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Title: The role of geriatric assessment prior to chemotherapy in elderly patients with cancer

Issue Date: 2015-11-17

Chapter

Introduction

1



Introduction

Background

The care of elderly patients is a challenging task. Clinicians have to make difficult decisions influencing and causing disability, which may have major impacts on the quality of life and functioning. It is therefore important for the clinician to use a multidimensional approach, which takes into account aspects of social, mental, and physical health when taking care of elderly patients. The process of aging is associated with loss of functional reserve of multiple organ systems, increased prevalence of chronic diseases and enhanced susceptibility to stress. This process occurs at different ages, resulting in a large variance in phenotype of elderly persons with a certain biological age. The concept of frailty as a state of increased vulnerability to adverse outcomes may be a more valuable entity [1].

One third up to one half of the patients with cancer older than 70 years of age can be qualified as frail [2]. The increasing prevalence of cancer in the elderly, together with the process of aging, results in a large heterogeneity within the group of elderly patients with cancer. Geriatric assessment (GA) may be a useful tool in the management and follow-up of elderly patients with cancer. A GA provides the combined objective and subjective information on comorbidity, nutrition, cognition, functional and psychosocial status [3, 4]. In elderly patients, cancer treatments should be adjusted to life expectancy and the expected increased risk of toxicity aiming for optimal efficacy, acceptable toxicity and the highest attainable quality of life.

There is a paucity of data in the literature concerning treatment strategies of patients with cancer older than 70 years of age. They are often not mentioned in guidelines or state of the art reviews and not in relation to existing comorbidities and limited life expectancy [5-7]. Due to age restrictions elderly patients are often excluded from trial participation and therefore, clinical recommendations are frequently not evidence based [8]. In general, findings from studies in patients with cancer cannot be extrapolated to elderly patients. For example, the prediction of recurrences of breast cancer by the Adjuvant! program proved to be unreliable in patients older than 65 years of age [9]. In other words, it is largely unclear what the predictors are for the outcome of treatment in the older patient group. Moreover, systematic data on toxicity of chemotherapy are limited in elderly patients [10], although some progress has been made in recent

years [11, 12]. It is of great importance to collect and analyze more data on the various forms of treatment of the elderly group of patients with cancer. Although a survival benefit of chemotherapy of the elderly with lymphoma has been demonstrated [13], this is less clear for elderly patients with a variety of solid tumors. It is likely that the use of standard chemotherapy in the elderly –developed and tested in patients with cancer of younger age groups– may contribute to substantial toxicity and consequently excess number of deaths. In this elderly group there is a need for better predictors to select those patients who are likely to benefit from standard chemotherapy [14, 15].

The above mentioned multidimensional approach of the elderly patient with cancer is at present often executed by performing a comprehensive geriatric assessment (CGA). A CGA should be helpful to determine a coordinated and integrated plan for treatment and long-term follow-up of the elderly patient with cancer [4]. Research on the different characteristics of the elderly patient with cancer and the predictive value of a CGA, both for the feasibility of treatment with chemotherapy and the overall survival, forms the basis of this thesis.

Epidemiology

The older population is an important and fast growing segment in the Western world [16, 17]. The incidence and mortality of patients with cancer increases with age. Worldwide, cancer accounted for 8.2 million deaths in 2012. The most commonly diagnosed malignancies were lung (i.e., 1.82 million), breast (i.e., 1.67 million), and colorectal tumors (i.e., 1.36 million) [18]. Projections show that these numbers will increase strongly in the following years rising to more than 13 million worldwide in 2030 [19].

In the Netherlands, the proportion of elderly persons among the total population aged 70 years and over will rise for men from 10% in 2015 to 19% in 2045 and for women from 13% in 2015 to 22% in 2045 (figure 1). This age influence will become stronger by the improved life expectancy of the elderly due to improvement of healthcare and living conditions.

