A novel non-invasive ventilation mask to prevent and manage respiratory failure during fiberoptic bronchoscopy, gastroscopy and transesophageal echocardiography

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ABSTRACT

Fiberoptic bronchoscopy (for difficult intubation, bronchoalveolar lavage or biopsies), gastric endoscopies and transesophageal echocardiography (for transfemoral aortic valve replacement, MitraClip or left atrial appendage closure), are widespread diagnostic and therapeutic procedures. Non-invasive ventilation during upper endoscopies can be used to prevent or treat acute respiratory failure especially in high risk or sedated patients. We describe a novel full face mask specifically developed not only for “elective” non-invasive ventilation during upper endoscopies but also for emergent application without probe removal. The mask is formed by two halves fixed only at the upper extremity allowing opening and closure while the probe is in place. Position of the port and shape of the mask allow easy insertion (through the nose or the mouth) and handling of different sized probes. The mask, commercialized as “Janus”, preserves arterial oxygenation during procedures in spontaneously breathing patients with or at risk of hypoxemia (mainly fiberoptic bronchoscopy for guided tracheal intubation or for bronchoalveolar lavage). In patients requiring a true ventilatory support (like patients with neuromuscular disease or those deeply sedated), Janus also allows effective manual or mechanical ventilation. Its use can improve safety, patient’s comfort (as sedation can be titrated to the desired effect without fearing respiratory depression) and efficiency, avoiding time wasting and allowing procedure completion. Prospective trials are required to confirm its effectiveness.

Keywords: non-invasive ventilation, endoscopy, transesophageal echocardiography, gastroscopy, bronchoscopy.

INTRODUCTION

Upper endoscopies (UE) mainly include fiberoptic bronchoscopy (FOB), transesophageal echocardiography (TEE), gastroscopy, and endoscopic retrograde cholangio-pancreatography (ERCP). They all require the probe to be passed through mouth or a nostril. Upper endoscopies can have diagnostic or therapeutic aims, and are performed electively or in urgent/emergent conditions. Not rarely they are life-saving, like FOB-guided tracheal intubation in difficult-to-intubate hypoxemic patients. Moreover, medical progress continuously adds new properties to endoscopic examinations, like ultra-sonography, enhancing their relevance but also increasing their complexity and length.
Sedatives are frequently administered to improve patient’s comfort while avoiding general anesthesia (1, 3). Sedation avoids the risks and the logistical requirements of general anesthesia, but increases the risk of hypoxemic and/or hypercapnic respiratory failure (2, 3). The incidence of cardiac or respiratory complications is usually low in healthy subjects. High-risk patients, however, are often scheduled for UE (sometimes as a less dangerous, second choice treatment for patients unfit for surgery) and the incidence of complications during UE can be high in these patients (2, 3).

Non-invasive ventilation (NIV) was extensively evaluated as a tool to prevent or to treat acute respiratory failure (ARF) in a wide range of settings (4-7). NIV application during UE has been recently reviewed, and proved to be potentially useful but also challenging, as traditional masks do not allow emergent ventilation without prior removal of the probe and interruption of the procedure (8). Recently specifically designed masks for NIV support during UE have been commercialized. Unfortunately, all of them must be applied in advance, before UE begins, without knowing if the patient will require or not NIV: this can allow safer procedures but at the expense of an overuse of masks. Furthermore, until now no mask could be applied in case of ARF during UE without removing the probe: as a consequence, the procedure has to be interrupted with wasting time and money and with potential negative consequences for the patient as the scheduled procedure is not completed.

NIV is the most extensively studied life-saving technique in critically ill patients (9) and its beneficial effects on survival extend to the perioperative period (10). Its use is going to increase and expand in different settings.

We describe a novel mask (manufactured and commercialized with the name “Janus” by Biomedical srl, Florence, Italy) allowing emergent application and NIV support during every kind of UE without removing the probe. The mask can also be applied electively, as it allows an easy introduction and handling of probes of different sizes through the mouth or the nose.

**Janus: an innovative mask**

Janus is a disposable mask to support ventilation by NIV during UE in a few seconds without the need of removing the probe or to interrupt the examination. The mask (Figure 1) is designed as follows: it is formed by two halves fixed in the upper extremity but free in the lower, so that it can be opened and then closed around the probe. Two semi-circular holes are present in the middle of the two parts of the mask, containing suitable gasket meant to complete a round hole for the insertion of endoscopic probes when the mask is closed. A plastic cap closes the hole when the mask is closed but the hole not utilized, for example to treat transient post procedure ARF or while waiting for sedation wash-out. The hole for endoscopic probes is positioned in Figure 1 - The Janus mask that allows fiberoptic bronchoscopy, gastroscopy and transesophageal echocardiography while delivering continuous positive airway pressure.
A new NIV mask for endoscopy

a suitable position for mouth and/or nose insertion; the shape of the mask and the orientation of the hole make the insertion of the probes very easy, without additional handling of the mask.

Two ports are present, one on the left and one on the right side of the mask, to connect the mask to the ventilator circuit or to other means of manual ventilation: in this way ventilation can be achieved even in patients in lateral decubitus. Finally, fastening means to secure the mask to the patients are pre-assembled to make the securing as fast as possible.

The insertion hole of the mask is suited for all endoscopic probes, as the gasket elements offer a sufficient (even if not complete) seal around different size of probes. The present mask can be used by any clinician (such as - but not limited to - anesthesiologists, intensivists, cardiologists, gastroenterologists, thoracic surgeons, pulmonologists) using UE when acting in intensive care units, in the Emergency departments, in ordinary wards (hematology, cardiology, thoracic surgery, medicine, etc.) and above all in their own offices for in- and outpatients (e.g. endoscopic gastroenterology, echocardiography, bronchoscopy …).

Moreover, its use does not require a ventilator, as an effective respiratory support can be easily delivered by manual bag ventilation + oxygen by every clinician.

The mask can be also applied electively, before the procedure, in patients to be deeply sedated or with labile respiratory function: in this condition NIV is started before the procedure, as a preventive tool, and maintained as long as required also after the end of the procedure. This elective use of Janus is expected to increase the number of high-risk patients in which UE can be performed. Furthermore, it will also increase the number of patients who can receive an adequate level of sedation for unpleasant procedures.

Janus can be used to maintain or improve arterial oxygenation during procedures in spontaneously breathing patients with or at risk of hypoxemia: in this setting, the patient can be supported by manual or mechanical ventilation, or connected to a high-flow continuous positive airway pressure (CPAP) device. In patients requiring a true ventilatory support (like patients with neuromuscular disease or those deeply sedated), Janus allows effective manual or mechanical ventilation as well. It must be underlined that Janus application is intuitive and does not require a dedicated training. Janus can be easily used in elective or emergent conditions by every clinicians, such as cardiologists or gastroenterologists (Table 1).

Safety, efficacy and patient’s comfort can thus be improved.

There is a marked reduction of the risk of respiratory failure, no time wasting, no mask wasting, reduction of hospital costs, the possibility to reach the desired level of sedation without the fear of respiratory complications, the possibility to perform endoscopy in high-risk patients that nowadays are frequently denied the procedure, and the possibility to reduce the number of general anesthesia performed in these patients.

Main fields of application

NIV support during UE is feasible, safe and effective. A high success rate was reported even in patients at increased risk for intra-procedural respiratory failure like hypoxemic patients (8).

NIV has been evaluated in different kind of UE: most studies assessed NIV role during FOB, but recent data about NIV application during TEE and gastroscopy are available and encouraging (8).

Janus could make NIV use during UE easier and more effective, both in elective and emergent conditions.
Janus and FOB
FOB can be required to perform a bronchoalveolar lavage (BAL), or to remove bronchial secretions. It can also be used as an aid in predicted or unexpected difficult intubations.

The insertion and presence of the probe significantly increase the work of breathing, while arterial oxygen pressure can decrease by 20 mmHg, or even more if a BAL is performed (11, 12).

Cardiac or respiratory failure are more common in hypoxemic patients, and current guidelines recommend to avoid FOB in patients with an arterial oxygen saturation of 90% or less (13). In this severe conditions FOB is frequently denied despite being indicated (14); the same is true for sedatives during FOB, often not administered at the expense of patient’s discomfort and cardiac ischemic complications. NIV during FOB has been evaluated in different settings with promising results and without reported complication.

Table 1 - Characteristics of the Janus mask.

| Main advantages: |
|------------------|
| - Possibility to be applied emergently in a few seconds to treat acute respiratory failure while the upper endoscopy is ongoing, without removing the probe. |
| - A large central hole allowing an easy insertion (through the mouth or the nose) and handling of different size of probe. |
| - Presence of ventilator ports on both sides of the mask, allowing connection to ventilator circuit even in lateral decubitus. |
| - Possibility to titrate sedation to the desired level without fearing respiratory depression and avoiding general anesthesia. |
| - Possibility to schedule also high-risk patients (respiratory function can be supported by Janus). |
| - Intuitive application of Janus, not requiring training. |
| - Easiness of use, not limited to anesthesiologists. |
| - Cost-effectiveness: no wasting of time (patient can be sedated if intolerant) and of masks (use only if required), no interruption of the procedure. |

| Fields of application: |
|------------------------|
| - TEE (mitralclip, TAVI, left atrial appendage closure, evaluation before or after cardiac surgery in frail or uncooperative patients, awake cardiac surgery). |
| - FOB (bronchoalveolar lavage, suction of bronchial secretions, FOB-guided tracheal intubation in ICU or operating theatre ...). |
| - Gastroenterology: |
| - Gastroscopy in frail or uncooperative patients. |
| - Percutaneous endoscopic gastrostomy in amyotrophic lateral sclerosis patients. |
| - Long procedures like endoscopic retrograde colangio-pancreatography. |

| Settings: |
|----------|
| - Intensive care unit |
| - Operating theatre |
| - Emergency department |
| - Endoscopy service/office for in- or out-patients. |

| Who could use Janus: |
|---------------------|
| - Anesthesiologists |
| - Intensivists |
| - Cardiologists |
| - Pulmonologists |
| - Gastroenterologists |
| - Other specialists performing upper endoscopies. |

