Peer Review File

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Reviewer A

Thank you for the opportunity to review your work. It has been interesting to see your findings. However, I cannot recommend this submission for publication in its current form. The main issues are:

1. How relapse is presented - Relapse of deformity can present after successful Ponseti treatment. Factors associated with relapse have been explored in the literature - what is interesting to present are those specific to your own patient population.
   Reply: We have modified the data, see Relapse definition and highlighted box. Ponseti method is one the most following technique in the Clubfoot Department, Medical Teaching Institute, Lady Reading Hospital Peshawar to successfully correct clubfoot deformity. However, like others developing countries ponseti method entails a relapse rate also here in Peshawar. A relapsed clubfoot patient becomes burden on the parents, hospital and government because he/she has to repeat ponseti method again i.e. casting and maintenance. In most cases parents quit the treatment due to stress, anxiety and depression. As a result these people gradually move towards disability and suffer socially (by stigmatizing) and financially (unable to get normal jobs etc). Societal and treatment burden can be decreased-even ended- if the relapse causing factors are better understood. A lot of literature is available on the efficacy of ponseti method in management of clubfoot in Pakistan; however a space is present in the awareness and understanding of the risk factors associated with relapse after ponseti method. Therefore it is important to find out the background factors of the relapsed clubfoot. This study is intended to determine the risk factors that lead to relapse. After finding these factors, this study will help the health sectors to design strategies regarding future prevention.

2. Be careful of your language when describing association and risk. Statistical analysis only gives an association not an absolute yes/no. You can only identify an association, significant or not.
   Reply: Modified it

3. Your methodology needed some more robust references for identification of compliance and relapse. The Pirani score is generally not the best tool to assess relapse in older children. What was the age range of your cohort? It is useful to the reader to give some of your patient demographics, such as average Pirani score, age of starting treatment, how many casts, tenotomy rate, and average length of brace compliance. What brace did you use? All of this helps the reader to understand your patient group.

I think the results table is too simplistic and needs more detail. You need to justify your use of the chi-squared test by reporting on whether your data were normally distributed or not. Chi-squared is for binary categoric data so with parent's education level you may have used another test?

Reply: Clubfoot department LRH Peshawar uses only Pirani scoring system. Foot Abduction Brace is used in Clubfoot department. The data is not normally distributed. I think we can also use Chi-sqaure test to find association of education level with relapse. This statistical analysis was approved by Khyber Medical University Advanced Studies & Research Board.

4. There are a few issues in terms presentation of some alternative views from accepted international consensus on factors associated with relapse and ponseti treatment. I think this all needs reworking.

Reply: Views are presented along with the references.

5. I think there is a good paper here but needs a significant rewrite with a better understanding and appraisal of the existing literature base, a review of results and presentation of raw data. I would focus the rewrite on what treatment, relapse and factors influencing this are for your specific patient cohort and why this might be similar or different to other centres. - see attached submission with comments

Reply: I have visited three different clubfoot centers in Peshawar, Pakistan. This the only center that has focused on stretching exercises along with other variables. Distance is another factor that may impact the treatment protocols.

Reviewer B

Thank you for the opportunity to review this manuscript which explores the rate of relapse in a population in Pakistan. I would like to commend the authors for this detailed retrospective review on an important topic.

There are areas which can significantly improve this manuscript:

1. The length of follow-up is recommended. Gelfer et al in a recent systematic review noted that relapse rates increased with length of follow-up. Quantifying the time to relapse will also allow for a direct comparison to the relapse rates in the literature.
   Reply: added in the revised manuscript, see methods

2. Definitions earlier in the manuscript would benefit - several of these were well identified in the discussion such as stretching protocols.

2. Line 124 noted that Pirani Score >0 was defined as relapse. Often a score of 0.5 -1 is present at the end of treatment (e.g. empty heel 0.5). It may be worth considering if relapse could be overestimated in this population compared to other populations.
   Reply: Redefined it

3. The results section would benefit from further statistics in the text, or it may be worth signposting Table 1 at the start of the results section.
   Reply: Added in the results.

Further exploration of rate of relapse is recommended:

5. What was the age of first relapse? Is relapse calculated per foot or per participant?

Are some of the relapses subsequent relapses? E.g where a child has multiple relapses. This can artificially inflate the results - so the relapse rate appears higher, however more relapses are taken up by one individual.

