measurements of tumour load, how to calculate a prognostic index from a few individual measurements.
Results: The proposed model shows characteristic non-linear patterns in tumour kinetics over time. It allows to quantify the individual tumour size kinetics based on baseline measurement and one or more time points of response evaluation. Specifically, the model allows predicting the nadir of tumour size reduction for individual patients. In contrast to a previous report by Piesseveaux et al. our model demonstrates statistically significant correlations of both, baseline and response parameters, with TTP and OS.
Conclusions: It is possible to set the findings of Piesseveaux et al in a general formal framework which allows formulating more predictive rules for different clinical outcomes based on early tumour kinetics for first-line patients with mCRC. However, in times of sequential chemotherapies a more elaborate data acquisition is needed especially with regard to second- or even third-line treatment. Further validation of mCRC studies with regard to the proposed model is planned.

6116 POSTER

Trends in Incidence, Treatment and Survival of Stage II T4 Colon Cancer Patients

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Background: Stage II T4 colon cancer patients are considered at high risk for recurrent or metastatic disease. Therefore, adjuvant chemotherapy (CT) should be considered, according to the Dutch clinical practice guideline.
Methods: All patients with stage II T4 colon cancer diagnosed in the Netherlands between 2000–2009 were included (n = 3065). Trends in the proportion of stage II patients with a T4 lesion over time was examined, as well as patient characteristics, adjuvant CT administration and number of examined lymph nodes. Furthermore, crude and multivariate survival analyses were performed.
Results: *Incidence*: The proportion of stage II colon cancer patients with a T4 lesion increased over time from 12% in 2000 to 14% in 2009 ($p = 0.012$), with large differences between geographic regions, ranging from 9% to 17% ($p < 0.0001$). T4 tumours were diagnosed more often in female than in male patients ($p < 0.0001$).
Treatment: Adjuvant CT was administered to 18% of T4 patients; 31% of those aged <75 years and 4% aged ⩾75 years. The proportion of T4 patients <75 years treated with adjuvant CT increased from 14% in 2000 to 42% in 2009, while for those aged ⩾75 years it increased from 1% to 10%. Besides, there was a large geographic variation in the proportion of T4 patients aged <75 years treated with adjuvant CT, ranging from 18% to 45% ($p < 0.0001$).
The proportion of T4 patients with ⩾10LNs examined increased from 28% in 2000 to 76% in 2009 ($p < 0.0001$).
Survival: Crude 5-year survival of T4 patients <75 years receiving adjuvant chemotherapy was 71%, compared to 56% for T4 patients not receiving adjuvant chemotherapy ($p < 0.0001$), while for patients aged ⩾75 this was 38% vs. 33% respectively ($p = 0.0124$).
Multivariable survival analysis showed that administration of adjuvant CT and male gender were positive prognostic factors for survival in T4 patients, in contrast to older age (⩾75 years) and <10LNs examined, with variation between geographic regions.
Conclusion: Adjuvant chemotherapy administration in colon cancer patients with a T4 lesion increased over time, but still only a minority of T4 patients received adjuvant chemotherapy. Adjuvant chemotherapy administration is an independent positive prognostic factor for survival in both age groups, which might be caused by selection of the fitter patients without comorbidity, which need to be further investigated. However, the effect of adjuvant chemotherapy remained after including comorbidity to the model in a subset of patients.
More attention should be given to the treatment of high risk stage II T4 patients.

6117 POSTER

Use of Adjuvant Chemotherapy in High-risk Stage II Colonic Cancer Patients in the Netherlands 2000–2009

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Background: A subgroup of stage II colon cancer patients are considered at high-risk for recurrent disease based on tumour obstruction or perforation, T4 lesion, <10 lymph nodes (<10LNs) examined, lymphangio-invasion or a poorly differentiated tumour. According to Dutch clinical guidelines these patients should be considered as comparable to stage III and therefore, adjuvant chemotherapy should be considered.
Methods: All patients diagnosed with primary colon cancer stage II from 2000 to 2009 in the Netherlands Cancer Registry were included (N = 23,124). The proportion of high-risk patients(based on T4 or <10LNs) receiving adjuvant chemotherapy(CT) was determined. Determinants of adjuvant CT administration and their impact on survival were determined. Variation between regions in adjuvant CT proportion was analyzed.
Results: In the period 2000–2009, 6% stage II colon cancer patients received adjuvant CT.
Patients aged ⩾75 years received adjuvant CT very rarely, (11% vs. 1%; $p < 0.0001$), while patients with a T4 lesion, <10LNs and patients diagnosed in a more recent period, received adjuvant CT more often. Furthermore, there was a large variation in adjuvant CT administration between geographic regions. Adjuvant CT administration increased in all (sub)groups of patients after introducing adjuvant CT for high-risk stage II colon cancer patients in the guideline in 2005.
Of the T4 patients (n = 3,064) 31% of those aged <75 years received adjuvant CT. Crude 5-year survival for patients receiving adjuvant CT was 71%, while this was 55% for those not receiving adjuvant CT ($p < 0.0001$). Multivariate survival analysis for patients with a T4 lesion showed that age ⩾75 years and <10LNs were negative prognostic factors, in contrast to adjuvant chemotherapy and male gender. Furthermore, survival differed by geographic region in patients with a pT4 lesion.
Of the patients with <10LNs (n = 10,264), just 12% aged <75 years received adjuvant CT.
Crude 5-year survival for patients with and without CT was 70% and 71% respectively ($p = 0.19$). Multivariate survival analysis for patients with <10LNs showed that age ⩾75 years and T4 stage were significant negative prognostic factors of survival, in contrast to adjuvant CT and male gender.
Conclusion: Just a minority of the high-risk stage II colonic cancer patients received adjuvant CT, with a large variation between geographic regions, despite the fact that adjuvant CT is generally known to improve survival in high-risk stage II patients.

6118 POSTER

Randomized Phase II Study of S-1, Oral Leucovorin, and Oxaliplatin Combination Therapy (SOL) Versus MFOLFOX6 in Patients With Untreated Metastatic Colorectal Cancer (mCRC)

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Background: FOLFOX is a standard first-line regimen for mCRC. Monotherapy with S-1, an oral fluoropyrimidine, showed a response rate of 37% for mCRC, and its combination with oxaliplatin (L-OHP) or oral leucovorin (LV) demonstrated response rated of 50%, 57%, respectively, and all six patients at the recommended dose in the phase I trial of S-1 plus LV plus L-OHP (SOL) showed PR. We conducted a randomized phase II trial to evaluate efficacy and safety of SOL compared with mFOLFOX6 as first-line treatment of mCRC.