TEE = transoesophageal echocardiography; TAVI = transfemoral aortic valve replacement; FOB = fiberoptic bronchoscopy; ICU = intensive care unit.
A new NIV mask for endoscopy

Several technical solutions have been described (8). Technical complexity is higher when FOB is performed for tracheal intubation, as T-adapter for FOB cannot be used. NIV can also be continued into the post-procedural period, if indicated, and particularly when BAL is performed. Janus could be the logical solution for most conditions, and it is the only mask that can be emergently applied while FOB is performed without removing the probe. Janus could be of particular relevance when tracheal intubation is required in hypoxemic patients. It is well known that these patients suffer a high incidence of severe complications during intubation, like cardiac arrest (15). NIV has been already proposed as an effective tool to pre-oxygenate the patient (16, 17).

Janus allows FOB-guided tracheal intubation without stopping NIV, preserving arterial oxygenation as long as required and hopefully facilitating the training curve for this challenging procedure. Once the patient has been intubated, the mask can be easily opened and removed.

NIV during TEE
Transesophageal echocardiography (TEE) is commonly performed with different aims before, during and after cardiovascular invasive procedures and surgery (5, 18). The duration of the procedure, the supine position and the presence of the probe can all contribute to patient’s discomfort: sedatives are frequently required in intolerant patients. However, the presence of the probe, the supine position (in orthopneic patients) and the administration of sedatives can cause ARF. NIV has been applied during TEE to prevent or treat ARF, allowing sedation while preserving the cardiopulmonary function (8, 19, 20). NIV was also applied for continuous TEE in high-risk, orthopneic patients undergoing percutaneous aortic valve implantation, a procedure that lasts about 100 minutes (20). TEE examinations are becoming more and more common, even in high-risk patients; frequently, they last for long periods to allow accuracy, so sedation can be required in uncooperative patients. A growing application of NIV during TEE in the next future can be anticipated: Janus could be the interface of first choice, as it allows an easy introduction and handling of the TEE probe and can be applied electively (before the procedure) or emergently. Several procedures (transfemoral aortic valve replacement, mitral clip, left atrial appendage closure and trans-septal puncture in anticoagulated patients among others) are nowadays performed under general anesthesia because of prolonged TEE and could be performed under sedation plus NIV with Janus in the future. Alternatively, the above procedures are already performed in sedated patients but without the beneficial guidance of the TEE to avoid general anesthesia.

NIV during gastroscopy
A limited number of studies described NIV successful support during gastroscopies, mainly during the positioning of percutaneous endoscopic gastrostomy in amyotrophic lateral sclerosis patients (8, 21, 22).
NIV could be indicated to prevent ARF in high-risk patients, like patients affected by obesity, chronic obstructive pulmonary disease (COPD), coronary artery disease, muscular dystrophy or neurologic disease. NIV could also allow a safer sedation, avoiding respiratory failure, in intolerant or uncooperative patients and in patients undergoing long or painful procedures like endoscopic retrograde colangio-pancreatography. Janus could help preventing or treating ARF in this setting, as it allows the passage of different sizes of probes. The presence of ventilatory ports on both sides of Janus facilitates its use also in lateral decubitus, often used during gastroscopies.
Limitations

Janus is not designed for prolonged (days) NIV treatment: even if it is comfortable and can be used for several consecutive hours, even allowing the patient to drink small amounts of water without removing the mask, its application should be limited to the peri-procedural period. Moreover, due to its unique design (the central hole, the groove between the two halves) air leaks can be more pronounced compared to common NIV masks, even though usually this is not a problem, in particular when the patient is supported by CPAP or manual ventilation. If connected to a ventilator, due the higher than normal air leakage, the ventilator could alarm and the trigger become insensitive: a controlled pressometric ventilation will be effective and safe, but alarms must be turned off. Close monitoring of the patients is required. To the best of our knowledge, no study is currently available on Janus: prospective trials are required to confirm its expected benefits in terms of safety, efficacy and cost-effectiveness.

Ventilation by Janus present the limitations common to any other mask-ventilation: in particular, adequate ventilation can be difficult or even impossible in case of obstruction of the airway or elevated airway resistance (such as acute asthma) or elevated thoracic compliance (like in morbid obese). The equipment for tracheal intubation should be promptly available. On the other hand, suctioning of secretions from the mouth (a common problem) is very easy with Janus, passing through the central hole near the probe.

Finally, at present only one size of Janus is available: it fits most adults, but not pediatric patients or very small adults. Pediatric sizes should be soon available.

CONCLUSION

“Janus” is the first mask specifically developed to allow elective or emergent NIV support during upper endoscopies to prevent or treat acute respiratory failure. Its use can improve safety, patient’s comfort (as sedation can be titrated to the desired effect without fearing respiratory depression), and efficiency, avoiding wasting of time and allowing the completion of the procedure. General anesthesia could be avoided for many procedures thanks to the Janus mask. Prospective trials are required to confirm its benefits.

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A new NIV mask for endoscopy

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