



## Letter to the Editor

**Impact of Using a Novel Gastric Feeding Tube Adaptor on Patient's Comfort and Air Leaks During Non-invasive Mechanical Ventilation**

**Impacto del uso de un nuevo adaptador de sonda de alimentación gástrica en la comodidad del paciente y en las fugas de aire durante la ventilación mecánica no invasiva**

Dear Editor,

We share the concerns expressed by Quintero et al.<sup>1</sup> on comfort and air leakage during non-invasive mechanical ventilation (NIMV) with the need of using oral or naso-oral probes. The authors designed their device aiming to decrease air leaks to improve patient comfort, which is related to success of NIMV.

After reading the article, we found several discussion points.

First. We think that the selection of patients included as their own controls is a success.

Second. Quintero et al.<sup>1</sup> included 196 patients but there is no flowchart explaining how many patients met the inclusion criteria and how many were excluded and the reasons.

Third. To assess comfort, they used a qualitative ordinal scale with only 5 options to choose from. When using that type of scales, there could be a tendency of regression toward the central value, so that measurement bias could appear.

Fourth. It is not explained if patients begin with NIMV using the adaptor or the conventional tube. If a patient first receives the most uncomfortable one, when it is changed to the comfortable one, his perception of comfortability may be higher. We believe that this matter should have been addressed.

Fifth. The authors estimated a sample size of 191 patients and they included 196 patients in the study but comfort was evaluated only in 99 patients with Glasgow Coma Scale of 15, so sample size was not reached for one of the outcome of interest.

Sixth. Respiratory and hemodynamic parameters during NIMV, such as inspiratory and expiratory tidal volumes, oxygen saturation

and respiratory rate, were better in the NIMV with tube adaptor group, but it is difficult to know if it was the result of TA-NIMV alone or the sum of both therapies.

Seventh. Therapy was performed according to individual needs, so patients could have received different therapies and that heterogeneity could make patients non-comparable.

Quintero et al.<sup>1</sup> concluded that the use of their tube adaptor to adjust NIMV mask interfaces in patients in whom oro or naso-oral tubes were in place, significantly reduced air leaks and improved subjective comfort perceived by the patient during NIMV support.

As there has been no important changes in recommendations published within the past 15 years regarding the use of NIMV for various forms of respiratory failure<sup>2</sup>, we believe that proposals like Quintero's gastric feeding tube adaptor may improve the assistance of patients with respiratory failure during NIMV, even though further studies should be performed to correct biases.

**References**

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**Reply to “Impact of Using a Novel Gastric Feeding Tube Adaptor on Patient's Comfort and Air Leaks During Non-invasive Mechanical Ventilation”**

**Réplica a “Impacto del uso de un innovador adaptador para la sonda de alimentación gástrica en la comodidad y las fugas de aire durante la ventilación mecánica no invasiva”**

Dear Editor,

We would like to thank Dr. Úbeda et al., for being interested on our manuscript.<sup>1</sup> All patients requiring non-invasive mechanical ventilation and having in place one or more naso-oro-enteric tube(s) were consecutively included over a period

of 16-month, unless contraindications for non-invasive ventilation were present.<sup>1</sup> A total of 1258 patients required invasive mechanical ventilation during the study period, while 516 were subjected for at least one run of NIMV. From these last patients, 196 met the inclusion criteria and consequently, they were subjected to the study intervention consisting of conventional NIMV (C-NIMV) run for 60 min followed by other 60 min of NIMV using the tube adaptor (TA-NIMV) (or in the inverse order), maintaining a “washout period” of at least 4 h between runs.<sup>1</sup> No patients fulfilling the inclusion criteria were excluded, so our results are well adjusted to the reality. Order to start with conventional or tube-adaptor NIMV was alternatively assigned in a 1:1 relationship according to the inclusion sequence until the sample was

completed. Although sequential assignments might introduce bias, NIMV was provided by all the group of physiotherapists according to patient requirements, thus preventing researchers from choosing an order favoring one or other intervention. In addition, such sequential change in the order to start with C- or TA-NIMV should prevent that one intervention was selected as more comfortable.

Dr. Úbeda et al. are also concerned for the problems derived from using a visual analog scale to evaluate the comfort provided by the tube-adapter device during NIMV. It is highly possible that measurements provided by this type of scales are skewed toward the neutral values. Nevertheless, the significant difference observed between C- and TA-NIVM reinforces the message about the ability of the tube adapter to improve the patient's comfort during a NIMV run, since the inherent characteristics of visual analog scales could even underestimate its potential role.

Other studies evaluating comfort during NIMV included a lower number of patients, with not clues about sample size calculation, which suggest that convenience samples were used.<sup>2,3</sup> Conversely, sample size in our study was calculated on the basis of air leakage rates which retrieved a higher number of patients to be included than if calculation had been based on comfort estimates and of course, far higher than previously used convenience sample sizes. Comfort was reported from 99 patients able to clearly understand the visual analog scale, a number well above that necessary to demonstrate a significant difference regarding this endpoint, with a power of 80%.

It is difficult for us to claim that improvement in some respiratory and hemodynamic parameters was the result of TA-NIMV alone or the sum of both therapies. Nevertheless, tidal volumes, respiratory rates and oxygen pulse saturation were obtained during C- or TA-NIMV runs maintaining a “washout period” of at least 4 h between them. As previously mentioned, starting with C-NIVM followed by starting with TA-NIVM in the next patient and so sequentially, should prevent favoring one intervention over the other. Thus, better respiratory parameters during the use of the tube adapter keep the logic and support the hypothesis about less air leakages with better adaptation to NIMV and improvement in respiratory mechanics and oxygenation.

Finally, we agree with Dr. Úbeda about heterogeneity could make patients non-comparable. Nevertheless, we think that our

study provides a notion on the feasibility and possible effectiveness of this new tube adaptor to prevent air leakages to improve comfort during conventional NIMV. Finally, whether using this new tube adapter during NIMV in patients having in place one or more naso- or oro-enteric tube(s) could improve clinical outcomes is a question yet unanswered.

### Author's Contribution

The authors declare writing the core content and agree with the current version of the manuscript.

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