

Screening implementation of lean body mass in cancer patients receiving first-line chemotherapy.

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Description of the initiative

•**Background:** 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 for 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 behaviour in their variability

•**Objectives and scope:** 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)

Resources & enablers

- A research fellow is needed to collect data, maintain the dataset and analyze the data.
- Specify how the grant will be spent: Salary of the fellow.
- What factors will make it successful? The initiative is endorsed by the largest Italian society of clinical nutrition (SINPE) and of oncology (AIOM).

Planned activities & deliverables

- Outline the steps to be taken:
- What are the concrete deliverables of the project? Provide data showing that measuring lean body mass is important to evaluate patient nutritional status and response to chemotherapy.
- What achievements are possible in the next 12 and 24 months? Complete the data collection and analysis.

Results/outcomes & expected impact

- How will the findings be implemented? 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
- How will this project advance patient care / contribute to optimal nutritional care? This project will collect data that will provide in the future a standard reference to evaluate how nutritional implementation may affect lean body mass
- What makes the project innovative? No data are available in the literature on this specific issue
- Will the project be likely to influence national nutrition policy? Not in the immediate future. But it may become a cornerstone for future trials.
- Is the project transferable to other settings / countries? The measurement is easy and cheap. It can be transferred in any setting.