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Integrative cancer care in a certified Cancer Centre of a German Anthroposophic hospital

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ABSTRACT

Objective: The concept of integrative oncology (IO) comprising guideline-oriented standard and add-on complementary medicine has gained growing importance. The Anthroposophic-integrative Cancer Centre (CC) at the hospital Gemeinschaftskrankenhaus (GKH) in Berlin has been implementing IO concepts during recent years. Furthermore, it is a certified CC and has been annually audited by national cancer authorities since 2012. The objective of the present study was to evaluate IO concepts of the certified CC GKH.

Methods: Clinical, demographic, integrative treatment and follow-up data were analyzed between 2011 and 2016. In addition, CC GKH quality measures were compared with those of nationwide benchmarking CCs.

Results: Between 2011 and 2016, 2,382 primary cancer patients, median age 66 years, were treated at the CC GKH. 70.1% of the patients showed either Union for International Cancer Control (UICC) stage 0, I, II or III and 25.6% were in UICC stage IV. IO therapies included surgery (64.4% of patients), radiation (41.2%), and application of cytostatic drugs (53.9%), add-on mistletoe therapy (30.5%), and non-pharmacological interventions (87.3%). Regarding psycho-oncological support and quota of patient's enrollment in studies the CC GKH performs above nationwide benchmarks. Research outcomes including safety issues, clinical impact as well as patient's health-related quality of life are continuously evaluated and integrated into hospital's decision-management.

Conclusion: This analysis reveals that IO concepts are applied to a high proportion of male and female primary cancer patients of all age groups, indicating a successful implementation at the certified CC GKH. Ongoing clinical evaluations have been initiated and cost-effectiveness comparisons are under analyses.

1. Introduction

Improved survival of European oncological patients being assessed between 1999 and 2007 by the EURO CARE-5 study¹ as a result of improved cancer management caused the European Commission to call for ensuring evidence-based guidelines and accessibility to high-quality

and specialized Cancer Centres throughout Europe.² In 2008 the German “National Cancer Plan” (NCP) has been initiated³ by the German Ministry of Health to further develop key fields of actions such as cancer screening, extension of health-care structures in oncology and quality assurance, securing efficient oncological treatment and strengthening of patient orientation.³ During the optimization of the

Abbreviations: CC, Cancer centre; CTx, chemotherapy; HRQL, health-related quality of life; IO, integrative oncology; IQR, interquartile range; NPI, non-pharmacological interventions; UICC, TNM staging according to Union for International Cancer Control; VA, Viscum album L.

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NCP and cancer treatment a three-step model of oncological care was developed indicating Organ Cancer Centres (C), Cancer Centres (CC) and Comprehensive Cancer Centres (CCC). Certified Centres have to verify their professional and technical competence during annual audits and have to demonstrate an established quality management system. CCs are specialized departments with guideline-oriented high standard procedures that roof at least three organ specific centres demanding a wide spread of structural and professional expertise.^{3–5}

To manage the physical, emotional, social and spiritual impact of a cancer diagnosis, people often seek a number of anti-cancer concepts beyond guideline-oriented treatment.^{6–9} In recent years, the field of integrative oncology (IO) has gained emerging impact as a linkage of conventional and evidence-based complementary medicine therapies.^{7,10} Based on a systematic North-American and European consensus approach, IO has recently been defined as a “...*patient-centered, evidence-informed field of cancer care that utilizes mind and body practices, natural products, and/or lifestyle modifications from different traditions alongside conventional cancer treatments. IO aims to optimize health, quality of life, and clinical outcomes across the cancer care continuum and to empower people to prevent cancer and become active participants before, during, and beyond cancer treatment...*” [11]. IO’s impact on health related quality of life (HRQL) has already been acknowledged worldwide and implemented in several academic and medical oncological institutions^{11–15} and international treatment-based guidelines for IO have been defined in the last three years.^{16–18}

The CC GKH contributes fully to the framework of the NCP and additionally applies integrative therapies within a patient-centered context to oncological patients. It comprises the certified Breast Cancer Centre (BCC, certified since 2012), the certified Colorectal Cancer Centre (CRCC, certified since 2013) and the certified Lung Cancer Centre (LCC, certified since 2017). In the present study we descriptively evaluated how implemented IO concepts are applied to primary cancer patients in our CC by mainly evaluating applied standard and add-on complementary cancer therapies. First comparisons of quality measures and outcome items between the CC GKH and nationwide benchmarking CCs are shown.

2. Material & methods

2.1. Data source and assessment

Patients who were 18 years or older, who gave written consent, with a primary diagnosis of all-stage breast, colorectal or lung cancer seen between January 2011 and December 2016 at the certified CC GKH, Berlin, Germany were included.

