Author's response to reviews

Title: Laryngeal Mask Airway for neonatal resuscitation in a developing country: evaluation of an educational intervention.

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Author's response to reviews: see over
Dear Editor,

thank you for your letter for your and the reviewers’ comments concerning our manuscript: ‘Laryngeal Mask Airway for neonatal resuscitation in a developing country: evaluation of an educational intervention’.

After carefully considering all of the comments and suggestions made by yourself and the reviewers, highlighted in bold print, we have thoroughly revised the manuscript making all appropriate modifications and corrections. We are now submitting the revised manuscript for your evaluation and, hopefully, publication as a original article in your Journal. I am also sending you, here attached, a detailed point-by-point response to the reviewers’ comments. We would like to take this opportunity to thank you and the Reviewers for your efforts to improve the manuscript and for the time that you have and will dedicate to our work.

Point to Point Response to the Editor and Reviewers of Birth.

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Laryngeal Mask Airway for neonatal resuscitation in the developing countries: evaluation of an educational intervention.
Vincenzo Zanardo, Alphonse Simbi, Massimo Micaglio, Francesco Cavallin, Leon Tshilolo and Daniele Trevisanuto

Dear Prof Zanardo,

Your manuscript has now been peer reviewed and the comments are accessible in PDF format from the link below. Do let us know if you have any problems opening the file.

Referee 1:
1. Major Compulsory Revisions
1.1 The title promises more than it delivers and should be more specific to the topic that is actually covered in this paper, which is around training of TBA’s.

The new title, as you can see, is: “Laryngeal Mask Airway for neonatal resuscitation in a developing country: evaluation of an educational intervention”.

1.2 The description of the methods is generally very unclear. It is not clear what is the difference between the five items and the twenty nine questions and how they relate. It is also not clear what is the relationship between the 28 TBA’s, the 21 medical personnel and the 7 non-medical personnel. It seems to be implying that
the 21 medical personnel are TBA’s which does not make sense. Later on they are referred to as physicians. It is also not clear what a non medical TBA would then be in this case. This needs to be clearly explained in detail.

We have rewritten that section and now it is hopefully simplified and clear.

“A 3-day NRP course was held in the CEFA, Kinshasa, the Democratic Republic of Congo (DRC), in September 2006. The course consisted of a number of didactic sessions proportionally divided into the seven steps of the NRP: (i) principles of resuscitation; (ii) initial steps in resuscitation; (iii) bag mask ventilation; (iv) chest compressions; (v) tracheal intubation; (vi) medications; and (vii) special considerations (3), followed by practical on-hands skill stations, including LMA positioning and bag-ventilation in a neonatal manikin (Neonate Airway Trainer; Laerdal, Norway).” (Patients and methods section, first paragraph).

1.3 It is also not clear why the places of origin of the 7 non-medical personnel are given and not the others.

As explained above, the manuscript has been rewritten and we have listed where all of the participants were coming from.

“Twenty-eight local birth attendants, (21 physicians and 7 midwives) from the Congo Brazzaville (1), Benin (1), Camerun (1), and the remaining all from DRC, participated in the course/workshop.”

1.4 Further on there is also reference to a 25 item questionnaire derived from the Neonatal Resuscitation Manual but it is not clear how this relates to the 5 plus 29 items referred to in the first paragraph.

Again, the manuscript has been rewritten to clarify these points.

“All of the participants took a 28 question test, an adaptation of a standard one contained in the AHA/AAP Neonatal Resuscitation Manual (3) and a practical trial evaluating their proficiency in managing LMA both before and after the course (11). The participants had 60 minutes to complete the test, which included multiple choice, fill in, and true/false questions. The test, which was written in French, was strictly supervised.”

1.5 The description of the statistical analysis does not make sense, especially the first line in that section. Also the broader question that comes in here as alluded to earlier is who the physicians were compared to the TBA’s and how the physicians fitted into this evaluation.

We have eliminated the term TBA’s as its meaning can be misconstrued. Please, see at item 1.4.

