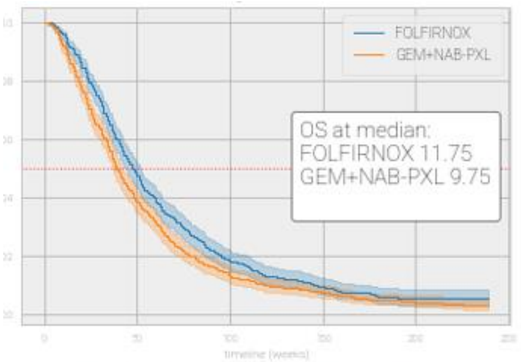

Figure 1 OS. Cohort of interest: Males

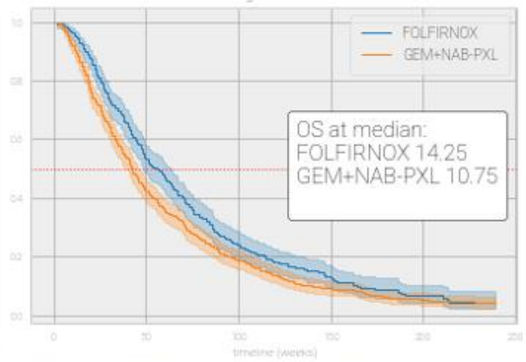

Figure 2 OS. Cohort of interest: Females

Overall Survival	coef	exp(coef)	se(coef)	coef lower 95%	coef upper 95%	exp(coef) lower 95%	exp(coef) upper 95%	p
treatment	0.54	1.71	0.02	0.50	0.57	1.65	1.78	<0.005
metastasis	0.34	1.41	0.04	0.27	0.42	1.31	1.51	<0.005
interaction	-0.33	0.72	0.05	-0.43	-0.24	0.65	0.79	<0.005
gender	0.07	1.08	0.02	0.04	0.11	1.04	1.11	<0.005

Table 1 Cox Model Summary

tests for treatment arms	p	-log2(p)
log rank	<0.005	564.34
wilcoxon	<0.005	569.64

Table 2 Significance

RESULTS:

The initial cohort from claims data of 32k is narrowed down to treatment sub-cohort of 17k, and then further down to the targeted cohort of 2.4k with metastatic patients aged 50+, which is large enough to be split by gender and still draw statistically valid conclusions.

For the targeted cohort, KM curves (Fig. 1) and (Fig. 2) show treatment benefit of FOLFIRINOX over Gemcitabine/Nab Paclitaxel regimen regardless of gender.

Cox Proportional Hazard Model (Tab. 1) confirms significance of treatment arms (Tab. 2) as well as metastasis and gender in overall survivability calculated over treatment sub cohort.

CONCLUSIONS:

Survival benefit was shown for patients with metastatic pancreatic cancer treated with FOLFIRNOX over gemcitabine/nab-paclitaxel. Our proprietary detection algorithm identifies attributes of chemotherapy regimens in claims data and can be used to provide insights into oncology treatment regimens in large populations of oncology patients, which is especially important when comparative analyzes of clinical effectiveness are limited.

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