OPEN PEER REVIEW

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What is "Open Peer Review" process?

An "Open Peer Review" process is making the details of all review process (including reviewers, associate editors, and EICs comments) as "Public" as it is agreed by EIC, Authors, and reviewers.

Advantages of "Open Peer Review" process

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- Education of both authors and new students
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You can find out more at:
https://brieflands.com/briefland/knowledgebase/category/tree.html#opr.html

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Peer Review Report for "Association of Leukemia and Congenital Heart Disease in Patients with Down Syndrome"

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Review Timeline:

Submit Date: 29 Jul 2019
Revised Date: 7 Dec 2019
Accepted Date: 20 Dec 2019

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | **Revision** (0) — 7 Nov 2019

Dear AE,
The manuscript is a retrospective study with an evaluation of the patients' records. The report of this study as short communication recommended because limitation of analysis data. It is recommended to add limitation of study like small numbers, retrospective study.
Thanks.

REFEREE: Reviewer | **Revision** (0) — 11 Nov 2019

Dear AE,
This paper sounds good. Reviewing the statistics of the manuscript needs to be written in more detail.
Thanks.

REFEREE: Reviewer | **Revision** (0) — 13 Nov 2019

Dear AE,

The authors have performed a retrospective descriptive study on 118 patients with Down syndrome over an eight year period. They have concluded that angiography increased the incidence of leukemia in children with Down syndrome, whereas, their study method does not support this conclusion.

Below kindly find the comments that should be addressed:

1. A table on demographic characteristics of the patients should be added.

2. In Table 3, p=0.078 refers to patients with leukemia and those without leukemia . Authors should write the statistical test and then mention the P value. For with and without angiography, they should put the same P that they have mentioned in the abstract that is > 0.05.

3. There is only 6 child with leukemia , four of which had angiography. Whereas,29 patients with Down syndrome had angiography but did not develop leukemia. How did the authors conclude that:" history of angiography may increase the leukemia incidence. "

For such a conclusion, the authors should have adequate number of patients in two arms:

Group 1: patients with Down syndrome, congenital heart disease who have not undergone cardiac catheterization and angiography

Group 2: patients with Down syndrome, congenital heart disease who have undergone cardiac catheterization and angiography.

Then compare these two groups with an appropriate statistical method and to see whether there is any significant difference between the frequency of leukemia between these two groups.

The first shortcoming is that study design is not right and should be revised.

The second problem is that the study population in each group is not enough to get any reasonable conclusion.

Furthermore, the authors state:

" Two cases had leukemia without CHD. The odds ratio of leukemia in patients with Down syndrome, in association of congenital heart disease, and in patients who had history of angiography were 1.79 and 2.79 respectively (P> 0.05)." . Then they conclude that angiography may increase the incidence of leukemia. These two statements are not in concordance with each other.

4. The dose of radiation should be mentioned.

5. How many of patients underwent interventional catheterization? What were the interventional procedures? How many of those with interventional catheterization developed leukemia?

6. What was the time period between the cardiac catheterization and angiography and development of leukemia?

7. Before stating the P value, the statistical test that was used should be mentioned.

8. A brief note on statistical analysis should be added to the abstract.

9. Typographical errors like " ASD secondum" should be corrected.

10. Grammatical errors should be corrected.

Regards

REFEREE: Associate Editor | **Revision** (0) 21 Nov 2019

Dear EIC,

The manuscript is studied, and there are some comments which should be addressed by

the author. According to the comments, the document needs major revision.
Kind regards,

REFEREE: EIC | **Revision (0)**

21 Nov 2019

Dear Authors,
Thank you for submitting your manuscript to Iran J Pediatr. Your manuscript has now been reviewed by three reviewers and an Associate Editor. I now have the reports of the Referees, which suggest that your manuscript might be suitable for publication following a number of revisions. I attach some reviewer comments and invite you to submit a revised version of your manuscript addressing the points made.
Regards

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear Editor in chief

The following changes were made, according to reviewers' comments:

1. The net numbers were changed to percentages and expressed in text and tables.
2. The increased risk of leukemia in CHD cases with Down syndrome after angiography were calculated with Odd's ratio, and expressed with Confidence interval. The CI level of P>0.05 was considered as reliable.
3. Increased risk was not reliable if P value = 0.078, so this was expressed in the text, but according to its clinical importance, this was emphasized.
4. There were no other demographic data except sex and age in the patients' documents, so these data were added to the text, and new table was not drown.
5. According to the request, angiographic data were added
6. Due to incomplete TOF diagnostic criteria in some cases of AVSD/TOF, these patients were classified as AVSD group, and TOF cases were listed separately in table 3.
7. Limitation of study was added to the manuscript. In this section, the author emphasized that the duration of angiography and the radiation dose in patients were not known. In addition, it was stated that some of demographic data are incomplete.
8. Grammatical changes applied.
9. Abbreviations were corrected, and applied in text and tables.
10. Typographical errors were corrected.
11. 10 deceased cased, who also had the history of angiography but not had good follow up, were added to the text.
12. Funding support was added to the text.
13. Authors contributions was added to the manuscript.
14. Based on the above changes, conclusions were applied to the text and abstract.

Thanks for your kindly attention

Hossein Esfahani

07.12.2019

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Revision (1)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Associate Editor | **Revision** (1) 20 Dec 2019

Dear EIC,
The authors have modified the manuscript accordingly and have provided specific answers in an accurate manner. I suggest that this version is suitable for publication in the Iran J Pediatr.
Thanks.

REFEREE: EIC | **Revision** (1) 20 Dec 2019

Dear Authors,
The second round of peer review of your manuscript has been completed, and I am pleased to inform you that your manuscript has now been accepted for publication in our journal.
Thanks.