arTs Università degli Studi di Trieste
Archivio della ricerca – postprint

Author's reply to "Letter to the editor: Surgical resection of oral cancer: en-bloc versus discontinuous approach"

Giancarlo Tirelli[1] · Alberto Vito Marcuzzo[1] · Fabiola Giudici[2] · Margherita Tofanelli[1]

Accepted: 12 June 2020

Keywords Oral cancer · Head and neck cancer · Oral oncology

Dear Editor and Colleagues,

We wish to thank you for the opportunity to discuss the delicate/thorny topic of selection bias in the observational study. We agree that the retrospective design has an intrinsic disadvantage to often compare groups with a different background that might jeopardize the statistical results and thus leading to data misinterpretation. We appreciated your consideration and the reviewers' insightful comments concerning our manuscript. We have considered the observations carefully and here is our reply.

We know that the propensity score matching (PSM), mimicking randomized controlled trials, may reduce selection bias, so treatment groups can be balanced on baseline covariates.

However, to simulate a randomized trial was not suitable to accomplish the aim of the study. In fact, we focused on two different surgical approaches that have different indications as described in materials and methods section:

> "The choice of treatment was based on the National Comprehensive Cancer Network (NCCN) guidelines [1]. An en-bloc resection (EBR), in which the primary tumor and cervical nodes are resected in continuity, was indicated in the case of direct extension of the primary tumor into the neck, mylohyoid muscle invasion or when a segmental mandibulectomy was required. In other cases, a discontinuous resection (DR) was preferred, in which tumor resection and neck dissection are performed at the same time using a transoral access and a cervical access, respectively."

In our cohort, the advanced T stages classified following the eighth edition were treated with an EBR significantly more often than the early stages. This result could support the idea that more aggressive/advanced tumors require more aggressive surgery to achieve radicality, in contrast to EBR with T–N tract removal despite the tumor stage.

This discussion aimed to highlight that the randomization might not reproduce the real decision process because the treatment choice in these conditions cannot be randomized.

Moreover, the aim of the study was the evaluation of Kaplan–Meier estimates of survival functions.

In a nonrandomized clinical trial or an observational study, the samples in different groups may be biased due to some confounding variables. Other adjustments of survival estimation based on matching or stratification have been considered, which stratify observations according to the values of some confounding variables and then combine the survival estimates in each stratum. These estimators require observations available at time t in all the strata. When some strata have small numbers of individuals, the survival function can only be estimated for a small part of the observation time. However, stratification and matching approaches may have difficulties to get well-matched data when a confounding variable is continuous or many confounding variables have to be considered.

The PSM creates two subpopulations excluding most the cohort with a consequent small number at risk set, which would not allow a reliable estimate of the Kaplan–Meyer curves.

✉ Alberto Vito Marcuzzo
avmarcuzzo@gmail.com

[1] ENT Head and Neck Surgery Clinic, ASUGI Trieste, Trieste, Italy

[2] Department of Medical Science, ASUGI Trieste, Trieste, Italy

Compliance with ethical standards

Conflict of interest The authors declare that there is no conflict of interest and that this research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

1 National Comprehensive Cancer Network (2019) Head and neck cancers (version 2.2019). https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed 16 Jul 2019