

Review report

Final title: Effect of concurrent chemoradiation with cisplatin versus concurrent chemoradiation with carboplatin in locally advanced carcinoma cervix: A quasi-experimental study

Title at submission: Concurrent chemoradiation with cisplatin versus carboplatin in the treatment of locally advanced carcinoma cervix: A quasi-experimental study



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Ethical approval

Approved by IRB of Bangabandhu Sheikh Mujib Medical University (No. BSMMU/2022/8489, dated 28 Aug 2022).

Trial registration number

Not available

Declaration

This article encompasses MD thesis of Dr Syed Md. Asadul Hoque

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Reviewer: Md. Jahirul Islam, ORCID: 0000-0002-8825-1319

Overview

This study compares two chemotherapy drugs for advanced cervical cancer: cisplatin and carboplatin. Both treatments worked equally well. However, carboplatin caused fewer side effects. Patients had less anemia, vomiting, and kidney problems. Other side effects were similar in both groups. These results suggest carboplatin is a good alternative. It may be better for patients who cannot tolerate cisplatin. This study helps oncologists choose safer treatment options.

- 1 **Comment** As a whole it is a good article but some minor issues need to be addressed. In exclusion criteria "eligible participants unwilling to participate" should be included. In result section % sign was used in each line. It should be given once in the heading in parenthesis. Regarding statistical test it was not mentioned which particular test was done (Chi-squared test or Fisher's Exact test). In-text citations should be corrected (indicated in the pdf file).

Response The article is revised as per the comments.

Reviewer: Anonymous

Overview

This article is a Quasi-Experimental Study on treatment response & toxicity pattern of Concurrent chemoradiation with cisplatin versus carboplatin in the treatment of locally advanced carcinoma cervix. Title seems not to be self explanatory. Rationale of the study should be stated. Story telling could have been more precise. Discussion could have been more critical & comprehensive.

- 2 **Comment** Is the title appropriate? = **No**
I suggest the following:
Efficacy of Concurrent Chemoradiation with Cisplatin versus Carboplatin in the Treatment of Locally Advanced Carcinoma Cervix: A Quasi-Experimental Study
OR
Comparison of treatment response and toxicity of Concurrent Chemoradiation with Cisplatin versus Carboplatin in the Treatment of Locally Advanced Carcinoma Cervix: A Quasi-Experimental Study

Response Revised the title to:
"Effect of concurrent chemoradiation with cisplatin versus concurrent chemoradiation with carboplatin in locally advanced carcinoma cervix: A quasi-experimental study"

- 3 **Comment** Is the rationale/justification for conducting the study clear? = **No**
Few lines expressing the rationale to conduct the study in the context of Bangladesh should be added.

Response Added the rationale for conducting the study in Bangladesh on Page 5 (Lines 111-116).

- 4 **Comment** Are statistics used appropriately and described fully? = **No**
Statistics are not described fully.

Response Statistical analysis details added on Page 7 (Lines 179-186).

- 5 **Comment** Is the storytelling straightforward, clear (i.e., does not impede scientific meaning or cause confusion), and logical? = **No**
Line 82 - should be rephrased with clear information.
Line 9 - Please define/ give more information on LACC (?operational definition).
Line 19 & 21 - Please correct grammar/ write full sentence.

Response Rephrased for precision
We defined it in the last of method section (Lines 188-191).
Grammar and sentence structure have been corrected.

Reviewer: Md. Nazmul Hasan , ORCID: 0000-0002-5737-5124

Overview

The author had tried to do a clinical trial comparing two treatment for advanced cervical carcinoma, one was cisplatin based(standard treatment) another was carboplatin based(comparing arm). The final outcome showed two arm showed similar efficacy but, carboplatin arm showed less side effect profile. However, the study design was weak to prove this kind of comparison, a RCT would be appropriate. Odd ratio or Hazard ratio could have been considered with CI along with p value to express the level of significance.