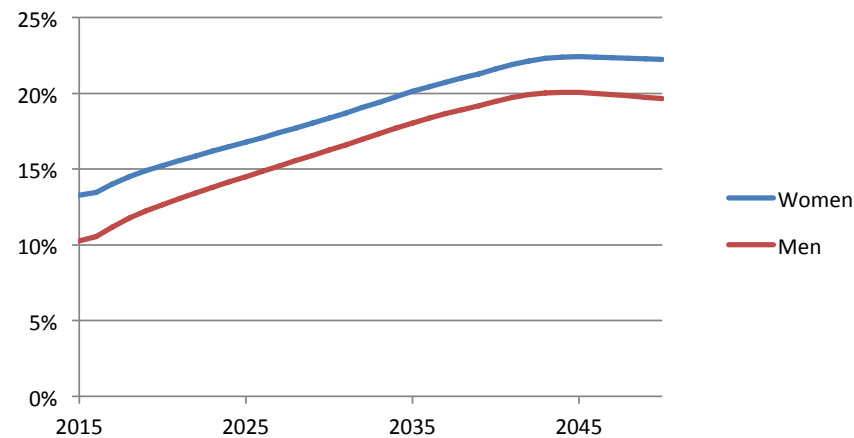
Advancing age is a high risk factor for cancer. Figure 2 shows the incidence of all cancers and specifically non-Hodgkin lymphoma, breast- and colon cancer in the Netherlands in 2013 [20]. In the Western world and also in the Netherlands, more than 2-3 times as many of the invasive cancers occurred in patients aged 70 years and older. More than forty percent of all new patients were between 60 and 75 years old of age, while thirty percent were 75 years or older [20, 21].

Results of the population-based EUROCare-5 study of cancer survival in Europe show improving rates in cancer survival. Five-year survival rates were higher for patients diagnosed between 2005 and 2007 than for patients diagnosed between 1999 and 2001. The increase in relative survival was over 5% for patients with rectal cancer, prostate cancer, and non-Hodgkin lymphoma [22].

Projections for the year 2015 show increasing survival for lung-, colorectal-, prostate-, stomach cancer and leukemia in men, and for breast-, colorectal-, uterus-, stomach cancer and leukemia in women. However, the lung cancer death rate in women is rising sharply and expected to take over the breast cancer death rate soon. Pancreatic cancer shows a slowly rising death rate in both sexes between 2009 and 2015 [23].

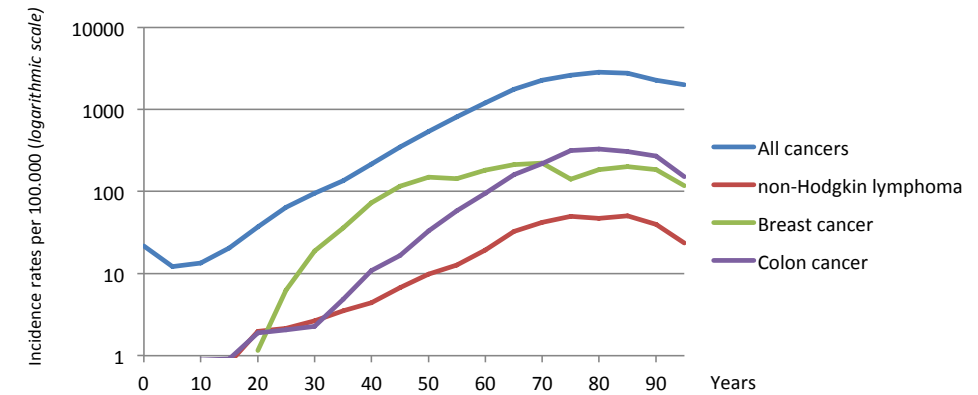
The rising incidence and prevalence of cancer with increasing age, in combination with increasing comorbidities, functional-, mental- en social shortcomings specific for older age, will complicate the care for elderly patients and will require special expertise in both oncology and geriatrics by physicians and other caregivers.

Figure 1. Projection of the expected proportions of men and women aged 70 years and over relative to the whole population until 2050.



