Predicting mortality and adverse events in patients with advanced pancreatic cancer treated with palliative gemcitabine-based chemotherapy in a multicentre phase III randomized clinical trial: the APC-SAKK risk scores

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Background
The prognosis of advanced pancreatic cancer (APC) is poor and differs considerably among patients. Therefore, it is clinically relevant to identify patients with APC who are more likely to benefit from palliative chemotherapy with reduced risk of toxicity. To date, there is no prognostic score universally recommended to help clinicians in planning the therapeutic management.

Methods
Using individual patient data from 319 cases of APC treated with gemcitabine-based chemotherapy and enrolled in the SAKK 44/00-CECOG/PAN.1.3.001 randomized trial, several baseline variables, including inflammatory markers, were analysed as predictors of mortality and/or grade 3 or 4 chemotherapy-related toxicity and separate risk scores were developed.

Results
Median survival of the study patients was 7.9 months (interquartile range 3.7-13.3 months). Independent predictors of mortality included increased Aspartate transaminase (ASAT), low performance status, increased derived neutrophil to lymphocyte ratio, increased Carbohydrate Antigen 19-9 (CA 19-9), low haemoglobin, presence of pain, presence of metastasis and increased alkaline phosphatase (ALP). During the study, 117 patients experienced at least one grade 3 or 4 adverse event. Independent predictors of toxicity included white blood cells, ALP, renal function and bilirubin levels at baseline. Both models displayed moderate levels of discrimination (C-statistic 0.68 and 0.64 for mortality and toxicity, respectively) and adequate calibration.

Conclusions
We developed simple-to-use prognostic scores for mortality and severe toxicity for patients with APC. These scores can be useful in daily practice to identify
patients with increased risk of death or toxicity and to plan the most appropriate therapeutic strategy to improve survival and quality of life. Further prospective studies to validate such scores are needed.

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