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Medication safety in patients treated with oral antitumor agents: a prospective, randomised investigation to improve patient safety and well-being by intensified clinical pharmaceutical / pharmacological care (AMBORA)

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Background

During the last years, prescription rates of oral anticancer drugs increased rapidly. In contrast to an intravenous therapy patients profit from a higher convenience and flexibility.[1] On the other hand the independent drug intake at home requires a close patient guidance. To prevent treatment failure management of drug-drug or drug-food interactions, side effects, or non-adherence is essential. There is a growing need for an effective care concept for patients treated with oral antitumor agents. [2]

Aim and objectives

The aim of this study is to find out whether integrating a clinical pharmacist/ pharmacologist into an multiprofessional care team can improve patients' safety, knowledge and well-being.

Material and Methods

For this purpose, 200 patients will be randomized with a follow-up period of 12 weeks for each patient. Patients who start a treatment with a new oral anticancer drug are included regardless of the tumor entity. While the intervention group receives an intensive care program with 4 structured patient interviews and self-designed information material, the control group only receives routine clinical care. Patients in the intervention group additionally receive a structured side effect and medication management, where drug related problems (DRP) are discussed in an multiprofessional team. Primary outcome parameters are the number of drug related problems (medication errors and side effects) regarding the oral anticancer drug and patient satisfaction (TSQM questionnaire) after 12 weeks. A selection of further outcome parameters is shown in *Figure 1*.

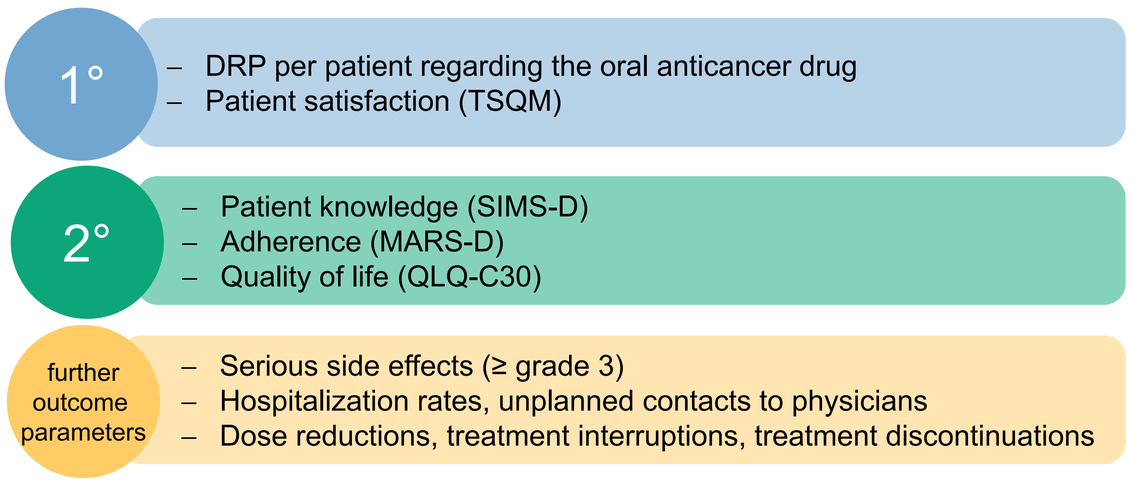

Fig. 1: Outcome parameters (selection)

Results

For this interim analysis, 100 patients were included (*Table 1*). The most frequently prescribed oral anticancer drugs until now were palbociclib and pazopanib (*Figure 2*).

Characteristics	Control (n = 54)	Intervention (n = 46)	Total (n = 100)
Age, median ± SD, years	66.8 ± 9.9	65.6 ± 12.7	66.2 ± 11.3
Gender (% female)	46.3	50.0	48.0
Number of active ingredients, median ± SD	8.3 ± 4.8	8.5 ± 3.5	8.4 ± 4.2

Tab. 1: Baseline demographic characteristics of the patients

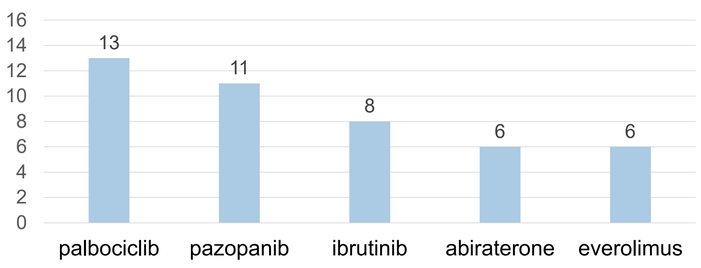

Fig. 2: Number of prescribed drugs (top 5)

Acknowledgements

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In the intervention group the number of drug related problems regarding the oral anticancer treatment was reduced (7.5 vs. 5.9 per patient; p=0.066; *Figure 3*) and patient satisfaction was significantly increased (79.1 vs. 94.1 p<0.001; *Figure 4*).

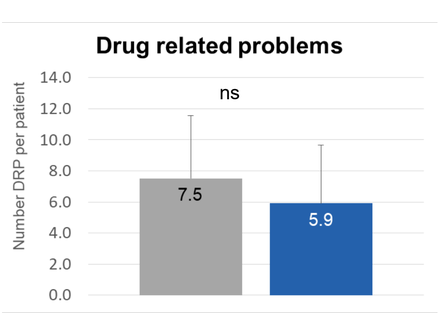

Fig. 3: DRP per patient

1°

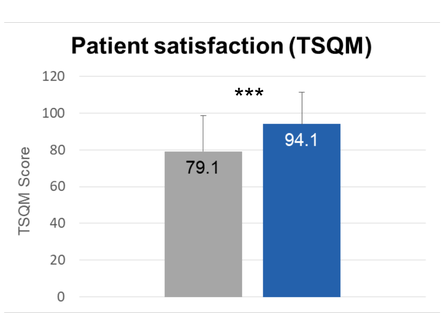

Fig. 4: TSQM-Score, category „Convenience" after 12 weeks

Patients in the intervention group suffered less from serious side effects (0.7 vs. 1.3 per patient; p=0.076; *Figure 5*), were less frequently admitted to a hospital and had less unplanned contacts to physicians (*Figures 6 and 7*).

further outcome parameters

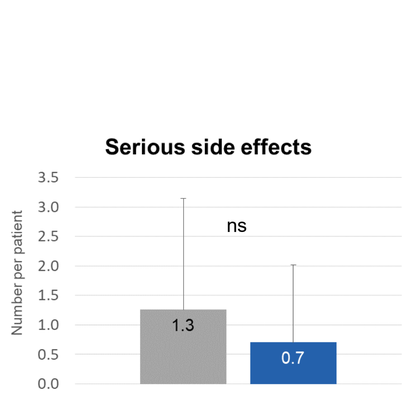

Fig. 5: Side effects ≥ grade 3 per patient

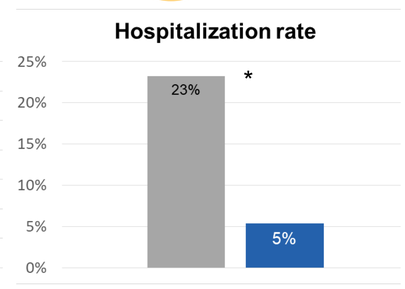

Fig. 6: Hospitalization rate per group

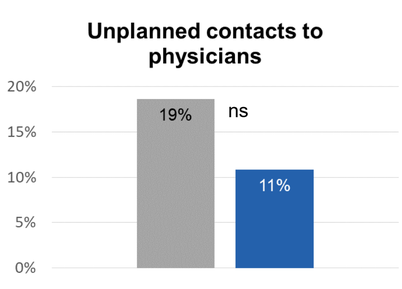

Fig. 7: Rate of unplanned contacts to physicians per group

Dose reductions, treatment interruptions and discontinuations due to toxicity were less frequently necessary in the intensive care group (*Figures 8 – 10*).

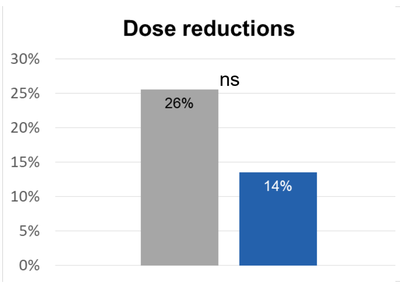

Fig. 8: Dose reductions per group

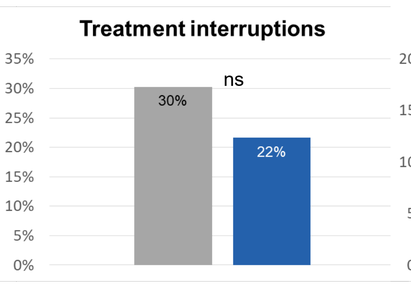

Fig. 9: Treatment interruptions per group

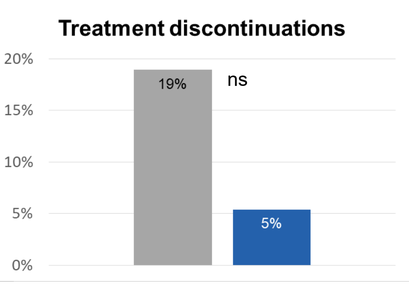

Abb. 10: Treatment discontinuations per group

ns: statistically not significant; *: p<0.05; **: p<0.01; ***: p<0.001; Control group; Intervention group

Conclusion and relevance

The high rate of drug related problems in this patient population indicates that cancer patients treated with oral anticancer drugs must be considered as a high-risk patient group. The results of this interim analysis indicates that an early intervention can reduce serious side effects and increases patients' satisfaction. The integration of a clinical pharmacist/clinical pharmacologist in a multiprofessional care team increases medication safety in patients treated with new oral anticancer drugs.

References

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Update 2021:
In the meantime the AMBORA study has been completed. A total of 202 patients were included. Outcomes shown in this interim analysis were confirmed with the final data analysis. The results of the AMBORA study are accepted for publication in J Clin Oncol.[3]

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