Reviewer's report

Title: Epidemiological characteristic of Orofacial Clefts and its associated congenital anomalies. Retrospective study

Version: 1 Date: 02 Oct 2018

Reviewer: Najlaa Mohd Alamoudi

Reviewer's report:

Reviewers Comment:

Title:
If you can change the article title to be "Epidemiological characteristic of orofacial cleft and its associated congenital anomalies"

Abstract:
The aim to be change to two points which include:

1. The prevalence of orofacial cleft

2. The relationship between gender, ethnicity, citizenship, clinical phenotype and the various congenital malformation associated orofacial cleft in Italy across the period 2001-2014.

In the abstract or title you have to mention in the type of study that was used (population based retrospective study).

Conclusion: The first statement is good

- Need more conclusion to be included

- The last statement need to be removed (We have also reviewed OC patients' clinical management and their multidisciplinary therapeutic needs and approaches.)

Introduction/Background:

1. Rational of the study was not mentioned

2. Aim need to be corrected as mentioned in the abstract section of aim.

3. The background is short need to be increase.

4. The paragraph statement from line 19 page 3 (In addition to the one outcome from EUROCAT) until the end need to be added in the Materials and Methods section.

5. Also this abbreviation EUROCAT need to be written in full name in this section
Materials and Methods:

1. Add IRB approval number in this section.

2. Explain more, how the data was collected e.g by single author or more and inter and intra-examiner reliability test was done or not?

3. Please explain and give an idea about ICD9 or ICD 10 code and what is the difference and why you choose ICD 10 code

4. How the data were interpolated, explain.

Results:

- Title of the tables should be place on the top of the table.

- Figure 2 and 3 the legend should be on the bottom

- Figure 2 and 3 legend is not clear please illustrate and correct. Vertical and Horizontal axis should have the proper name of the comparing group.

- Please mention the detail in the figure.

- Occurrence prevalence rate of OCS in live birth, still birth and TOPFA is not clear.

- The statement in line 13 page 7 (the proportion in rate diagram ...........) the statement was incomplete, no verb, what did the authors want to say. Please edit.

- The word casuistry (please explain) more.

- Line 28 Page 7, Explain your calculation on the prevalence rate of single OC.

- You mentioned that the multiform syndromic and chromosomal, the CLP had the highest rate 50% followed by CP 35%. But the highest of it is CP.

- Within the table 4 there's a column label MCA NOS tot, Please removed it as it is confusing as you have already the total of 112*.

- Line 1 page 9, (The four major and most represented statistical categories were cardiovascular defects........) Please correct in the paragraph the percent of major associated anomalies in descending order.

- In Line 51-52 page 9, table 5, ventricular septal defect, has to be corrected in this table with the percent accordingly. Please also add the percent in the table.

- Line 19-34 page 10 Please clarify the statement in the paragraph.

- Line 5 Page 11, table 6, Please write the title properly . The table should be self-explanatory.
- Line 8-9, Page 12, the table should include information about table 6, but the author mentioned here about the table 4.

- Line 13, Page 12 Please explain, (among which MCA (first) and Pierre Robin sequence/syndrome (PR) (second) were the most commonly observed.) The table does not include any information about the Pierre syndrome.

- Line 20 Page 12, the author mentioned the reference 4, that should be written in discussion not in the result section.

- Line 30 Page 12 No information about PR syndrome.

- Line 30-39 Page 12, I cannot match the percentage of the data in this page with the results of table 6.

Conclusion:

Line 9-10 Page 18, (We have also considered OC patients' clinical management and multidisciplinary therapeutic needs) There is no data presented about it. Its either you removed it or edit it.

List of Abbreviation

Add the abbreviation and full name of EUROCAT

Declaration

Add the ethical approval number

Figure Captions:

Figure 2 and 3 in the legend should be corrected.

Figure 3 10.000 -is it 10 or 10,000 or 1,000?? What is this decimal?
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.

No

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

No

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 am able to assess the statistics

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

Needs some language corrections before being published

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