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Editorial

The Use of Parenteral Nutrition in Malnourished-Hypophagic Cancer Patients Should Not Follow the Recommendations of the Current International Guidelines

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DEAR EDITOR,

I read with interest the recent paper "Parenteral Nutrition in Patients with Incurable Cancer: Exploring the Heterogenous and Non-randomised Clinical Landscape" which appears in the November issue of Current Oncology [1].

The study describes the practices and actual outcomes of parenteral nutrition (PN) in patients with incurable cancer at Norwegian hospitals and concludes that in this real-world cohort, up to 80% of the patients would not meet the eligibility criteria of previous trials due to cancer diagnosis and treatment, gastrointestinal tract function, weight loss criteria or complications such as ascites.

This is noteworthy because it is one of the first papers to deal with PN in a real-world setting, as opposed to ad hoc studies.

It is especially impressive that most of the patients receiving PN in the real world had an inflammation-related weight loss and no chance of reasonable cancer treatment options, all characteristics that in the recent ESMO Clinical Practice Guidelines [2], for the treatment of cancer cachexia would disqualify patients from receiving PN. The non-expert clinicians who follow the ESMO Clinical Practice Guidelines would deny PN to many patients who however should be worthy to be treated because, according to this real-world study, 20% or more of them reported some benefit from PN, whereas a very low percentage (5%) decided to withdraw the intravenous nutrition. This percentage is quite similar to that found in a large prospective observational study of cancer patients receiving home parenteral nutrition in Europe [3].

The authors highlighted the heterogeneity in how patients with incurable cancer receive PN, and emphasised the importance of individualised PN treatment, carefully and safely managed to meet the patients' palliative care situation, however they did not speculate on the problematic gap existing between the real-world practice and recommendations of the guidelines.

I guess that one of the main reasons for such discrepancy is the replacement of the term "Nutritional Support" by "Nutritional Medical Therapy," aligning with the view that nutrition is prescribed by health professionals. However, the term "therapy" has important implications, especially in oncology, where the efficacy of a drug requires a validation through randomized controlled trials (RCTs). In fact, nutrition is not simply a drug and the ASPEN Board of Directors, and the Clinical Guidelines Task Force [4], stated more than 20 years ago that "a major distinction between therapeutic trials of the efficacy of a drug or procedure and the feeding of nutrients known to be essential to the maintenance of human health and survival must be made. Withholding a drug or invasive procedure will not produce disease in otherwise healthy humans, whereas essential nutrients must be provided to both healthy and ill people. Patients with advanced malnutrition or who are at risk for becoming severely malnourished must be fed to prevent death by starvation."

According to this perspective, when facing with a severely malnourished, weight-losing cancer patient, the

oncologist should primarily ask, "Is there a reason for denying a nutritional support to this patient?" rather than "Is nutritional support recommended for this patient?" Consequently, the clinician may face with a paradoxical situation: in fact, weight-losing cancer patients with severe hypophagia are expected to get the best benefit from nutritional intervention, however, it would be unethical to have a control group of malnourished, hypophagic patients who are not adequately fed, making impossible to demonstrate any benefit through RCTs.

This issue was emphasized in the introductory article [5], to the ESPEN Guidelines on Parenteral Nutrition to explain the scarcity of recommendations on the use of parenteral nutrition in oncology supported by robust evidence. The lack of evidence-based efficacy was one of the main reasons for the underutilization of nutritional support, as highlighted in a series of interviews conducted at five European centres providing care to head and neck and oesophagus cancer patients [6]. Obviously, the alternative to achieve an equipoise [7], should be having a control group of patients who are able to eat even in a suboptimal way. However, comparing two groups which are "less different", strongly reduces the statistical power of the comparison and the chance of finding a significant result. In all RCTs on PN, both in non-malnourished [8], or malnourished [9] cancer patients, the control group received some form of nutritional support, ranging from 20.1 to 26.0 Kcal/Kg/day [8,9], or like the intervention group [10], with a protein intake of 0.7 g/Kg/day or slightly less [8-11]. This may be the reason why these studies are viewed by the scientific community as negative or less convincing.

Some of these studies investigated the potentially "adjuvant" role of PN to improve the quality of life or the survival of cancer patients on oncologic therapy, with very poor results.

One should ask, however, if it is reasonable to expect a potential benefit of the quality of life of advanced cancer patients, whose general condition is compromised by the presence of pain or fatigue or nausea or a more or less latent feeling of despair. How could the gain of some grams of lean tissue achieved through PN reasonably improve the quality of life of a patient?

As regards the survival of patients receiving an oncologic therapy, a condition sine qua non to expect a benefit from an "adjuvant" PN could occur only in those patients candidate to a potentially successful oncologic therapy which, however, cannot be performed because of the severe state of malnutrition or the poor nutritional intake: two conditions that for ethical reasons -we cannot deny any nutritional support to the control group- and for unavailability of very active treatments, were never met in the literature.

Equating nutrition to a pharmacologic therapy means to scotomize the basic concept that nutrition is a necessary, even if not sufficient condition, to maintain a patient alive and that no therapy can be successful if the patient is not fed.

It appears clear that in the real-world practice PN is viewed more as a care than as a therapy, where for care we mean the conscious, intentional act that requires understanding patients beyond their medical history and aligning treatments with their values and needs [12].

In conclusion, I fully agree with the findings of the authors (1) that PN should be initiated in response to insufficient intake, regardless of other conditions and a large review of the literature showed that PN can at least double the length of the survival when used in cancer patients who are severely starving [13].

Quite recently, Sharma et al. [14], have pointed out that within the group of survivors -that is cancer survivors from the time of diagnosis through the balance of life-, there is a subgroup of persons who are diagnosed with advanced cancer that is likely incurable. They are the so-called "individuals living with likely incurable cancer" (ILLICs) according to the definition of the USA Department of Health and Human Services [15]. The number is uncertain but there were an estimated 623,405 individuals in the United States living with the most common metastatic cancers in 2018. This number is projected to increase to 693,452 in 2025, an 11% increase in only 7 years.

Therefore, this paper by Erichsen et al. [1], is a timely warning that the cancer patient population which is potentially candidate to receiving an intravenous nutritional support, is expanding in the high-income countries and that further investigations and pragmatic real-world trials are necessary to bridge the gap between the current literature and clinical practice.

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