1.6 Under Results, the 21 medical and 7 non medical TBA’s again need to be clarified.

Again, TBAs have been eliminated. Please, see answer at item 1.4.
1.7 The comment in the second paragraph about knowledge gained being very impressive is not appropriate in the results section and should be in the discussion.

The paper has been rewritten and now should be in the correct order.

1.8 The different number of correct answers with different tests which then increased and the relevance of the two different tests is not clear to me. Why in such a simple study is it necessary to use two different statistical tests and not decide to use one and justify that?

Bonferroni’s adjustment was adopted after the McNemar test to support the analysis of results regarding the two different groups of participants.

1.9 In Discussion, the arguments made about perinatal and neonatal deaths in developing countries occurring in the home are only relevant if this is made on the basis of the fact that TBA’s are in attendance in these homes as therefore it is worth training the TBA’s. However, most of these presumably were not in the presence of TBA’s so it is not clear what the argument is that is being made here.

This is true. There is no point in talking about home births if the birth attendants are not in the home. This part has been eliminated.

1.10 It is stated that the LMA cannot be considered a substitute for other basic equipment, but what other equipment is being referred to? Will a bag and mask alone not make a big difference and possibly bigger difference than LMA’s?

This part of the Discussion has been rewritten.

“There is also evidence that mouth-to-mask and bag-and-mask resuscitation are comparable techniques with regards to neonatal mortality and morbidity. The evidence that room air (26,27) and mouth-to-mask could be satisfactory used for neonatal resuscitation (28) suggests that firstly, it is reasonable to promote the basic elements of resuscitation of newborn resuscitation, as routine part of newborn care. Meanwhile, where feasible, all birth attendants should be trained to provide positive ventilation with other conventional methods currently used in neonatal resuscitation, bag-and-mask or bag-and-LMA ventilation.”

1.11 In the third paragraph there is repetition of results and there is a section of that paragraph which has little relevance.

We have rewritten that part of the work.

“We evaluated by a survey questionnaire the capability of learning and properly using in a manikin model LMA by trained physicians and midwives.” (Discussion section, second paragraph).

1.12 In the 4th paragraph the statement “the feasibility of sealing up this approach is unclear” does not make sense.

The statement has been removed.
1.13 In the same paragraph there is a statement about feasible and cost effective approaches for community level providers but it seems that the discussion does not address this issue at all.

Again, we have removed this part of the test.

1.14 In the last part of this paragraph there are 2 statements which appear to be in conflict, namely the statement that mouth to mask and bag and mouth resuscitation are comparable techniques compared to the following statement that mouth to mask is satisfactory. Then the jump from that to the suggestion that staff training alone and LMA’s may be sufficient is a logical leap which does not make sense to me.

This part of the discussion has been rewritten.

1.15 In the next paragraph the statement is made that less skill is required to achieve and maintain effective PPV with the LMA but it is not clear in the literature referenced who was using the LMA and what level of skill is needed in order to achieve that. In this study there is no attempt to measure whether the LMA could use sufficient and effective PPV.

Again, that part has been rewritten and the appropriate reference listed.

“The LMA may offer many practical, cost-effectiveness, and sustainable advantages over the face mask for TBAs and also for community health workers in developing countries. LMA allows a low pressure airtight seal against the glottis (11,12) and studies on the efficacy of ventilation by medical and paramedical personnel in neonatal training models have shown that the LMA combines ease of insertion and adequate airway patency in a short time (17).“ (Discussion section, fourth paragraph).

1.16 In the tables, it is once again however not clear why such complicated statistics are used for something that is so simple.

See answers at items 1.5 and 1.8.

2 Minor Essential Revisions

2.1 In the introduction the use of the word “nevertheless” in the first paragraph does not make sense.

The text has been rewritten.

2.2 Also the sentence at the end of the first paragraph about the neonatal resuscitation program and the American Heart Association does not make sense. It seems that this has been broken into two sentences accidentally.

The text has been rewritten.

2.3 The paragraph at the end of the introduction also does not make sense because of language issues.
The text has been rewritten.

“The aim of this study is to assess the knowledge gained by local birth attendants (physicians and midwives) who participated in a NRP course and workshop on LMA organized for local birth attendants in the Democratic Republic of Congo.”

