

Implementation Of An On Co-geriatrics Model In Low And Middle Countries (Lmics): Comprehensive Geriatric Assessment (CGA) Protocol In Andes Mountains

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1. Abstract

1.1. Background: People over the age of 65 years are the fastest-growing segment of the population in Low and Middle-Income Countries (LMICs). Thus, in those regions, the rise of chronic noncommunicable diseases (NCD) such as heart disease, cancer, and diabetes reflect changes in lifestyle and diet, as well as aging. Cancer represents one of the most frequent NCDs among elderly LMICs. Comprehensive geriatric assessment (CGA) is a recognized and useful instrument in the management of older adult patients.

1.2. Methods: A protocol for a clinical trial on the application of CGA in outpatient oncogeriatrics services in the Andes Mountains of Colombia, a low- and middle-income country (LMIC) was presented. This clinical protocol could represent a valuable contribution to support the development of CGA technologies in oncogeriatrics for the elderly and offer insights on possible configurations, based on the implementation context and use case.

1.3. Results: Based on existing proposals in the literature on CGA in oncology and on the proposed intervention approaches of interdisciplinary teams in oncogeriatric services, a protocol for a clinical trial on the

application of CGA with a multidisciplinary consultative model in older adults is presented. In addition to the traditional domains included in the CGA, it includes the assessment of the risk of toxicity due to oncology-specific management and the estimation of life expectancy due to non-oncologic disease burden.

1.4. Conclusion: With the implementation of this model and the realization of a pilot test, we seek to make recommendations for adjustments to therapeutic modalities in oncogeriatrics, detect geriatric syndromes and conditions in elderly with cancer and define palliative care needs either through continuous oncologic support or as exclusive palliative care.

2. Keywords:

Older patient, Oncogeriatrics, Cancer, Comprehensive Geriatric Assessment, Clinical Protocol, Clinical trial, Andes Mountains

3. Introduction

People over 65 years of age constitute the fastest growing segment of the population in Low and Middle-Income Countries (LMICs) and multiple sources estimate that, by 2050, 80% of older people, aged 60 years and older, will live in LMICs, so in the next decades the proportion of older adult population will exceed that of High-Income Countries (HICs) [1]. Reflecting the changes in diet, habits and lifestyle as well as aging, is clear that in LMICs the chronic non-transmissible diseases, such as diabetes, cancer and heart disease, will be more common [2]. For instance, in general, the cancer incidence and mortality is growing rapidly worldwide; this situation reflects both the aging and growth of the population and modifications in the prevalence and distribution of major cancer risk factors, several of which are associated with socioeconomic development. [3]. According to available data, 63% of registered cancer deaths occurred in the less developed regions of the world. For example, in Colombia, cancer was the third leading cause of death for the period 2000-2006; about 58.8% of cancer deaths in men are represented by tumors of the stomach, lung, prostate, colon, rectum, and leukemia; cervical tumors, as well as tumors of the stomach, breast, lung and colon and rectum, accounted for 52% of cancer deaths in women [4].

In recent decades, the involvement of multidisciplinary teams in cancer care for the elderly has increased and several oncogeriatric services have been implemented in LMICs [5]. Since then, oncologists and geriatricians have attempted to integrate comprehensive geriatric assessment (CGA) approaches in the oncologic setting. Several recommendations and reviews on screening tools have been published [6]-[9]. Thus, sufficient

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evidence is now available on the effect of CGA on the management of elderly oncology patients, focusing on oncologic treatment decisions, identification of baseline geriatric impairments and frailty, implementation of nononcologic interventions, patient-physician communication, and impact on treatment outcomes [10]. The geriatric assessment resulted in further discussion of goals of care and improved communication. In most of the included studies, the geriatric assessment also reduced toxicity/complication rates (especially if assessment results were considered during decision-making), increased the likelihood of treatment completion, and improved physical functioning and quality of life [10].