CBS 2014

Figure 2. The incidence rate of cancer per 100.000 subjects per year (crude rate, CR) of all cancers, non-Hodgkin lymphoma, breast- and colon cancer in the Netherlands in 2013



The comprehensive geriatric assessment

CGA in the general population.

The health status of the elderly is compromised by unknown disabilities and unreported needs, as such reported in the literature for the first time in 1964 [24]. The need for geriatric assessments in a geriatric unit was recognized and described in 1987. In this way, a (C)GA has been developed as a tool to find deficits and define frailty in elderly patients in order to create a tailor-made treatment- and intervention plan [25]. A meta-analysis of trials with CGA showed a larger likelihood to live at home and improved survival through the application of CGA [26]. A controlled trial on the effects of intervention programs with geriatric expertise and management did not show advantage in survival, but demonstrated mental and physical improvement of functions [27]. Other studies demonstrated the usefulness of the application of frailty criteria to guide interventions in health care of the elderly patient [28-30].

Comprehensive geriatric assessment in patients with cancer and the application of screening tools.

Elderly with cancer form a heterogeneous group of patients. Chronological age as an indicator for health risks can differ significantly from biological or functional age. CGA can be used to systematically assess medical, functional, cognitive, social, nutritional and psychological parameters in older people with cancer [31-33].

38]. There is, however, much controversy about which elements should be part of the CGA and there is a great overlap of the different domains between the assessments and screening tools. To conduct a full CGA is time consuming and probably not necessary for every older patient. Therefore, a two-step approach by using a brief assessment or screening tool has been developed to identify patients who need a full CGA [39-41]. However, it must be realized that currently used screening tools lack adequate sensitivity, specificity and sufficient discriminative power to replace the full CGA [40, 41]. Recently, the International Society of Geriatric Oncology (SIOG) updated recommendations on geriatric assessment (GA) in elderly patients with cancer [4]. The panel recommended that the following domains should be evaluated in a GA: functional status, comorbidity, cognition, mental health status, fatigue, social status and support, nutrition, polypharmacy and presence of geriatric syndromes.

Functional status includes person’s ability to perform tasks of everyday living, such as eating, bathing, dressing, toileting, transferring, using a telephone, doing laundry, and handling finances. This may be measured by the Activities of Daily Living (ADL) [42], the Instrumental Activities of Daily Living scale (IADL) [43] and the Eastern Cooperative Oncology Group Performance Status (ECOG PS) [44]. Mobility can be measured by the Get Up and Go test (GUG) [45] and muscle function by the Handgrip strength test (HGS) [46].

Mental status assessment includes cognition and mood and can be measured by the Mini-Mental State Examination (MMSE) [47], the Geriatric Depression Scale (GDS) [48], the Hospital Anxiety and Depression scale (HADS) [49] and the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) [50].

Physical status assessment includes the number of prescribed drugs and comorbidity; the latter may be measured by the Charlson comorbidity index (CCMI) [51] and The Cumulative Illness Rating Scale for Geriatrics (CIRS-G) [52]. The nutritional status can be measured by the Mini Nutritional Assessment (MNA) [53].

The different domains form a part of and are measured by screening tools. The most frequently used tools are the Vulnerable Elders Survey (VES-13) [2, 54], the abbreviated CGA [55], the Flemish version of the Triage Risk Screening Tool (fTRST) [56, 57], the Groningen Frailty Indicator (GFI) [58] and the Geriatric 8 (G8) [57, 59-61].