> **Reply:** The mean age of relapse clubfoot is 3.60 ±3.3 months. Relapse is calculated per foot. Multiple relapses have taken as a single relapse. Modified and revised.

Minor:

6. Suggest avoiding the term 'babies' e.g. Line 23: studied all babies - this manuscript was noted to also cover those who were walking age. Consider changing to children.

Reply: Corrected

7. The abstract and key findings presented new information after the results. E.g. Conclusion abstract: Late treatment, Key findings - living area.

Suggest ensuring key findings are covered in the results first.

Reply: Corrected.

8. Line 70 notes: early relapse. Suggest providing a definition for 'early' feedback.

Reply: Corrected.

9. Line 76: noted length of stay: this requires greater detail. Is this related to overall length of initial casting treatment?

Reply: yes, it's total duration of casting treatment.

10. Line 103 - noted first phase of treatment. Suggest defining what is comprised of in this phase.

Reply: First phase means casting phase. Corrected.

11. Line 105: Inclusion criteria number 5 is not required as it is covered well with Inclusion criteria number 1.

Reply: Corrected.

12. Exclusion criteria noted well. Consider if atypical clubfoot was included or excluded.

Reply: Excluded

13. Line 168: Morcuende requires spelling check.

Reply: Corrected.

14. Line 174: you noted that non-compliance is not wearing brace 75% of time. It may be worth noting if you followed this definition for your study. If not, suggest revising the sentence to state that other studies have used this definition.

Reply: See references 14 and 15.

15. Paragraph from Line 180: There are some contradictory statements including 'started as soon as possible', less than 6 months of age, less than one year of age. Suggest revising this paragraph.

Reply: Corrected and revised.

16. Sentence at Line 197-198: Our study also found that low level of parents....etc. appears repetitive in this paragraph as was well covered in the opening sentence of that paragraph.

Reply: Corrected and revised.

17. Sentences: Line 210-213: the last two sentences of this paragraph would benefit from referencing.

Reply: Added.

18. Suggest review throughout for grammar. There is a change between past and present tense which would benefit from review throughout.

Reply: Corrected and revised.

19. Table 1: Consider changing the heading "Normal Clubfoot' to? Non-relapsed clubfoot.

Reply: Corrected and revised.

Reviewer C

Thank you for allowing me to review the manuscript. It was very interesting. I have several comments.

1. I understand that English is likely not the author's mother tongue. However, there are many grammars and English errors that need to be addressed. I suggest having it reviewed by a native English speaker.

For instance, in the title there are 2 "the" before ponseti. Ponseti should be capitalized, as well as Peshawar and Pakistan.

Throughout, rather than say The Ponseti Method, it should rather be "the Ponseti method."

Reply: Corrected and revised.

3. Abstract, line 19 – CTEV is more than a muscular abnormality; the bones and soft tissues (tendons/ligaments) are also involved.
   Reply: Corrected and revised.

4. Highlight box: Line 43 – delete etc. at the end of the sentences
   Reply: Deleted

Introduction

5. Lines 60 to 62 – the authors quote an incidence of 1.24 per 1,000 births worldwide. Do the authors have an incidence in the peoples of the Peshawar area? That would be interesting to include if it is known.
   Reply: No literature is present on this.

6. Line 75 – what is meant by social security? Is that socioeconomic status?
   Reply: Yes.

7. Line 95/96 – don't need to say Excel sheet. Just say they were recorded.
   Reply: Corrected and revised.

8. Lines 107/108 – who determined if they were a neurogenic or syndromic clubfoot? And how where they defined as such?
   Reply: Pediatric orthopedic surgeon determined if they were a neurogenic or syndromic clubfoot.

9. Line 114 – just say “The Pirani score measures six clinical signs of contracture”
   Reply: corrected

10. Line 186 – do you mean as the child gets older?
    Reply: yes

10. Line 205 – What is Kelly Gray B? A reference/author? Please clarify and include in the references if a published study.

Reply: An author, see reference number 25

11. Line 222 – do you mean “babies parents”?
Reply: Children parents.

12. Line 230 – please include the reference number of Sheta et. al.
    Reply: reference number 31.

13. Table 1: What is meant by a p value of 0? Is it < 0.001, 0.0001, etc. Please clarify. Also, for most p values simply report to 2 digits, ie. 0.118 would be 0.12, etc.
    Reply: corrected and revised.

14. What is meant by matric education level? And was the level of the mother or father, or the highest for either the mother or father?

Reply: Secondary School Education.