Reviewer’s report

Title: Low-dose decitabine priming with intermediate-dose cytarabine followed by umbilical cord blood infusion as consolidation therapy for elderly patients with acute myeloid leukemia: a phase II single-arm study.

Version: 0 Date: 16 Apr 2019

Reviewer: Matthew Barth

Reviewer's report:

The authors report on a small Phase 2 trial of a novel consolidation therapy for older patients with de novo AML and compare this to a separate cohort of conventionally treated patients. Overall the reported survival rates reported compare favorably to historical values for elderly AML patients though it is a small population of apparently very favorable elderly patients with nearly all of the patients having ECOG scores of 0-1. The lack of information about the comparison group make a true interpretation of the results difficult.

1) The authors discuss many studies of various consolidation therapies studies in elderly AML, but provide no background on what their standard of care would be for such a population as a reference point.

2) In the Treatment Protocol section, it states that "patients were allowed to receive…” maintenance chemotherapy, but there is no discussion of how many received this maintenance. Was this truly optional and if so how many received additional maintenance chemotherapy and for how long? What is the total duration of the therapy in general? Is this maintenance therapy the standard approach? Was toxicity measured and reported during these subsequent maintenance cycles as well?

3) Several patients fell into a favorable risk group and could theoretically be cured without consolidative SCT. Are these favorable risk patients routinely treated with SCT based approach?

4) The comparison with a "control" group of AML patients is not statistically appropriate considering the study was not designed as a case-control study. Additionally, there is no information at all provided about the treatment regimen for the "control" cohort making the comparison nearly useless. There are also no confidence intervals provided for any of the analyses reported to help better gauge the true statistical impact of the reported comparisons.
5) In the discussion on page 16 line 16 the authors state 2y OS and LFS but earlier report 1y rates.

6) Most of the historical comparisons have significantly longer follow-up periods of 2-3 years compared to only 1y survival data reported in the current study. The short interval and lack of ability to compare durability of responses compared to other previously reported data reviewed in the discussion section needs to be stressed in the interpretation of the results.

7) In the Table, there appears to be as much as double the rate of Grade 3-4 hematological toxicities including neutropenia and anemia in the UCB group compared to the TCG group. This should be discussed, as opposed to saying there was no difference in toxicity as stated in the body.

8) In Figure 1, if you're going to go so far as to compare the two groups you may as well plot their survival together. Again there are no confidence intervals on the curves.

9) There are numerous instances of errors with English grammar throughout the paper that would benefit from further review/editing to improve readability.

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.

Unable to assess

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

Yes

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
Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal