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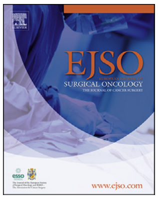

Correspondence

“A systematic analysis highlighting deficiencies in reported outcomes for patients with stage IV colorectal cancer undergoing palliative resection of the primary tumor” by DP Harji et al

Dear Sirs,

I read with much interest the paper from Harji et al. [1] They reviewed 59 papers recently published in which a comparison was made between patients with stage IV colorectal cancer who had primary tumor resection or not. They concluded, that there are so many missing data that any assumption is error prone.

I completely agree with their conclusion, as it is testified by the different and contrasting results reported by the many published studies.

To this we should add two important points: quality of life is never analyzed and in this clinical scenario quality of life represents a key point for the patients and their families, and there has been an overuse of statistical methods that implies a clear statistical flaw.

The majority of the Authors reviewing data has used propensity score matching or has used instrumental variable analysis, trying to quantify hidden variables, for instance determining that patients surviving less than 90 days had no surgery.

The propensity score, and any adjustment, involves calculating the conditional probabilities of being in the treated group given a set of covariate, and then analyzing the outcome using the weighted data.

The major criticism to these retrospective analyses is that there is the possibility of hidden variables, which have a significant effect on outcome. We clearly know that all the studies have not included well known, and for sure not hidden, “significant” variables: number of liver metastasis, their size, liver function, general conditions of the patients (Karnovfsky or other classification methods), metastases in other sites, T of the tumor, K ras type).

To this we should had a very simple consideration: if a selection was made a priori, we cannot have the ambition to cancel that selection with a statistical method.

But at the same time, I disagree with the Authors that prospective randomized studies will give all the answers we expect. Patients with stage IV colorectal cancer and unresectable metastases represent a significant heterogeneous group, and it will require a long time before an adequate number of patients can be enrolled. At the same time, we are assisting to a surprising introduction of many new techniques in this clinical setting, that probably any consideration of today is going to change in an immediate future: continuously new chemotherapeutic agents are tested and introduced, laparoscopic surgery is becoming almost routine, with reduced morbidity. We are just starting to understand that each single patient responds differently to the same chemotherapeutic agents on the basis of genetic characteristic. Radiofrequency ablation and chemoembolization of liver metastases is a field in continuous evolution.

This movement of ideas, and consequent changes in clinical practice can be analyzed only in a “real time” analysis. National statistics offers the possibility to analyze a large number of patients, almost in real time, in the real world, which is quite different from the “virtual reality of academic trials”.

From the corrected analysis of Harij et al., we should draw a different conclusion: we have to invest more resourced to improve the quality of national statistics. There is the need for a Consensus of experts who have to define all details about the data to be collected, and how to report these data to National Statistics. To these clinical data, blood samples of the patients should be stored. Genetic assessment per se has a negligible meaning if the clinical outcome of a specific cancer is not available, and genetic assessment will play a major role in the future to decide the optimal therapeutic approach for each single patient, considered in his/her individuality.

At the same time, we are facing a difficult situation: the privacy of each single patient should be absolutely preserved. In several countries there is the risk that National Statistics will be not available in the near future, in the name of respect for privacy.

We should prevent this risk, perfecting methods to collect data and at the same time to preserve the privacy of patients. Respect for the privacy of the patients is fundamental; but if initiatives are taken by governments in the name of respect for the privacy of the patients, before we take the appropriate steps to take ourselves care of this matter, there is the risk that we will not be able to do anything anymore. In such a situation we face the risk to appear as those who do not respect the needs of the patients. And this will be quite inappropriate and not right for us and for sure not the right consideration of our efforts to help patients.

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Conflict of interest

The author has no conflicts of interest to disclose.

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References

[1] Harji DP, Vallance A, Selgimann J, Bach S, Mohamed F, Brown J, Fearnhead N. A systematic analysis highlighting deficiencies in reported outcomes for patients with stage IV colorectal cancer undergoing palliative resection of the primary tumour. Eur. J. Surg. Oncol. 2018 Oct;44(10):1469–78. https://doi.org/10.1016/j.ejso.2018.06.012. Epub 2018 Jun 23. Review. PMID: 30007475.

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