CGA in oncology extends beyond the traditional medical evaluation, oriented not only to the disease but also to the assessment of cognitive, affective, functional, social, economic, environmental, and spiritual capacities, as well as to an analysis of the patient's preferences in relation to anticipated guidelines [11]. At the same time, CGA can also be used as a variety of instruments to identify reversible deficits and design treatment strategies to reduce those deficits. CGA is also used in treatment decision-making by oncologists, which helps to stratify patients prior to potentially high-risk therapy [12], [13]. A systematic review evaluated the effectiveness of CGA in predicting/modifying outcomes (e.g., treatment decision impact, treatment toxicity, mortality, and use of care). After a CGA evaluation, the oncologic treatment plan was altered in a median of 28% of patients (range 8-54%), primarily to a less intensive treatment option [9]. Due to the particularities of the elderly patient, an individualized and multidimensional approach is necessary, which guarantees intervention in multiple areas, and which aims for recovery not only from the disease but also for the return to their home and to their previous activities, with a spectrum of care ranging from disease prevention to treatment and intervention measures [14]. Thus, the oncogeriatric approach can prevent oncologic interventions with potential harm to the elderly cancer patient and can also offer the possibility of advancing further interventions to those who, with other less objective tools, have been classified as non-candidates for active treatment [13]. This oncogeriatric approach allows early reintegration into society, end of life without toxicity or added suffering for both the patient and his family, and maximize the financial resources invested in health.

However, despite international recommendations suggesting the application of CGA for all oncology patients over 65 years of age [5], [15], [16], there is no specific model for incorporating geriatrics into oncology care and the approach to be used depends on local interest, funding, and availability of resources [17]. Among the main barriers to implementation are the shortage of geriatric-trained personnel, unfamiliarity with the tools to be used, and limited time for their application [18]. The literature describes multiple models of care for the elder person with cancer. These models have been adjusted according to the availability and resources of each care facility [5]. A recent review summarizes the following six models of care [18]:

1. Shared care model. Historically oncologists have split management with a primary care provider to address non-oncologic problems. This model has been limited by the fragmentation of the medical

system that creates communication problems and often lacks a geriatric focus.

2. Screening and referral model. This consists of performing a basic screening in the initial care of the elderly person with cancer, in order to detect patients in need of evaluation by qualified personnel using a CGA. It has the advantage of taking little time without involving an increase in resources. With the disadvantage of requiring the patient to see multiple physicians.
3. Multidisciplinary consultative model. Also known as the integrated model, it is described as the gold standard for CGA. This involves a multidisciplinary assessment in which geriatricians, oncologists, palliatives, nutritionists, rehabilitators, and social workers, among other professionals, participate. A comprehensive diagnosis is then obtained to make treatment decisions according to the patient. The results may be limited by the final decisions of the treating oncologist, with the difficulty that most patients are not followed longitudinally.
4. Geriatric-driven/embedded consultative Model. It consists of the geriatrician's support to an oncologist in the diagnostic and decision-making process, through a consultation. The geriatrician performs the oncogeriatric evaluation and provides recommendations.
5. Geriatric oncologist as a primary provider. Dual-trained geriatric oncologists can provide comprehensive care and have the advantage of greater control over outcomes; however, it is limited by the small number of qualified providers.
6. Self-administered geriatric assessment. The patient completes questionnaires and relies on trained personnel, requires fewer resources, with the disadvantage of needing experienced personnel to interpret the tests, and may be limited in care by the availability of resources with identified needs.

The objective of this study is to evaluate the general characteristics of geriatric patients diagnosed with oncologic disease in an outpatient setting, using a protocol based on Comprehensive Geriatric Assessment (CGA). The adapted model of care includes a multidisciplinary consultative model.

4. Methods

4.1. Program design

The proposed multidisciplinary consultative model is applied to elderly patients diagnosed with solid cancers, who are going to receive oncospecific management, detected in the city's oncology centers, and evaluated under an outpatient clinic modality.

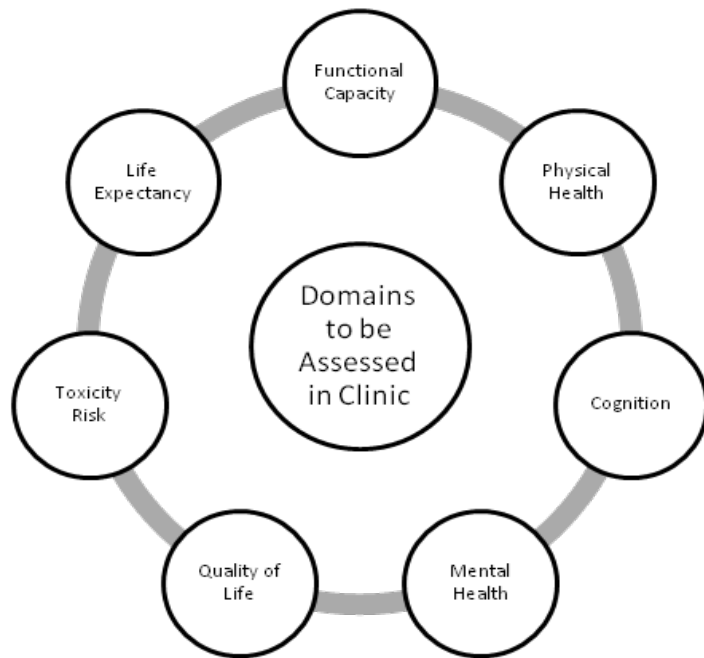
4.2. Data collection

The program is aimed at older adults, aged 65 years and older, with a recent diagnosis of one of the following cancers: breast, prostate, gastric, colorectal, lung, cervical, and/or endometrial cancer.