Different assessments and screening tools

Assessment tools	Geriatric domain	A/S	Scale	Interpretation
ADL ^[42]	Functional status	A	-	Measures limitations in self care activities
IADL ^[43]	Functional status	A	-	Measures ability to complete activities required to maintain independence in the community
ECOG PS ^[44]	Functional status	A	0-5	Higher scores indicate poorer performance (i.e., functional impairment)
GUG ^[45]	Functional status	A	1-5	Higher scores indicate a higher level of abnormalities of gait, balance or difficulty by stand up from a chair, walk a short distance, turn around, return, and sit down again.
HGS ^[46]	Functional status	A	Grip strength in kg	Measurement of muscle function
MMSE ^[47]	Cognitive function	A	0-30	≤ 23 indicates cognitive dysfunction
IQCODE ^[50]	Cognitive function	A	1-5	≥ 3.31 indicates cognitive decline over past ten years
GDS ^[48]	Mental status	A	0-30	Measurement of severity of depressive symptoms
HADS ^[49]	Mental status	A	0-21 for anxiety or depression	≥ 8 indicates anxiety or depression
CCMI ^[51]	Comorbidity	A	-	Classification of comorbidity
CIRS-G ^[52]	Comorbidity	A	0-4 per item	Evaluates cumulative comorbidity in 14 items
MNA ^[53]	Nutritional status	A	0-14 (Screening) 0-16 (Assessment)	< 17 pts indicates malnourishment 17-23.5 pts indicates a risk of malnutrition
VES-13 ^[54]	Frailty	S	0-13	A score ≥ 3 indicates vulnerability
aCGA ^[55]	Frailty	S	-	≥ 1 among a total of 15 items of GA (3 of ADL, 4 of IADL, 4 of MMSE and 4 items of GDS) indicates increased geriatric risk
fTRST ^[56]	Frailty	S	1-6	Higher score indicates an increased geriatric risk profile
GFI ^[58]	Frailty	S	0-15	≥ 4 indicates frailty
Geriatric 8 (G8) ^[61]	Frailty	S	0-17	≤ 14 indicates an increased geriatric risk

