Prognostic value of bioimpedance vectorial analysis in cancer patients receiving first-line chemotherapy: a prospective, multi-center cohort study

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Description of the initiative: To provide an objective numerical scale for nutritional assessment, that may reflect muscle stores according to the creatinine-height index by using bioimpedance vector analysis (BIVA). The advantages of this method are the independence from patients' weight and cognitive functions and the absence of limitations related to the use of predictive equations for body composition. In particular, it will be used a unique parameter of nutritional status that has not been validated in cancer patients yet, and may provide useful additional data aimed at improving the accuracy of BIVA

Rationale/Background of the initiative: Protein-calorie malnutrition is a frequent comorbidity in cancer patients. The causes of this condition are manifold, including local (tumor bulk) or systemic factors. Oncologic treatments may also be responsible for the deterioration of nutritional status by increasing energy needs and/or the alteration of nutrients intake and absorption. Hence, nutritional support is recommended, in order to improve clinical outcomes, prevent or treat malnutrition, improve the effectiveness and the tolerability of anti-cancer therapies. It is also known that the impairment of nutritional status is associated with higher mortality and a more frequent need to interrupt anti-cancer treatments .Several recent studies demonstrated the prognostic value of phase angle (PhA) in relation to mortality or postoperative complications in different clinical settings. Bioimpedance vector analysis (BIVA) was shown to be consistent in evaluating patients in whom anthropometric assessment is not reliable due to changes in hydration levels. Particularly, PhA was found to be significantly associated with mortality, disease progression, incidence of postoperative complications and length of hospital stay in patients with cancer. A PhA less than 5.1° (or a standardized PhA <-1.65) was associated with an increased rate of mortality. BIVA enables a more accurate and reliable monitoring of nutritional treatments in patients with possible changes in hydration levels and is associated with muscle function variations, as well .However, the above-mentioned studies were mostly retrospective, included patients with different cancer stage and disease duration, and have been conducted in small populations. Furthermore, the potential difficulty in interpreting the changes in the impedance vector on the BIVA nomogram (CXR graph) according to different clinical conditions has prompted the need to create new, easy to interpret indexes with a linear behavior in their variability.

Scope of project, activities, implementation: The aim of the study is to evaluate the prognostic value of PhA in cancer patients with advanced solid tumors, receiving first-line chemotherapy. The Primary end point is: Overall survival (OS) and progression-free survival (PFS) at 1 year since diagnosis by baseline standardized PhA (SPA; cut-off <-1.65

The secondary end points are: 1. OS and PFS at 1 year since diagnosis by baseline PhA (cut-off <5.1°), nutrigram™ (cut-offs: males, <660 mg/m/24h; females, <520 mg/m/24h), NRS 2002 (cut-off >2), and recent 6-month unintentional weight loss (cut-off ≥ 10%). 2. OS and PFS at 1 year since diagnosis by changes of PhA, nutrigram™, body weight and BMI at 4-6 months since diagnosis (first line chemotherapy completed).3. Dose-limiting toxicity by baseline PhA (cut-off <5.1°), nutrigram™ (cut-offs: males, <660 mg/m/24h; females, <520 mg/m/24h), NRS 2002 (cut-off >2), and recent 6-month unintentional weight loss (cut-off ≥ 10%).4. Correlation between PhA, nutrigram™, BMI and Karnofsky index at diagnosis. 5. Correlation between PhA, nutrigram™, BMI and quality of life (ESAS scale) at diagnosis.6. Correlation between PhA, nutrigram™, BMI and quality of life (ESAS scale) at 4-6 months since diagnosis (first line chemotherapy completed).

The following assessments will be performed: general clinical and demographic data: age, gender, diagnosis, disease stage, any previous surgical procedure; cancer treatment and related complications: type and dose of chemotherapy, adverse events (any type) and dose-limiting toxicity (any type); anthropometry: body weight, 6-month unintentional weight loss, body mass index and food intake (percentage of estimated requirements). based on these parameters, nutritional risk will be defined according to the Nutritional Risk Screening 2002 tool (NRS 2002); body composition, PhA, SPA e nutrigram™: according to vectorial impedance analysis; quality of life will be assessed using the Edmonton Symptom Assessment Scale (ESAS); performance status will be assessed using the Karnofsky performance status scale.

Resources needed: one research nurse.

The innovation of this project is the evaluation the prognostic ability of body composition in patients receiving first-line CT measured with a simple and inexpensive tool. The results may potentially convince on a large scale to assess the above parameter to better estimate outcome and also implement nutritional therapy for the high risk patients. The close collaboration between SINPE and AIOM (the largest italian society of oncologist) may simulate oncologists worldwide to be more receptive and accurate in measuring the nutritional status and need of cancer patients.

Results/Outcomes, Conclusions: Expected results and outcome: If at least 120 patients per group of the following tumor types will be recruited (stomach, pancreas and biliary tract, head-neck, lung, breast, colon-rectum), a HR = 3.67 could be observed in case of a 12-month survivorship of 44% in the high-risk group.