2.4 Under “Methods”, CEFA should be explained.

“CEntre de Formation et d’Appui Sanitaire.”

2.5 The term “Congo Republic” is not one that is normally used; it should be “Democratic Republic of Congo” or DRC.

Ok: see item 2.3.

2.6 In the first paragraph under Methods there is a reference to the AHA Neonatal Resuscitation Manual but reference number 2 refers to the International Liaison Committee’s consensus. I think this reference is thus incorrect.

Ok. This has been corrected (3).

2.7 The second paragraph under Methods needs some language work.

The section has been rewritten.

2.8 In the same paragraph it is stated that “prior to this training in NRP was largely theoretical by a certified NRP instructor”. It is not clear whether this is referring to the same course or to previous courses.

The section has been rewritten.

2.9 There is a statement in the next paragraph that participants “took the 2 test examinations under standardised conditions”. What does this mean? Also, what was the language of the test?

The section has been rewritten. See item 1.2

2.10 It is not clear what “ease and positioning insertion time” refers to.

The section has been rewritten. Please, see next item 2.11

2.11 It is also not clear how “the degree of approval, sustainability and cost effectiveness” were tested.

They were not tested. We asked the participants to express their opinion about these characteristics.

“The theoretical test was followed by a mannequin demonstration trial during which the trainee was asked to attempt LMA insertion in less than 15 seconds (defined as evidence of effective lung / thorax expansion). Finally the participants were asked to anonymously
express their opinion about their degree of satisfaction (high/low) with the course, and the sustainability and cost-effectiveness (yes/no) of LMA in their respective countries.”

2.12 The last paragraph in the results section is also not clear.

That section has been rewritten.

“The practical trial on LMA revealed that the physicians and midwives were skillful in their attempts at LMA insertion. One physician and one midwife failed, respectively, 3 and 2 times to insert LMA correctly. All the midwives and physicians, with the exception of one, expressed a high degree of approval with regard to neonatal resuscitation by LMA, and considered it sustainable and cost-effective in their own country. Table 3”

2.13 There are some errors in the tables (one is called a figure and the other one a table but I presume they should both be tables).

OK. They have been corrected.

2.14 In Table 3 there is also a spelling error in “attempts”.

OK, amended.

2.15 The table is difficult to understand the way it is laid out. It is not understood what is meant by the figures given next to attempts to successful insertion under the two columns and also what is meant by the ratios given under degree of approval i.e. 20/1 and 7/0.

Table 3 has been improved. Please, see item 2.11.

3. Discretionary Revisions

3.1 The section has been rewritten.

“The knowledge and the practical skills in neonatal resuscitation using LMA that was learned by the participants (physicians and midwives) at a neonatal resuscitation course/workshop are outlined in Tables 1 and 2.”

“In addition, the degree of approval by physicians and midwives of the neonatal resuscitation by LMA and their opinions on his/her sustainability and cost-effectiveness are reported in Table 3.”

3.2 The first line of the discussion needs to be reworded.

The section has been rewritten.

“Neonatal mortality, amounting to an estimated 4 million deaths worldwide each year takes place, in 98% of cases, in developing countries. ...”

Referee 2: 
Reviewer’s report
The authors report on lack of knowledge in use of LMA for neonatal resuscitation. The aim of their study was to test the capability of learning and properly using LMA in a mannequin model. Despite the undoubtable importance of the issue addressed by the authors, data lack from originality and are not clearly presented.

Major comments:
- there is a real difficulty to understand the background for the group construction and the content of the 3-day NRP course.

The section has been completely rewritten.

"The course consisted of a number of didactic sessions proportionally divided into the seven steps of the NRP: (i) principles of resuscitation; (ii) initial steps in resuscitation; (iii) bag mask ventilation; (iv) chest compressions; (v) tracheal intubation; (vi) medications; and (vii) special considerations (3), followed by practical on-hands skill stations, including LMA positioning and bag-ventilation in a neonatal manikin (Neonate Airway Trainer; Laerdal, Norway). (Methods section, first paragraph.)

- although described in the methods part, I could hardly understand what the tests were about.