Data source and assessment were performed as recently indicated¹⁹ and shortly described hereafter. Demographic data as well as information on diagnosis, histology, surgery and previous treatment regimen were retrieved from the Network Oncology (NO) registry. NO is an accredited clinical registry of hospitals and out-patient practitioners specialized in Anthroposophic-integrative oncology.²³ Retrieved data included application procedures of multimodal integrative therapies consisting of a combination of guideline-orientated conventional oncological care and add-on complementary therapy. Documented TNM stages or metastases were queried with their according date and translated into Union for International Cancer Control (UICC) stages according to the 7th edition of TNM Classification of Malignant tumours.²⁰ The disease stage was described according to UICC staging. Conventional therapies including chemotherapy, surgery or radiation were queried with their according date. Applied pharmaceuticals of systemic therapies including chemotherapy, targeted therapy and mistletoe (*Viscum album* L. = VA) therapy were documented. Targeted therapy included monoclonal antibody therapy (e.g. bevacizumab, trastuzumab, rituximab etc.), tyrosine kinase inhibitors (e.g. imatinib, gefitinib, erlotinib, etc.) and immune checkpoint inhibitor therapies (e.g. nivolumab, pembrolizumab etc.). Detailed information on the

amount and type of add-on non-pharmacological interventions (NPI) per patient was obtained. Complementary add-on therapies listed on a structured weekly plan were handed out to the patient according to the CC GKH manual.¹⁹ Numbers of patients that were followed-up were retrieved from the surveillance and study centre. Follow-up was performed during the first year three (CRCC) and six months (BCC, CRCC, LCC) after first diagnosis and annually during the next four years. During follow-up, consenting patients were asked for their self-rated HRQL. Continuous variables were described as median with inter-quartile range (IQR) and categorical variables were summarized as frequencies and percentages. Chisquare analysis was performed to detect differences in IO application between BCC, CRCC and LCC (software R, Version 3.3.0). Central structures and standardized processes of the CC GKH are documented and annually updated in the quality management manual (“Handbuch Onkologisches Zentrum Havelhöhe”, last version: June 2017) and have already been described.¹⁹

2.2. Ethics

The study complies with the principles laid down in the Declaration of Helsinki. This study is an observational study of the NO registry study which has been approved by the ethical committee of the Medical Association Berlin (Berlin – Ethik-Kommission der Ärztekammer Berlin). The reference number is Eth-27/10. Written informed consent has been obtained from all patients prior study enrollment. The study has been registered at the WHO approved register German Register for Clinical Trials (Deutsches Register Klinischer Studien, DRKS), trial registration number DRKS00013335.

2.3. Comparison with nationwide benchmark centres

Median number of primary cancer patients was assessed for the total time period since the year of first certification of the respective Organ Cancer Centre. The median patient numbers of each certified Organ Cancer Centre of the CC GKH were compared to data of the nationwide annual benchmarking report 2017 (“*Jahresbericht 2017 der zertifizierten Onkologischen Zentren*”) covering quality measures from 97 certified nationwide CCs at 113 different sites in Germany.²¹ The quota is set each year by the DKG and DKH and is made publicly available.²¹ Descriptive analysis has been used to perform comparison between the CC GKH and benchmarking CCs.

3. Results

2.382 primary cancer patients were treated at the CC GKH between January, 1st 2011 and December, 31st 2016 (Table 1). The median age was 66.0 years (IQR = 56.0–74.0). The age distribution with regard to tumour entity differed with the highest proportion of breast cancer patients receiving their first diagnosis between 50 and 59 years while patients with lung (26.8%) or colorectal cancer (33.2%) were mainly between 70 and 79 years (Fig. 1). 51% of the patients showed early stage cancer (UICC stage 0-II), 22.3% UICC stage III and 25.6% metastasized (UICC stage IV) cancer at first diagnosis. Breast cancer represented the cancer entity with the largest proportion of stage I – stage III cancers while colorectal and lung cancer had the largest proportion of stage IV cancers (see Fig. 2). Among the total of 2.382 patients the proportion of the lung cancer patients was the largest (43.7%) followed by breast cancer (33.7%) and colorectal cancer (16.8%).

With regard to anti-cancer therapies, in 1.535 of 2.382 patients (64.4%) cancer-related surgery was applied, 982 patients (41.2%) received radiation, and 1.283 patients (53.9%) received cytostatic drugs, see Table 2. Minimal-invasive surgery has been constantly increasing compared to the rate of open surgery, see Fig. 3. Guideline-oriented follow-up was performed in 82% of all primary cancer patients during the past two to four years, i.e. 81.7% in the CRCC and 83.1% BCC (data not shown).

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