Saving face: better interfaces for noninvasive ventilation

Noninvasive positive pressure ventilation (NPPV) has assumed an increasingly important role in the management of acute respiratory failure because of its demonstrated ability to improve morbidity and mortality rates and to shorten hospital lengths of stay for appropriately selected patients, including those with COPD exacerbations [1, 2, 3, 4] and immunocompromised states [5, 6]. Although NPPV is generally perceived as more comfortable for patients than invasive mechanical ventilation, mask (or interface) intolerance remains a major cause of NPPV failure [7, 8, 9]. Failure rates range from below 10% [3] to over 40% [10], despite the best efforts of a skilled caregiver staff. Thus, improvements in mask design that enhance comfort and reduce complication rates are needed, with the presumption that they will lead to improved tolerance and reduced failure rates of NPPV.

In this issue of *Intensive Care Medicine*, Gregoretti et al. [11] report a controlled trial that demonstrates improved comfort ratings and reduced skin breakdown among patients using a prototype full face mask. They speculate that because the mask has a larger air-filled cuff made of thinner polyvinyl chloride than commercially available masks, it can achieve an adequate air seal using less strap tension. In addition, it may distribute pressure over a larger surface area on the face, reducing skin pressure at any one point such as the nasal bridge. The thin skin over the bony prominence at the nasal bridge predisposes to ulcer formation during use of most standard full-face and nasal masks. Another potential advantage of the prototype mask is that it has six points of attachment that may improve stability on the face. Also, the mask has an adapter for a nasogastric tube that eliminates the problems of air leak and facial skin ulceration that occur when the nasogastric tube is tucked under the seal of a conventional mask.

Although the findings of Gregoretti et al. are important because they demonstrate that relatively minor modifications in mask design can have important effects on patient acceptance and complications, they should not be taken at face value without considering a number of limitations of the study. Most importantly, studies comparing one mask type to another cannot be blinded. It is perfectly obvious to investigators, caregivers, and patients alike what mask they are using, and bias is virtually impossible to eliminate. For example, patients trying to please the investigators might be motivated to inflate comfort scores for the prototype mask. Other limitations are that the investigators used multiple different mask types in their control group and multiple different ventilators in both groups. These add confounding variables, although the effect should be to reduce the likelihood of finding significant differences.

The specific masks chosen for the control group also had a major influence on the results. Obviously, selecting conventional masks that are poorly designed or tolerated would slant the results in favor of the prototype. A corollary problem is that even if the best conventional masks then available were selected for the study, technology is continually advancing, so that by the time of publication the conventional masks may no longer be state-of-the-art. This concern applies to the Gregoretti et al. study because at least some of the conventional masks would be considered obsolete by today’s standards. Specifically, a newer face mask (Image 3, Respironics, Pittsburgh, Pa., USA) with a softer silicone flange has replaced the Respironics mask used in the study. This newer mask is likely to reduce nasal bridge ulceration in comparison to
the conventional masks, and might compare favorably with the prototype mask.

The 100% rate of nasal skin breakdown in the conventional group of the Gregoretti et al. study raises the concern that management of the conventional masks was suboptimal and may have predisposed to a high complication rate. This rate is higher than that reported in any prior study and it would have been rather disappointing if the prototype mask had not improved on it. Had Gregoretti et al. used artificial skin patches over the bridge of the nose, a practice that is recommended routinely at some centers [12], the incidence of skin breakdown might have been considerably less. Also, the use of nasogastric tubes in 35% of the patients using conventional masks, a surprisingly high number, may have predisposed to a higher rate of skin ulceration. Finally, even allowing for the comfort and complication differences, no evidence is provided that these differences translated into other outcomes such as improved mask tolerance rates or reduced intubation rates. Apparently, patients tolerated the greater discomfort and skin trauma of the conventional masks without discontinuing therapy any more often.

Allowing for the above limitations and concerns, if we accept that the prototype mask did enhance comfort and reduce skin complications compared to the conventional masks, we should ask by what mechanisms, because the answer may yield insights into optimal mask design. The authors speculate that the prototype mask achieved an adequate air seal with less strap tension and thus less pressure on the skin than with the conventional masks. They did not measure air pressure in the cuff or strap tension, and therefore this mechanism is speculative. However, there can be no doubt that greater pressure on the skin predisposes to skin breakdown, and therefore minimizing the pressure necessary to maintain an adequate air seal is critically important. Further, as the authors suggest, improved stability of the mask is likely to reduce skin trauma by decreasing friction and abrasion. Also, the nasogastric tube adapter may have been important in those patients requiring nasogastric tubes. Thus, masks with these design features are likely to improve comfort.

However, it is unlikely that any one mask will prove to be optimal for all NPPV applications. Most recent publications on acute applications of NPPV have used oronasal masks, largely because of the commonly held belief that patients with acute respiratory failure are “mouth breathers.” On the other hand, there is no convincing evidence that oronasal masks are more effective in the acute setting than nasal masks. Navalesi et al. [13] found that the oronasal mask lowers PaCO₂ more than a standard nasal mask after a 30-min trial of NPPV in patients with chronic respiratory failure, but that the nasal mask is better tolerated. Based on this evidence, the oronasal mask is a reasonable first choice for acute applications of NPPV, but switching to a nasal mask should be considered if NPPV is to be continued for more than a few days. Some patients, particularly those with claustrophobia, may still prefer nasal masks for acute applications.

Although the prototype mask studied by Gregoretti et al. appears to have some advantages over certain conventional masks, it is far from a perfect device. The 43% rate of skin breakdown was much lower than with the conventional masks, but is still unacceptably high. Also, there was a greater incidence of eye irritation with the prototype mask. Clearly, there is room for improvement. The ideal mask for noninvasive ventilation in the acute setting would certainly have some of the features incorporated into the prototype mask. The air seal should apply minimal pressure to avoid skin trauma, there should be a comfortable head gear system that affords good mask stability, and an adapter for nasogastric tube is desirable.

It is difficult to conceive of a single mask that would combine all of these attributes, and it is likely that a variety of mask types and sizes will continue to be necessary to satisfy individual patient needs. There will continue to be some demand for nasal masks in very claustrophobic patients and very small oronasal masks must be available for children and small adults. However, masks such as that described by Gregoretti et al. are likely to be suitable for the majority of noninvasive application in the acute setting. As mask designers learn from clinical experience as well as evidence-based studies, we are likely to come closer to the ideal.