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Trans sectoral care of geriatric cancer patients based on comprehensive geriatric assessment and patient-reported quality of life - Results of a multicenter study to develop and pilot test a patient-centered interdisciplinary care concept for geriatric oncology patients (PIVOG)

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#### ABSTRACT

Objectives: For older patients with cancer the maintenance of independence, functionality and health-related quality of life (HRQOL) is of great importance. Aiming to maintain HRQOL of older patients with cancer we developed an interdisciplinary care program based on comprehensive geriatric assessment (CGA) and patient-reported HRQOL comprising tailored supportive measures and telephone-based counseling during 6 month aftercare. *Materials and Methods*: Pilot-testing of the intervention took place in three centers at the University Hospital Halle to examine feasibility, acceptance and potential benefit. Patients ≥ 70 years with confirmed diagnosis of cancer, at least one comorbidity and/or one functional impairment, receiving curative or palliative care were eligible. Primary endpoint was global HRQOL (EORTC QLQ C30).

Results: Mean age of the participants (n=100) was 76.3 years (SD 4.8), 47% were female. On average they had 5 comorbidities (SD 2.8, min. 0, max. 15) and took 8 prescribed medications (SD 3.6, min. 0, max. 15). According to predefined treatment pathways, supportive care was triggered by summarized individual assessments that were presented to the treating physicians. Descriptive analyses showed that global HRQOL measured at the 6-month follow-up (n=57) had declined ( $\geq 10$  points) for n=16 (28%) and improved or remained unchanged for n=41 (72%) patients, although some functional scales (e.g. mobility, role function) and some symptoms (e.g. fatigue, pain) had worsened. The nurse-led telephone-based aftercare was well accepted.

Conclusion: The results show feasibility and potential benefit of the combination of CGA and HRQOL to complement standard assessments. Patient-reported symptoms and functioning indicate the need for intensified supportive therapy during aftercare.

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#### 1. Introduction

Cancer, although occurring in all ages, affects more often older people. For older patients with cancer the maintenance of autonomy, functionality and health-related quality of life (HRQOL) is of great importance. Oncologic therapy and aftercare however are often complicated by the heterogeneity of this population with respect to the biological age, number and severity of comorbidities, physical reserve and functioning. Therefore careful planning of oncologic therapy and aftercare under

consideration of the patients' individual risk factors and values is required [1]. Because frail patients are at a higher risk of adverse surgical outcomes, poor treatment tolerance and reduced HRQOL [2], the assessment of frailty is strongly recommended [3]. For clinical practice a comprehensive geriatric assessment (CGA) is recommended in order to detect risk factors like frailty and to guide treatment decisions [4–6]. The CGA comprises systematic assessments of the domains of physical functioning, mobility and falls, cognitive function and mood, nutritional status and social support. The benefit of the CGA to predict mortality and treatment toxicity [7–9] and to support physicians' decisions [10, 11] has been shown. The CGA results should be followed by targeted interventions [6,12,13] and supportive interdisciplinary care [14,15]. As sensitivity and specificity of short screening methods to decide which

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patients could benefit from a comprehensive assessment and predict the outcome of a comprehensive geriatric assessment so far are not satisfactory, it is recommended to refer all patients aged 70 and over for a comprehensive geriatric assessment [5,16]. However, CGA is still not part of clinical routine in most countries. Neither has the assessment of patient-reported outcomes (PROs), e.g. HRQOL, been integrated in clinical practice although broad evidence exists that patients benefit from PRO assessments in clinical routine [17]. In addition HRQOL can deteriorate and the burden of disease can increase after acute care [17–19] indicating the need for trans-sectoral care. Therefore, with the overall purpose of maintaining health-related quality of life (HRQOL) and functioning of older patients with cancer, we developed and pilot-tested a multicomponent intervention comprising CGA, assessment of HRQOL and telephone-based nurse-led aftercare in order to facilitate trans-sectoral supportive care [15].

#### 2. Materials and Methods

According to the Medical Research Council Guidance [20] we chose a two-step approach to develop and pilot test the multicomponent intervention.

#### 2.1. Development of the Multicomponent Intervention

Aiming to compare clinical procedures of the study centers with recommendations for CGA, representative medical records of oncologic cancer patients over 70 years old and with geriatric comorbidities were analyzed until data saturation was reached.

All components of the intervention including the selection of assessment instruments, definition of cut-off values, categorization of individual results and suggested treatment pathways were based on available evidence and discussed and consented with the members of the scientific advisory board.

Assessments were selected to meet two requirements: First to obtain a comprehensive picture of individual risk factors and resources of all the patients and second to judge the potential clinical benefit of the additional information in comparison to standard assessments and examinations by physicians and nurses.