Figure 1 shows the CGA domains used in the evaluation of patients, in addition to those traditionally included, it also includes the evaluation of the risk of toxicity and the assessment of life expectancy, which are key in

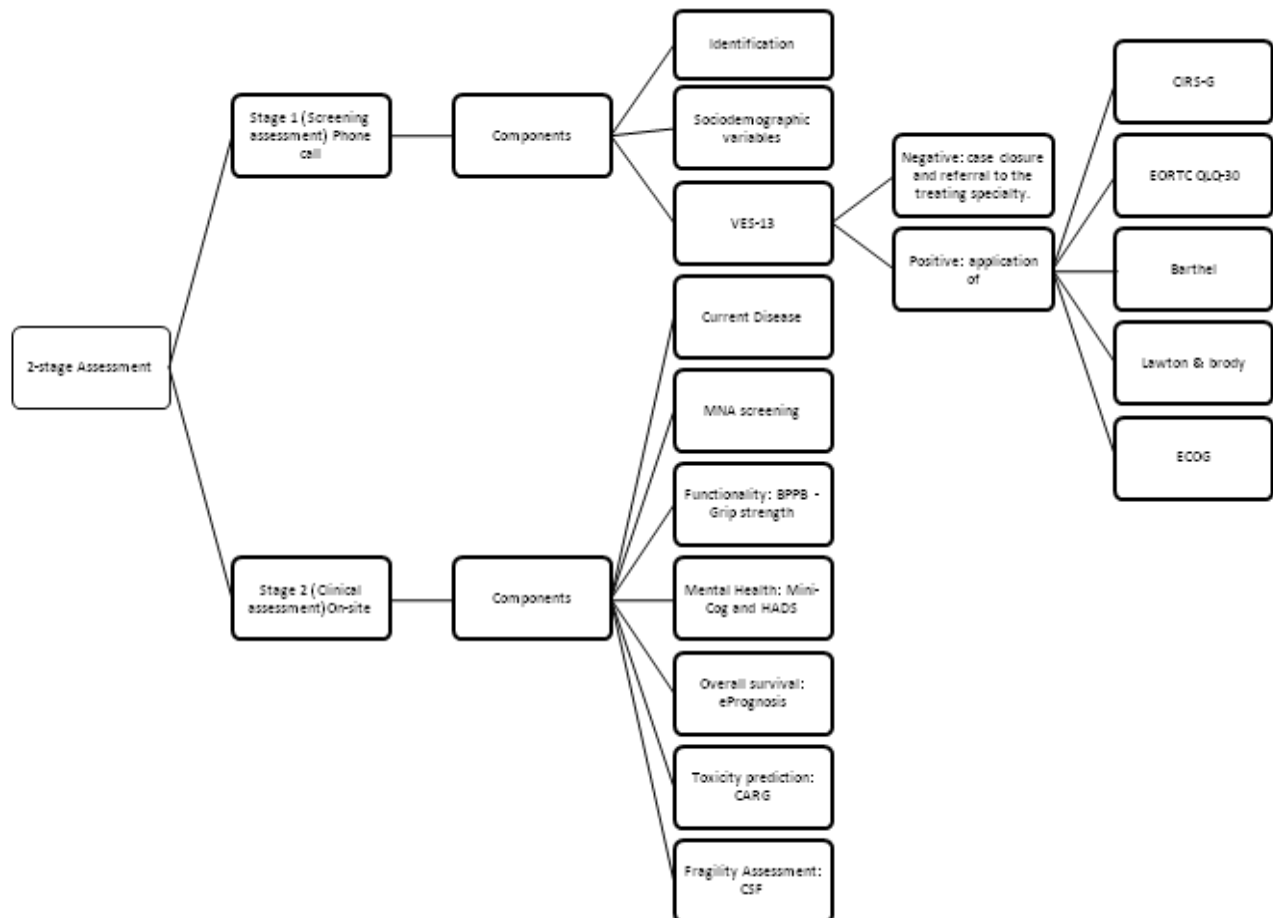
the evaluation of elderly people with cancer [10].

