Reviewer’s report

Title: Decision aids for second-line palliative chemotherapy: a randomised phase II multicentre trial

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Reviewer: Gabriella Pravettoni
Reviewer's report:

Dear Authors,

I read your paper entitled "Decision aids for second-line palliative chemotherapy: a randomised multicentre trial". Despite the interesting issue treated, there are some several concerns, as detailed below, that require many clarifications.

INTRODUCTION

- Scientific evidence are poorly discussed on the impact of DAs on advanced cancer patients. Overall, the introduction is very general and unspecific, often including only main conclusions of studies without a more in-depth discussion of the literature. Some important paper on topic was neglected (for example, Butler, M., Ratner, E., McCriddy, E., Shippee, N., & Kane, R. L. (2014). Decision aids for advance care planning: an overview of the state of the science. Annals of internal medicine, 161(6), 408-418.)

Also, authors do not provide concrete information about the exactly relation between DAs, anxiety and decision-making process concerning the treatment, while they are treated at the end of manuscripts. The theoretical framework is poor to support conclusion on risk perception and decision-making.

METHOD

- In the method section some incongruence are identified. For the assessment of the anxiety and depression were used HADS questionnaire, that it is a validated tool for oncological patients. Despite to this, subjects enrolled reported normal level of anxiety and depression (T1; T2; T3) (normal=0-7; borderline abnormal=8-10; abnormal=11-21).
- Also for the age, is not reported standard deviation. This should be inserted in order to understand better the composition of the sample. The age has a pivotal importance, because it can modulate the efficacy of DAs on cancer patient.

RESULTS AND DISCUSSION

- From Line 8 to Line 13 (page 17): "This study showed that DAs with outcome information could safely be offered to patients with advanced cancer considering second-line treatment."

This assumption seems an over-interpretation of the data, because authors did not found any statistical significance. The absence of statistical significant between anxiety level and DAs is not an index about the safety for advanced cancer patient. Overall, the safety for patients should be assessed.

- From line 40 to line 43 (page 17): "Nevertheless, other benefits regarding objective knowledge, risk perception, and involvement in decision-making were anticipated."

Also in this case the inference seems an over-interpretation. Indeed, Authors have found statistical significance only for knowledge, but not for risk perception and decision-making processes.

- From line 52 to line 55 (page 17): "Therefore, the population of patients with incurable cancer may explain the absence of results".

This sentence is confused and is not clear. Also the interpretation appear not clear. In order to claim that previous experience with chemotherapy may have reduced the added value of information on chemotherapy, it would be necessary to have a control item/question about this issue. Also for the suggestion that patients may regard active treatment as the only option to sustain hope, and that this was exemplified by the low valuations for refraining from further chemotherapy. This last question, in particular, is based on two non-significant results (p=0.068, p=0.067).

- From line 9 to line 17 (page 18): "A further strength is that we facilitated generalisability of the results by recruiting patients from a large number of hospitals, recruiting patients receiving first-line chemotherapy while applying broad selection criteria, and achieving an 82% informed consent rate."
I do not think that the generalisability of the results is linked with the numbers of hospital used for the enrolment. In my opinion, this is not a strength of the study.

Considering all comments above, even though the paper contains some interesting data, I am sorry to tell that it does not reach sufficient rating for to be recommended for publication. The paper has need to major revision before the publication.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

No

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

No

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

No

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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