Abbreviations: A/S, Assessment/Screening

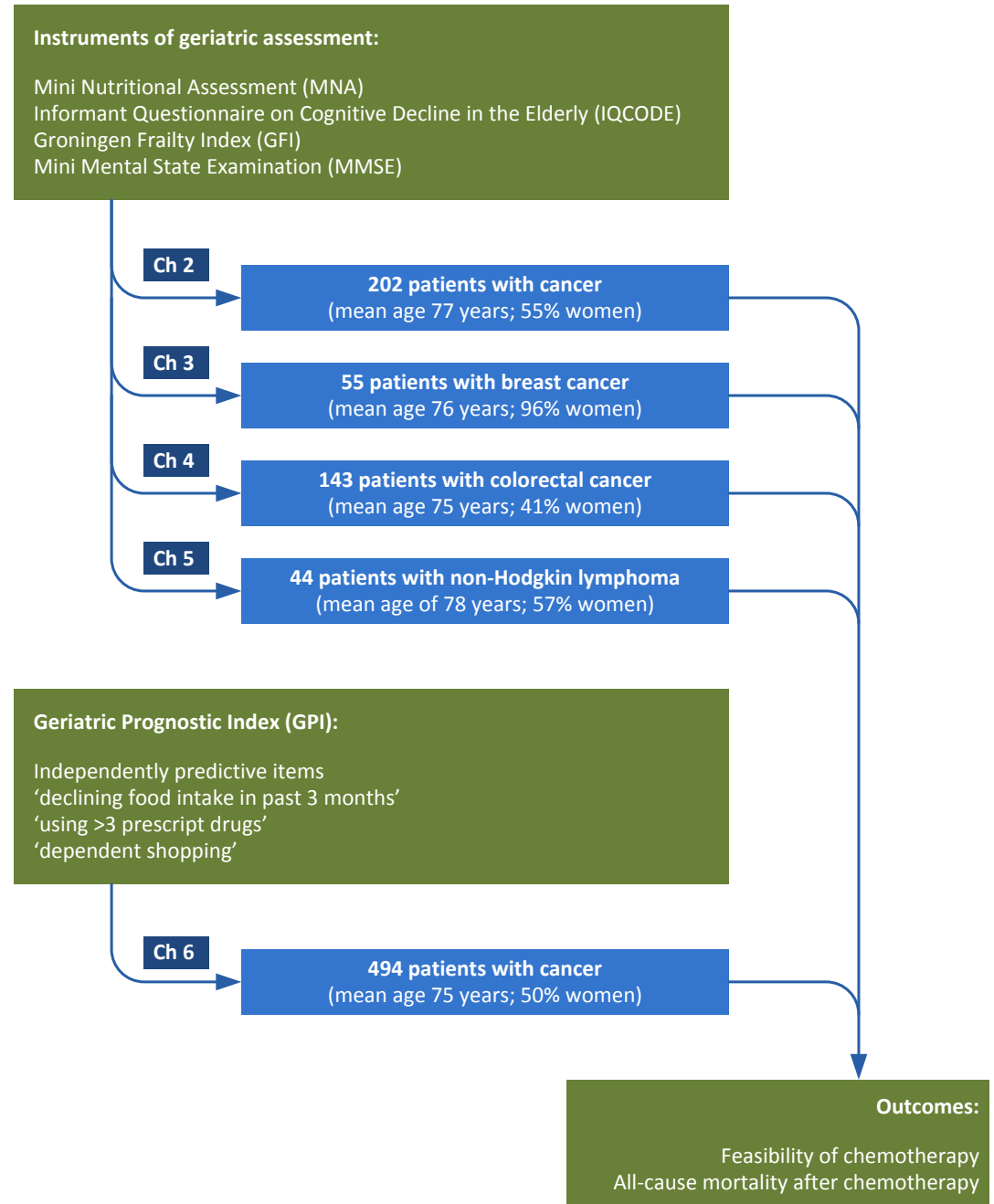
Aim and outline of the thesis

Comprehensive Geriatric Assessment in a broad sense is time consuming and expensive. Therefore, it was decided to concentrate on a limited dataset that comprised items of nutrition, comorbidity, functional status, psychosocial status, cognition, and laboratory values. The following questionnaires and tests were considered appropriate to obtain a practical GA: MNA, GFI, IQCODE, MMSE, and laboratory values of albumin, creatinine, lactate dehydrogenase and hemoglobin. If shortcomings occurred with the questionnaires a geriatrician and/or dietician could be consulted.

The main questions we tried to answer were firstly to assess the predictive value prior to the start of chemotherapy of the chosen GA with respect to the probability to complete the planned chemotherapy and overall survival and secondly to analyze and determine which elements of the chosen GA were independently predictive to complete chemotherapy and which elements predicted early mortality.

A first analysis of the role of GA in 202 patients with a variety of cancers, all of them treated in the Reinier de Graaf Hospital in Delft, is described in **Chapter 2**. Tumor-specific analyses are presented in **Chapters 3 through 5**. **Chapter 3** provides details on 55 patients with breast cancer. Analyses have been performed of the results of GA and laboratory tests for albumin, hemoglobin, creatinine and lactate dehydrogenase in relation to the outcome of palliative therapy with chemotherapy. The analysis of GA on 143 patients with colorectal cancer is described in **Chapter 4**, separately for patients treated with palliative or adjuvant intent. The additional value of GA and laboratory tests, apart from and in comparison with the age-adjusted International Prognostic Index, on the outcome of 44 patients with aggressive non-Hodgkin lymphoma treated with combination chemo-immunotherapy (R-CHOP), is described in **Chapter 5**. Finally, a more detailed analysis was performed to elucidate which elements of GA have the most impact on the outcome of the whole cohort of 494 patients collected in the region of the Comprehensive Cancer Center West (Reinier de Graaf hospital-Delft, Haga hospital-The Hague, Groene Hart hospital-Gouda and Leiden University Medical Center-Leiden) and selected by the treating clinician who estimated that chemotherapy was feasible on clinical grounds. The results of this analysis are described in **Chapter 6**. Based on these results we constructed a Geriatric Prognostic Index as risk profile for mortality prior to chemotherapy in the elderly. In **Chapter 7** our findings are summarized, discussed in a broader context and put in perspective.

Overview of the studies presented in this thesis



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