Reviewer’s report

Title: Two-stage optimal designs with survival endpoint when the follow-up time is restricted

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Reviewer: Tianmeng Lyu

Reviewer’s report:

In this paper, the author proposed a single-arm two-stage design for survival endpoint with restricted follow-up time. The proposed method uses the exact variance estimates and the author also proposed to adjust the nominal power level in design search to solve the under power problem. Please see the comments below:

1. Does the calculation in the proposed method depend on the assumption that the survival function follows a Weibull distribution? Could the author provide more details about the calculations in the appendix? i.e. how to know the information about $S_0(t)$ and $S_1(t)$? If they follow Weibull distribution, how to get the parameters for the Weibull distribution?

2. Page 4, section 2.1, could you please provide more details of the binary endpoint and also specify the relationship between binary response X and the survival outcome?

3. Page 16, Table 1, please specify what method is used to calculate the results under the column "survival endpoint".

4. Page 5, line 54, according to the appendix, the censoring time $C_i$ is equal to the limited follow-up time. It would be better if that can be clarified in this section as well, otherwise it is confusing whether the method uses limited follow-up time or not.

5. Page 7, line 17, could the author explain the way to determine the range for the critical value $C_1$?

6. Page 7, line 23-38, in these two paragraphs, the "optimal design" for sample size $n$ and the "two-stage optimal design" are mixed together and sometimes could be confusing.

7. Page 7, line 36, what does "identified optimal designs" refer to?

8. Page 8 line 47 - page 9 line 8, it seems that from "The proposed two-stage design..." to "... meet the power requirement" has already been described in the methods section, so I'm wondering if it is needed to repeat this part here since it could be distracting.

9. Page 9, second paragraph, could the author add more details about how to compare a design for survival endpoint to a design for binary endpoint? What is the definition of the binary endpoint and how was it simulated?
10. Figure 1-4, please include the definition of p1 in the footnote.

Minor comments:

1. Page 4, line 48, "promissing" should be "promising".
2. Page 5, line 8, "calcualted" should be "calculated as".
3. Page 9, line 52, "revised" should be "reversed".
4. Page 10, line 20, "follow time" should be "follow-up time".
5. Page 16, Table 1 title, "exponetial" should be "exponential".

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

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

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?
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