Reviewer’s report

Title: Safety and applicability of a pre-stage public access ventilator for trained laypersons: a proof of principle study

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Reviewer: Xiaobo Wu

Reviewer’s report:

The author and his team developed a pre-stage automatic respirator to assist the laypersons to do CPR. In the pilot study, the author tested the safety of applicability of this automated respirator on 52 healthy volunteers. The results showed that the leakage and airway occlusion can be detected with very high sensitivity and specificity. So it is concluded that this pre-stage automatic respirator was able to detect potential complications such as leakage and airway occlusion and is likely to help the laypersons to improve bystander resuscitation.

It is an innovative idea to develop a pre-stage automatic respirator which can be operated by laypersons during resuscitation outside hospital so that the laypersons will not worry about the potential infection brought by mouth-to-mouth ventilation. However, some issues in this manuscript must be addressed before it can be published. See my comments below:

Abstract:

1. Please change "52" to "Fifty-two".
2. Please replace "low cost" with "low-cost"

Background:

1. Paragraph 2: You are talking about the importance of ventilation during CPR, but the explanation is not very convincing. You need specifically explain why the ventilation during CPR is very important and what will happen if the ventilation is not provided during CPR.

2. Paragraph 3: The outline of this paragraph stated that only 32% of witness performed conventional CPR. But you explained the poor resuscitation efforts with the reasons why the laypersons do not want to perform mouth to mouth ventilation. Performing CPR and ventilation are two different issues.

3. Paragraph 4: You are trying to say respirators are not available for laypersons during CPR, but instead you focused on the use of public AED.
4. Except mouth to mouth ventilation and trachea intubation, is there any device or technique providing facial mask ventilation outside hospital?

Methods

1. "…and, was carried out in accordance with…” changes to "…and carried out in accordance with…”.

2. Change "was" to "were" in the sentence of "The hardware adaption,…".

3. The description of prototype setting can be more elaborate. It will be very great if the working mechanism of this prototype is given. Since the turbine is self-designed, more details are needed. Please give more information about the sensor system. Please give the full name of FCO2.

4. More information is needed to explain the results. For example, figure 2 and 3 show the waveforms of flow, pressure, FO2 and FCO2, but the illustration for each is very simple. You need to explain how these parameters change during the protocol.

5. Figure 2 and 3 represent sensor outputs with leakage and airway occlusion, respectively. But there is not figure of sensor outputs without leakage and airway occlusion.

6. The reduced lung compliance was induced in this study but there is not related data of flow, pressure, FO2 and FCO2. Can you provide these data?

7. The prototype tested in this study does not provide feedback of leakage or airway occlusion. All the analysis regarding leakage or airway occlusion were done off-line. The automatic detection and feedback of leakage and airway occlusion is part of safety of this prototype. Obviously the prototype is not complete.

8. I think it is not easy for the participants to stop breathing spontaneously and to tolerate ventilation and they need to do this for 1 minute. I will feel afraid when I stop breathing and tolerate ventilation. Is it your idea to do so or do you get this way from the other studies?

Discussion

1. "In the current literature, there is only a small number of publications addressing the effectivity of ventilation by laypersons." Please cite them.

2. "As PetCO2 may be low or even missing under resuscitation conditions,…" Can you provide some references for this?
3. "In order to adequately simulate the real emergency case,….reduced lung compliance" I know you want to simulate the real emergency case, what do you expect to see in the simulation of reduced lung compliance? What may be caused when the patients with reduced lung compliance are connected to the ventilator? The paragraph should have several citations for discussion.

4. "On the other hand, a real emergency case could dramatically result in coordination difficulties of the recommended 30 chest compressions and 2 rescue breaths per CPR cycle and, thus, additionally increase intrathoracic pressure." The chest compression and breath cycles of 30:2 is not difficult to operate in the real world. I have no idea about what you are trying to say. You can expand a little more to express your opinion with the references.

5. "To avoid gastric air insufflation, it is important to monitor and when indicated to limit the ventilation pressure" I think you want to say that the inspiratory pressure will be limited to avoid gastric air insufflation, right? Can you rewrite this sentence to make it easier to understand?

6. "Another crucial problem in mask ventilation is leakage..." In this paragraph, you are talking about the mask ventilation with or without leakage. I did not see any data about ventilation without leakage in Results. Does your device have any leakage? If your device has no leakage, how did you design this device to avoid leakage?

7. "For non-invasive mask ventilation, commercially available ventilation systems..." You are talking about leakage again in this paragraph, you can put the last and this paragraph together to talk about leakage. How do you compensate the leakage in your device?

**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.

Yes

**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.
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Acceptable

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