Fig. 1: Assessment domains in an oncogeriatric model.



The program protocol, Figure 2, consists of an initial assessment, divided into two stages. In the first step, the patient is assessed by telephone, where sociodemographic data are collected, and the informed consent form is filled out. Subsequently, the VES-13 screening scale is applied, which is used to assess the general condition of the oncologic patient and his or her need for CGA [19]. If the scale shows a score of 2 points or less, the patient is considered vigorous and does not require CGA; on the contrary, if the score is 3 or more, the patient is considered vulnerable, and the other scales of functional capacity, multimorbidity, quality of life and scales recognized in the oncology area such as the Eastern Collaborative Oncology Group Performance Status (ECOG-PS) are applied as triage for the treatment of the patient. In the second step, a face-to-face assessment is carried out, and data is collected on the current disease and personal history, as well as the specific assessments of each specialty. The following tools are applied: as for geriatrics, the physical health status, nutritional condition, functional capacity, and present comorbidities are evaluated. Geriatric conditions, such as frailty, are also assessed. In psychiatry, scales are applied to identify depression and anxiety, cognitive screening tests are performed, and quality of life is assessed. In the area of palliative care, scales are applied to assess life expectancy, morbidity burden, and toxicity risk assessment.

Fig. 2: Research flowchart



Fulfilling its intermediation role, during the nursing assessment, within the protocol, an interview will be carried out for subjective assessment of the immediate needs of the patient and family group, to detect urgent communication needs, emotional support needs for the patient and family, self-care education., promotion of adherence to treatment and adoption of healthy lifestyles, with interrogation directed at these areas and resolution of doubts in the same interview, as well as emphasis during the assessment of the benefits expected for each patient from the application of the protocol. Once the scales are applied, a meeting is held with all the specialists, including the hemato-oncologist, geriatrician, psychiatrist, psycho-oncologist, palliative care specialist, nursery, and physical rehabilitator. This evaluation is oriented to 4 specific objectives of the assessment:

1. Calculation of overall life expectancy.
2. Recommendations for adjustments of oncology therapeutic modalities, based on the analysis of toxicity risk and findings in the multidimensional assessment.
3. Detection of geriatric syndromes and conditions.
4. Definition of palliative care needs, either through continuous oncology support or as exclusive palliative care.

The control assessment is performed 3 months after the start of oncospecific management. In this assessment, all the previously applied instruments are applied again, with the exception of the toxicity scale.

4.3. Institutional approvals

The clinical assessment program has the pertinent institutional approvals from both the University of Caldas, (Manizales, Colombia) and the high-complexity centers where the patients are detected. Informed consent is obtained, initially by telephone during the initial assessment and then duly filled out in the established format during the on-site assessment.

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5. Results

The criteria for selecting the instruments to be used in the assessment of patients were based on a review of the available literature [18], [20], [21], and on a recent review of the interventions of interdisciplinary teams in oncogeriatric services, based on CGA [18]. The VES-13 scale [19], a tool validated in the Colombian population [22], which selects data on age, self-perception of health, basic and instrumental activities of daily living, and additional activities, will be used as a tool for detecting vulnerability in the elderly with cancer. In addition, the Eastern Collaborative Oncology

Group Performance Status (ECOG-PS) will be used in its Spanish version [23]. The ECOG PS has gone on to prove both prognostic and predictive utility in oncology practice [24]. In the physical health domain, the Clinical Frailty Scale (CSF) [25], widely used in oncogeriatrics to assess frailty, is included. Multimorbidity will be assessed by means of the Cumulative Illness Rating Scale - Geriatric (CIRS-G) [26], [27]. In the nutritional domain, the Mini Nutritional Assessment (MNA) tool will be implemented for the diagnosis of nutritional disorders, allowing the identification of patients at risk [28]. The functional capacity domain includes self-care and survival activities, which depend on neurological development and allow the survival of the individual [29]. The Barthel and Lawton-Brody scales have been implemented in assessment protocols for the elderly with cancer [30]. Among the numerous test batteries or composite measures of performance-based measures, the Short Physical Performance Battery (SPPB) will be used, which is one of the most commonly used instruments in oncogeriatric studies [31]. In addition, grip strength measured with a hand-held dynamometer is important for assessing cancer patients as it is associated with adverse outcomes in cancer patients [32].