As explained above, this section has been rewritten. See answer to Referee 1 at item 1.2

- the results part needs further revision. Especially the tables need to be revised concerning content and style (Table 1 is named "Figure 1", presents typing errors, illustration of significance ist NOT in congruence with the written part).

Table 2 uses abbreviations that were not defined before (FM,TI). Table 3: the content is unclear: insertion time remains unreported (except for those needing >15”), I do not understand the meaning of cost effectiveness.

Revision was done, i.e. on abbreviations, insertion time, and cost effectiveness. These improvements were also required by Referee 1. See next item and previous item 2.7 and items 2.13-15.

- I could imagine that statistics need either revision or clear demonstration of data: there is incongruence between the written part and what is shown in table 1.

The incongruence was amended, as required also by Referee 1 at item 1.5 and 1.8 and with a more clear demonstration of the results data in the Tables.

“Compared with the initial score, the overall knowledge gained by trained physicians and midwives who participated to a NRP course and to a workshop on neonatal resuscitation
by LMA increased, but with different percentages in the single questions constitutive the five steps, concerning: (I) features of the LMA; (II) LMA advantages over the face mask; (III) LMA advantages over endotracheal tube; (IV) LMA disadvantages; and (V) potential applications in neonatal resuscitation.” In particular, physicians …Table 1

“The “improvement”, defined by the number of correct answers in post-test coupled with a wrong answer in pre test, was statistically significant for physicians and midwives in all the five steps, except for the midwives that defining the “disadvantages” of LMA. The “improvement”, defined by the percent of correct answers in post-test coupled with a wrong answer in pre test, was statistically instead statistically significant for physicians in the steps reporting the advantages of LMA over the facial mask (p<0.02) and the potential applications of the LMA (p<0.005). Table 2”

- The Discussion reflects more the general aspects about the LMA than the results raised by the authors! There is need of more detailed discussion about the training program, the results (e.g., table 1 and 2 only describes theoretical knowledge) and the practical improvement of the subjects.

This was done in a new more detailed paragraph to discussing the training program, the results, and the practical improvement.

“In this study, we proved the capability of learning and properly using in a manikin model LMA by trained physicians and midwives, trained in a developing country to a NRP course and to a workshop on LMA. The knowledge gained by the physicians in the single questions and those included in the five steps, related to the features of the LMA, his advantages and disadvantages, and his potential applications in neonatal resuscitation, was superior than that achieved by the midwives. Physicians significantly increased in the post-test the overall number of correct answers. The “improvement”, as number of correct answers in post-test coupled with a wrong answer in pre test, was statistically significant in all the five steps in the physicians, and in four steps in the midwives, missing improvement on the knowledge of the “disadvantages” of LMA. Again, the “improvement”, defined by the percent of correct answers was statistically significant only in two steps related to the advantages of LMA over the facial mask and the potential applications of the LMA. These differences could account of the scientific and practical background and practical skills of the physicians, skill frequently required in delivery and/or surgery room. Manikin-based comparative practical skills on LMA insertion showed instead, a similar high efficacy between trained physicians and midwives, in terms of number of successful attempts and of time for placement. Unanimously, midwives and physicians, except one, also manifested an high degree of approval of the neonatal resuscitation by LMA, giving a positive evaluation of his/her sustainability and cost-effectiveness in a low income country.”

- Why was a positioning time of 15``used as a cut off? What was the mean insertion time? How did the authors prove correct placement?

This was explained. See item 2.11

- From my point of view, there are more limitations that should be addressed:
  --> Results of 28 TBAs is a small number,
practical improvement can only be shown fragmentary

These two statement were included in the limitations of the study.

“The gained knowledge and manikin skills improvement is related to a small number of TBAs and may be fragmentary and it is not verified in the asphyxiated neonates in delivery room and nor in the community.” (Discussion section, last but one paragraph).

I have concern about assessment of correct placement: did the authors measure gastric regurgitation? Did they measure tidal volume?

This was amended. Please, see Referee 1, item 15.

Minor comments:
- The manuscript is heavily worded. The information presented could be presented a lot more succinctly.