6 Comment Is the title appropriate? = No

The title is not consistent with the objective of the study. The title "Concurrent Chemoradiation with Cisplatin versus Carboplatin in the Treatment of Locally Advanced Carcinoma Cervix: A Quasi-Experimental Study" it seems the author was trying to compare between chemoradiation with cisplatin and only carboplatin actually they have compared chemoradiation with cisplatin vs chemoradiation with carboplatin. So, title should be representative of the actual work.

Response

Revised the title to:
"Effect of Concurrent Chemoradiation with Cisplatin versus Concurrent Chemoradiation with Carboplatin in Locally Advanced Carcinoma Cervix: A Quasi-Experimental Study"

7 Comment Does the abstract provide a complete and accurate description of the content of the article? = No

Method section of the abstract is inadequate. The outcome variables are not mentioned and statistical test to prove the hypothesis need to be mentioned. Follow up schedule should clearly be mentioned

Response

Follow-up schedule added in the method section of abstract (lines 53-55)
Statistical testing part is described in discussion section. If we add statistical tests in abstract, 250 words limit will exceed.

8 Comment

1. How many patients were screened , not mentioned within the text
2. How the sample was calculated not mentioned?
3. Nothing is mentioned about the margin of lost to follow up and mitigation measures of loss to follow up.
4. How the hypothesis was tested is not mentioned.
5. In a clinical trail, only p value can not be a measure of level of significance.
6. Outcome variables should be clearly mentioned
7. Intension to treat or per protocol analysis , which one or both had been considered.

Response

1. We mentioned it on study design and treatment section (Lines 138-139)
2. Sample size calculation added in page 5
3. Added on page 5 (Lines 123 -124)
4. Included in Statistical analysis section on Page 8
5. We responded about it on your feedback 1.
6. Included on Page 7 (line 153)
7. Per protocol analysis was done. Included in Statistical analysis section (lines 185-186)

9 Comment Is the study design robust and appropriate to the stated objective(s)? = No

1. Quasi-experimental study is not a proper study design to see this type of drug effect.

Response

While an RCT would provide more evidence, budget constraints and ethical concerns prompted a quasi-experimental approach. We addressed its limitation on discussion part.

10 Comment Are statistics used appropriately and described fully? = No

1. To compare of effect of two drugs only P value is not enough
2. Name of statistical is not mention any where either within the text and footnote of the tables.
3. Comparison between some value may not be appropriately expressed as sample value is very low like only 1 or 2 for some of the variables.

Response

1. We responded about it on your feedback 1.
2. Statistical tests are added in footnotes of every table.
3. Fisher exact test was done because there are small values to compare.

- 11 **Comment** Replace the Highlights with a key message in descriptive terms in 50-60 words.
- Response** Replaced with a key message on page 3.
- 12 **Comment** The introduction section should rationalize the standard treatment and the treatment under examination. Specify which statistical analysis was done for which variables instead of a generic statement. What ethical measures were taken during the study?
- Response** Definition of partial and complete response per RECIST criteria included on Page 7 (Lines 158-162). Statistical analysis details added on Page 7 (Lines 179-186). Ethical considerations addressed on Page 7 and 8 (Lines 166-177)
- 13 **Comment** Results:
Recruitment is very straightforward, which could be described without the help of the flowchart.
Table 1: Please P values to compare the baseline characteristics of the patients. It has implications in subsequent analysis.
Table 2: Explain in the footnote what is complete/incomplete response.
Merge 3-5 because they carry the same message. These are not primary outcomes either. I suggest comparing grade 0 with ≥ 1 for all variables because grades ≥ 1 have very small numbers.
- Response** Recruitment process is described on Study design and treatment section of methodology on page 6.
Added p-values in Table 1 for baseline characteristics.
Explained complete/incomplete response in Table 2 footnotes.
Merged Tables 3 and 5 into a new Table 4; However, we retained separate grading for toxicity due to clinical relevance.