In the mental health domain, the Hospital Anxiety and Depression Scale (HADS) [33] will be used to characterize affective symptoms. The MiniCog scale will be used to screen for cognitive impairment [34]. For the assessment of quality of life, considering the importance of this domain in the health of the elderly patient in the context of malignant disease, the European Organization for Research and Treatment of Cancer (EORTC) Core Quality of Life Questionnaire (QLQ-C30) EORTC QLQ-C30 v3 tool will be used [35]. The Cancer and Aging Research Group toxicity prediction score (CARG score) tool will be used to assess the risk of toxicity due to oncospecific management [36]. The Lee [37] and Schomberg [38] scales will be used to estimate life expectancy by non-oncologic disease burden. The pilot study will be conducted in the winter of 2023. We will follow the SPIRIT statement guidance on defining standard protocol elements for clinical trials [39], and the report of the pilot and feasibility trial protocols [40]. VES-13, Vulnerable Elderly Survey-13. MNA, Mini Nutritional Assessment. BPPB, Brief Physical Performance Battery. HADS, Hospital Anxiety, and Depression Scale. CARG, Cancer, and Aging Research Group toxicity prediction score. CFS, Clinical Frailty Scale. CIRS-G, Cumulative Geriatric Illness Rating Scale. QLQ-30, European Organization for Research and Treatment of Cancer (EORTC) basic quality of life questionnaire (QLQ-C30). ECOG-PS, Eastern Collaborative Oncology Group - Performance Status.

6. Discussion

6.1. Preliminary Findings

Most of the CGA tools included in oncogeriatric elderly assessments are selected based on theoretical approaches, taken from other clinical settings, or based on other pathologies [10]. However, CGA integrating standard medical diagnostic evaluation, emphasizes problem-solving and aids in the development of treatment and follow-up plans, in the coordination of management of care, and in the evaluation of long-term care needs in older adults with cancer. Currently, there are not enough

studies to evaluate the effectiveness of CGA in older patients with cancer. [7]. CGA is feasible and can identify patients at increased risk for adverse events, mortality, functional impairment, surgical complications, or chemotherapy toxicity, and consideration should be given to incorporating CGA in the evaluation of older adults with cancer [41]. However, CGA in oncogeriatrics has not been properly assessed in LMICs, including their ability to predict the individual risk for different adverse outcomes [5]. While there is robust evidence of the impact of CGA in oncogeriatrics, there are not many integrated models that have been evaluated in LMICs.

In the proposed assessment protocol, in addition to the known domains within the CGA, a series of prognostic, toxic profile and survival prediction “markers” are adopted for oncologic disease in patients over 65 years of age, to make the best decision for intervention or maintenance [42], [43]. These “markers”, together with the proposed CGA domains will prevent the elderly with cancer from having negative outcomes in their management as interventions with severely unfavorable impacts from the clinical point of view (poor control of oncologic disease, toxicity, and poor quality of life), from the social point of view (isolation and non-reintegration into their community) and finally economic (high health expenses) [43]. Due to all the aforementioned particularities of the elderly patient, an individualized but multidimensional approach is necessary, which guarantees intervention in multiple areas, and which aims not only at recovery from the disease but also at reintegration in the best possible way to life in the community, with a spectrum of care ranging from disease prevention to treatment and intervention measures [14]. Developing a CGA protocol will allow the development of the appropriate model for the management of the elderly with complex situations in oncogeriatrics.

6.2. Limitations

Several limitations identified in the development of this protocol should be mentioned. First, we must point out the limitation in the application time of the different evaluation instruments due to the fact that oncogeriatric patients intrinsically present easy fatigue, which makes it necessary to shorten the evaluation times to be able to apply the protocol in its entirety. Second, since this is a prominent academic and research initiative, at the moment it does not generate economic gains, thus limiting the interest of institutions that could implement the protocol on a larger scale. Third, this protocol was designed taking as reference research models with heterogeneous methodology, which may imply a limitation in the comparison with other studies and the generalization of the findings. However, it is important to note that the assessment instruments chosen for the protocol have been validated in a geriatric population with oncologic pathology.

7. Conclusions

This research will help identify where more evidence is needed to support the development of CGA in older people with cancer. Findings from this research could be used by researchers, clinicians as well as implementation teams as to the appropriate configuration of CGA evaluation and how to assess its efficacy. The need for future research contributions and

implementation of the research findings will be identified.

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