Reviewer's report

Title: Induction therapy with bortezomib and dexamethasone followed by autologous stem cell transplantation versus autologous stem cell transplantation alone in the treatment of AL amyloidosis: a randomized controlled trial

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Reviewer: Vaishali Sanchorawala

Reviewer's report:

Huang et al reports on a randomized trial of 2 cycles of induction with Bortezomib and dexamethasone followed by HDM/SCT vs HDM/SCT alone for newly diagnosed patients with AL amyloidosis. 56 patients were randomized and hematologic responses, organ responses and OS and PFS were superior for BD-HDM/SCT arm. This is a well designed clinical trial and the results are as expected.

Major revisions:

1) Toxicity of 40 mg of dexamethasone in a twice a week fashion needs a mention. It is hard to believe that 100% of the patients with renal involvement and median serum albumin levels of < 3 g/dL, on this trial did not experience grade 3/4 edema with such high dose dexamethasone. Discussion about this specific side effect and reduction in dose to 20 mg needs to be detailed.

2) 5 of 8 patients with infection during BD induction developed herpes zoster - were they no treated with acyclovir prophylaxis? This needs to be mentioned in the methods section as well as discussion section.

3) 18% of patients developed grade 3 neuropathy during BD induction - this is different than CAN 2007 trial experience. Comment and a discussion about use of subcutaneous bortezomib vs weekly bortezomib

Minor comments:

1) Are the nephrologists doing chemotherapy and stem cell transplants in China for this rare disease? There is no hematologist/oncologist as an author!

2) Background - line 3/4 - amyloid fibrils deposit in the tissues and not light chain fragments

3) Background - 2nd paragraph line 8 - Simple HDM/SCT therapy has many shortcomings, including a low hematologic complete response (CR) rate, a high TRM rate, and frequent relapse. This sentence does not belong in this paper of SCT for AL amyloidosis

4) Background - 3rd paragraph - 1st line - lenalidomide reference needs an update:


5) Why were patients with creatinine > 2 mg/dL excluded?

6) Methods section - 1st paragraph - line 9 - should read Left Ventricular EF

7) Study design - prophylaxis with antiviral and proton pump inhibitors given or not?

8) Hematologic and organ response criteria section of methods - 10th Annual International Symposium on Amyloid and AL amyloidosis - wrong title of the meeting!

9) Results section - 1st paragraph - AL amyloidosis leads to nephrotic syndrome and not nephritic syndrome!

10) Page 12 - should read Mayo and not mayo

11) Reference 27 should be replaced with:

12) references 35 and 36 are the same

13) Soften the conclusions - BD-HDM/SCT appears to be safer than HDM/SCT! Why? How did you reach that conclusion?

14) combine Table 1 and 2 as patient characteristics

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have no competing interests.