All individual results of the assessments were categorized using a traffic light system. According to the available evidence, categories were defined indicating green as a "normal" result within the cut-off range, yellow as a conspicuous result and red symbolizing a major problem or pathologic finding (e.g. timed up and go test (TUG)  $\leq$  10 s: green; 11–19 s: yellow and  $\geq$  19 s: red). Aiming to facilitate the utilization of the assessments in clinical routine, templates for the compilation of individual results were designed showing all assessments and the respective domains. If any of the assessments were categorized as red, the whole domain was marked red, to alert the physician.

Using a case-based approach, treatment pathways for diagnostic or supportive measures and referral were defined.

The telephone-based nurse-led aftercare (TBA) was specified including a patient-held diary and a handbook for the oncology nurses carrying out the aftercare serving as training material and easy reference. The handbook covered short descriptions of relevant symptoms with guidelines for assessment questions and measures to improve symptom management. For potentially dangerous conditions referral guidelines for medical treatment were defined.

Prior to the pilot-testing, all the health care professionals involved were trained to deliver the intervention. Physicians and nurses of the participating centers underwent a basic training with respect to the domains of the CGA and HRQOL, the assessment instruments used, relevance and interpretation of individual results and recommended treatment pathways. The assessments and the aftercare were carried out by study nurses, who were provided with additional training including theoretical aspects of the assessments, relevant symptoms and appropriate counseling and interactive practical training. The interactive

training included face-to-face and telephone-based communication with patients. Supervision was provided.

#### 2.2. Intervention

2.2.1. Initial Assessments in Addition to Routine Assessments and Examinations

Cumulative Illness Rating Scale (CIRS) [21]; handgrip strength [22], chair-rise test [23], timed up and go [24], 6 min walking test [25,26], four step balance test [27], mobility-related contextual factors (barriers and facilitators), Nutritional Risk Screening (NRS) [28], Mini-Mental State Examination (MMSE) [29], Patient Health Questionnaire (PHQ9) [30], Social Situation Subscale 1 [31] and HRQOL (EORTC QLQ-C30 [32], EORTC QLQ-ELD14 [33]).

The BRASS index to calculate post-discharge supportive needs [34], activities of daily living (ADL) and instrumental activities of daily living (IADL) being already part of the standard nursing assessment were complemented by questions as to whether help would be available if needed.

A geriatrician conducted a medication review of the prescribed drugs with respect to polypharmacy and potentially inadequate medication including face-to-face consultations if necessary. During the decision-making process patients were asked about their priorities concerning the treatment.

A trained oncology nurse (ON), in the position of a study nurse and not belonging to the regular staff, conducted the assessments in cooperation with a physiotherapist. All individual results (assessments and PRO) were summarized and allocated to domains of risk factors (nutrition, mobility, mood/depression, cognition and self-care). The ON was responsible to compile and communicate the individual results and to alert the regular staff to any relevant results (e.g. red markings). Diagnostic or supportive measures e.g. dietary or social counseling, physiotherapy or psychoncology were initiated according to the predefined treatment pathways.

#### 2.2.2. Telephone-based Nurse-led Aftercare (TBA)

Before discharge the ON introduced the TBA schedule (13 calls in 20 weeks; weekly calls during the first 8 weeks), the patient diary and the call-in option in case problems occurred between the scheduled calls. The ON made sure that the patient knew who to turn to for prescriptions and in the case of emergency. The patient diary aimed to aid early detection of supportive needs and medical issues. It comprised open questions and single items of EORTC questionnaires, focused on symptoms, daily functioning and HRQOL and templates to monitor pain, fatigue, mucositis and nutrition if indicated. The ON instructed patients on self-assessment and self-management and initiated medical supportive measures if necessary.

#### 2.3. Pilot Testing

The aim of the pilot testing was to test the feasibility and the acceptance of the developed intervention in different settings and for different groups of older patients with cancer. Pilot testing was conducted without control group and aimed to explore the feasibility of the intervention and to determine the need for modification of the intervention before implementation in a main controlled study.

#### 2.3.1. Sample Size

Due to the approximate number of older patients with cancer being treated in the participating centers, the duration of the project and the available resources, a convenience sample of n=100 patients was regarded sufficient for feasibility testing and to provide information on the outcomes for sample size calculations of future controlled studies.

The intervention was pilot-tested at three centers of the university hospital Halle/Saale (Department of Hematology/Oncology, Department of Radiotherapy, Department of Dermatology) to examine feasibility, acceptance and potential benefit considering a broad spectrum of patients' conditions and clinical routines.

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