OK, the manuscript has been revised and shortened, according also to the other suggestion of Referee 1 and Referee 3.

- Introduction is too long. Especially ll. 5-13 on page 2 ("In 1981, Archie Brain designed..") are too general and without relationship to the purpose of the study

OK, the manuscript has been revised.

- The authors have duplicated the information in the results (table 1) and the supplement file. May be it could be interesting to show the MC test which they report in the methods part but which is not shown.

This was included in the revises text. Please, see Referee 1, item 8.

- pages should be numbered.

OK

Reviewer’s report
Title: Laryngeal Mask Airway for neonatal resuscitation in the developing countries: evaluation of an educational intervention.
Version: 3 Date: 25 February 2010
Reviewer: Betul Ayse Acunas
Reviewer’s report:
Dear Editor,
I reviewed the manuscript entitled ‘Laryngeal Mask Airway for neonatal resuscitation in the developing countries: evaluation of an educational intervention’ which has been submitted to BMC Health Services Research.Below, you will find my comments about the manuscript:
- Major Compulsory Revisions
1-The title as well as the running title of the manuscript does not totally reflect the content of the article, it is better to change it as 'Laryngeal Mask Airway for
neonatal resuscitation in a developing country: evaluation of an educational intervention’.

There is a new title and the manuscript has been revised,

2- “Abstract” section is missing.

We have included an abstract.

3- “Introduction” section is quite long, it should be shortened and emphasis should be on NRP courses and especially on laryngeal mask airway use for neonatal resuscitation.

The introduction has been rewritten focusing on LMA in neonatal resuscitation

“Since its introduction into clinical practice, the LMA has gained increasing popularity for resuscitation of adult as well as pediatric patients, and more recently in neonatal resuscitation. Some authorities have made it a part of their guidelines and LMA has been included in the AAP and AHA Guidelines of neonatal resuscitation since 2000. (3,6)”

4- In “Methods” section, the characteristics of the course attendants (traditional birth attendants?) should be described more in detail (eg. Medical?; how many of them are physician/ nurse /health technician?; first NRP course?). Which version of NRP was conducted? What is the company of the neonatal manikin used? Second paragraph of the “Methods” section should be described more clearly. Besides, in this section 16th reference is missing.

This information is given clearly in the new text and the missing reference has been included. Please, see Referee 1, item 1.3

5- “Discussion” section is also quite long, to discuss the results of the study and compare the data with other studies (if there is any) will be sufficient.

The discussion of results was rewritten and shortened.

“The knowledge gained by the physicians in the single questions and those included in the five steps, related to the features of the LMA, his advantages and disadvantages, and his potential applications in neonatal resuscitation, was superior than that achieved by the midwives. Physicians significantly increased in the post-test the overall number of correct answers. The “improvement”, as number of correct answers in post-test coupled with a wrong answer in pre test, was statistically significant in all the five steps in the physicians, and in four steps in the midwives, missing improvement on the knowledge of the “disadvantages” of LMA. Again, the “improvement”, defined by the percent of correct answers was statistically significant only in two steps related to the advantages of LMA over the facial mask and the potential applications of the LMA. These differences could account of the scientific and practical background and practical skills of the physicians, skill frequently required in delivery and/or surgery room. Manikin-based comparative practical skills on LMA insertion showed instead, a similar high efficacy between trained physicians and midwives, in terms of number of successful attempts and of time for placement. Unanimously, midwives and physicians, except one, also manifested an high
degree of approval of the neonatal resuscitation by LMA, giving a positive evaluation of his/her sustainability and cost-effectiveness in a low income country."

6-The manuscript needs some language corrections before being published
- Minor Essential Revisions
There are some spelling mistakes:
1- Manikin was written as “mannequin” in “Introduction” and “Discussion” sections.
2- “Table 1” was written as “Figure 1” at legends.
3- The number of “Reference” was written after the sentence ended by a dot (should be before the dot). Besides, “References” are written down quite variably.

The entire manuscript has been edited by a mother tongue language expert and all of the references have been doubled checked.

It goes without saying that my co-authors and myself will be anxiously awaiting your reply.

Sincerely yours, Vincenzo Zanardo