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GERMANONCOLOGY.

Final analysis of patient-reported-outcomes (PRO) and early intervention to toxicities as tools for improving compliance of patients with metastatic colorectal cancer (mCRC) treated with aflibercept+FOLFIRI (A-FOLFIRI) under real-world-conditions in Germany

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Background

Modern oncological therapies of chemotherapy plus monclonal antibodies show very promising efficacy, but sometimes also a high rate of side effects, which end often in a permanent discontinuation. An addition of Aflibercept to FOLFIRI showed in 2°line of mCRC an advantage of 2.2 months in PFS and 1,4 months in OS with a median of 7 administered cycles and a median duration of treatment of 21 weeks, but in up to a quarter of patients toxicity-related or patient-triggered discontinuations were seen (1).

Rationale of study

The rationale of this study was to describe effects on treatment duration, compliance and the rate of permanent treatment discontinuations by using continious recordings of PRO and defined toxicities under the real-world-conditions of oncological practices in Germany.

Methods

The patients were treated with a standard protocol of A-FOLFIRI in several therapy lines.. The QoL and the VAS data were captured by a patient´s diary. In this diary also the mainly known toxicities of A-FOLFIRI (diarrhea, hypertension, fatigue, infections) with a high rate of permanent discontinuations in previous clinical trial were requested and constained with detailed instructions of handling for the patients.

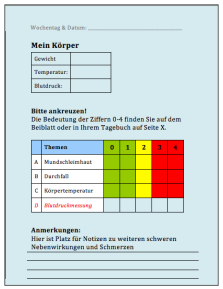
The patients with mCRC and an A-FOLFIRI treatment were assigned in 2 cohorts:

- **cohort 1**: standardized requests for PRO and toxicities
- **cohort 2**: no requests for RPO and toxicities.

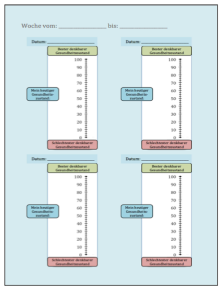
The assignments in the cohorts were based on decisions of the oncologists and consent of the patients for participation, whereas this participation in cohort 1 was voluntarily. The data were captured during the complete treatment of A-FOLFIRI and independently of the line of therapy.

Results

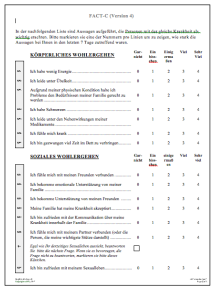
In cohort 1 used tools for QoL, VAS and toxicities:



Toxicity Tool based on CTC v4.0



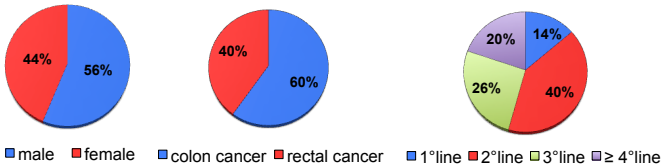
Visual analogue scale (VAS)



QoL based on FACT-C v4.0

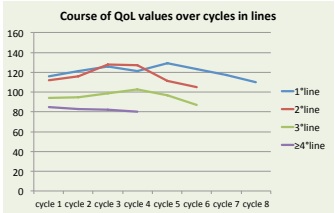
Base analyses:

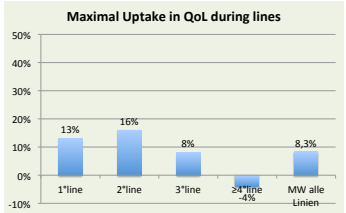
Between 01/2014 – 02/2016 n = 112 patients (56% male, 44% female, median age 71,8 years) with mCRC were treated with A-FOLFIRI in 18 oncological practices in Germany and data were sampled by eCRF and patient´s diaries. In cohort 1 (n=37 patients) got requests for QoL before start of every cycle and a diary for daily documentation of VAS and toxicities. In cohort 2 (n = 75 patients) patients were guided under standard practice of the oncologists. Over all data for QoL and VAS were available in 81% and 67%, respectively.



Analyses of QoL:

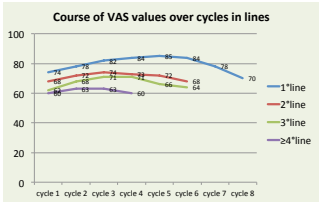
Over all lines the mean of uptake in QoL during the cycles in lines were 8,3% (range -4 to +16%) with a highest uptake in 2°line therapies.

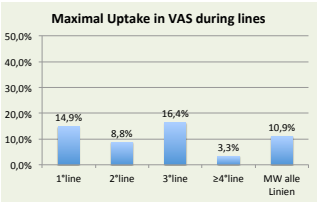




Analyses of VAS:

Over all lines the mean of uptake in QoL during the cycles in lines were 8,3% (range -4 to +16%) with a highest uptake in 2°line therapies.





Results of cohort's analyses:

	cohort 1 A-FOLFIRI with PRO	cohort 2 A-FOLFIRI without PRO
Number of patients	37	75
Number of patients in lines	1°= 5 / 2°= 15 / 3°= 6 / ≥4°= 9	1°= 9 / 2°= 27 / 3°= 22 / ≥4°= 17
Number of administered cycles (mean)	8,3	7,3
Duration of treatment (mean)	16,8	13,7
Dose reductions of A-FOLFIRI	17,3%	20,8%
Early discontinuations of A-FOLFIRI due to toxicity or patient´s wishes	13,1%	18,3%
Time-to-submission of toxicity from patient to oncologist	2,5 days	4,1 days

Conclusions

In this cohort study in patients with mCRC under A-FOLFIRI evaluations of PRO and early intervention to toxicities showed an enhancement of 1 cycle in the mean of administered numbers of cycles over all lines, a prolongation of duration of therapy of 3,1 weeks and a reduction of permanent discontinuations of 5,2%. The median time to submission of informations about defined toxicities to the oncologists could be accelerate from 4,1 to 2,5 days. An intensification of patient´s awareness and standardisation of informations about their performance could improve the compliance, reduce the rate of early discontinuations and prolong the duration of treatment with A-FOLFIRI. Such tools should be tested in a randomised trial with innovative telematic systems.

Literature

(1) Van Cutsem E et al: Addition of Aflibercept to Fluorouracil, Leucovorin, and Irinotecan Improves Survival in a Phase III Randomized Trial in Patients With Metastatic Colorectal Cancer Previously Treated With an Oxaliplatin-Based Regimen. J Clin Oncol 2012; 30:3499-3506.

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