

Heliox Should Be Available in Every Community Hospital

The June special issue of *RESPIRATORY CARE* features 6 symposium papers about the use of heliox gas. I agree with the guest editor, James Fink, that the issue is a "valuable resource for clinicians."¹ I write this letter because I think heliox has a special role in community hospitals; in fact, I believe that heliox should be available in every community hospital. In community hospitals, surgeons and anesthesiologists with advanced airway skills are not always readily available (eg, 10:00 pm Sunday on a holiday weekend). Patients who develop acute life-threatening upper-airway obstruction under such circumstances are in a terrible predicament. In addition, the respiratory therapist who will undoubtedly be summoned to such an emergency will be in the agonizing position of not having much to offer to the suffocating patient.

Heliox is unique in that it can reduce airway resistance, work of breathing, and improve ventilation without changing the diameter of the airway. This makes heliox a life-saving bridge to definitive therapy (eg, tracheostomy) for the patient dying of severe upper-airway obstruction. Are there large randomized controlled trials to support my contention? No, and there never will be. There are simply not enough patients in this predicament to study, and even if there were, it would be unethical to deny patients a potentially life-saving therapy, which would be required to have a control group.² We have used heliox at our community hospital for many years now, mostly for upper-airway obstruction, but occasionally for hypercapnic asthma exacerbations.³ We need to use it only a few times per year, but when we have needed it, heliox has proven to be a valuable tool to have available. Heliox is easy to administer, and directions for use can be kept with the tank if a department uses it only on rare occasions.

In my mind, heliox in a community hospital should be viewed no differently than an automated defibrillator stationed in a public place, in that, even if you need

it only once every 10 years to save a life, it is still worth having around.

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Heliox Therapy and Devices Cleared by the FDA: After the Engineers Produce Effective Designs, Why Do Clinicians Still Feel the Need to Jury-Rig?

The June 2006 special issue of *RESPIRATORY CARE*, on heliox therapy, reminds clinicians that there are still some shortcomings to applying heliox with equipment designed for oxygen and room air. The article by James Fink¹ addresses the issue of jury-rigging devices for heliox delivery in clinical practice. He cautions about the high risk of liability and the need for institutional safeguards,¹ and he strongly encourages clinicians to use heliox devices cleared by the Food and Drug Administration (FDA), to reduce risk. He discusses certain ventilators that have been bench-tested with heliox, and he lists several FDA-cleared heliox-delivery products available for rapid, first-line heliox treatment, two of which (Hope, B&B Medical Technologies, North Highlands, California; Flo-Mist, DHD Healthcare, Wampsville, New York) warrant comment that

partly explains why clinicians still may want to jury-rig heliox devices.

The Hope is powered by oxygen or air at 10 L/min to nebulize a solution. Heliox (up to 40 L/min or more) is then added via a separate port. With the Flo-Mist, 22–32 L/min of heliox gas can be added to the 13 L/min drive flow. The manufacturer claims that aerosol particle size and output are unchanged with heliox.

The way in which some devices are cleared by the FDA can cause 2 problems that cause clinicians to feel the need to use products in ways not cleared by FDA.

1. *Clinical practicality* may be lost when the package instructions for these 2 continuous nebulizer devices are followed. The addition of the heliox flow increases total output to 40–50 L/min, while the patient's average minute ventilation may be 5–10 L/min, depending on the severity of symptoms. The clinician may wonder if the high flow dilutes the medication delivery to the patient by 3–4-fold, and may not want to deliver heliox at more than twice the flow rate of average heliox therapy, because this uses (and wastes) much more helium. When novel devices are approved in this manner, it may "force" the clinician to try to apply the theory under relevant conditions linked to the approved standard.

2. *FDA requirements may be too restrictive*. New products are developed by engineers and designers, who spend months with bench and some "real-life" testing. Fink mentions that, while some jury-rigged devices can be innovative, it is safer to leave the testing to combination teams of clinicians and engineers.¹ Some products receive 510(k) clearance based on similar properties and specifications from the bench test alone.² This clearance is granted to manufacturers who demonstrate substantial equivalence to an existing cleared device. The use of heliox, in any percentage, is not included as the drive gas to power the nebulizer in those device studies. The FDA holds strict standards that these 2 products deliver appropriate aerosol particle size, whether the clinical application is practical or not. A study by Goode et al found that aerosol delivery improved when an oxygen-driven

nebulizer was used with a ventilator circuit containing heliox.³ Current FDA-cleared devices include a ventilator with noninvasive positive-pressure ventilation, which cannot be rapidly set up as a first line of therapy. Yet some treatment facilities may not be able to afford anything except small portable devices.

Will we see successful outcomes from any study that delivers heliox with continuous nebulization in the manner they were FDA approved? The efficacy of either product needs to be proven beyond the bench. We still do not have a clear concept as to what may work and what will not.

Finally, Fink offers an option for using a device in a non-FDA-cleared way; he writes that it is important to have detailed written procedures and staff training. This can be particularly helpful when clinicians infrequently see patients with, for instance, severe asthma, and outcomes are difficult to measure due to time constraints.

Manthous commented in an editorial on heliox and combination therapy trials that the correct experiment has not yet been performed for heliox therapy.⁴ His comments concern a review by Rodrigo et al, who found no evidence of decreased admissions or significant outcome differences between the various methods of aerosol delivery with heliox.⁵ Manthous speculated that, based on current evidence, to adequately power a study to identify a significant difference in intubation, more than 650 subjects would be needed.⁴ This is a daunting challenge for manufacturers of novel devices and a small share of the specialty market. We need clear knowledge about applying these devices under relevant conditions.

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The author responds:

I agree that clinicians need devices that are clinically practical. Many an FDA-cleared device has been viewed by clinicians as impractical. The major consideration for FDA clearance is that the marketed device is safe when used as instructed. Much of the FDA medical device program is oriented to assure that only safe devices enter or at least remain on the market. It is rare that a clinical institution can invest the required time and resources required to assure that jury-rigged devices are safe and perform as intended. Implementing such devices into clinical practice adds extensive risk.¹

I would suggest that the clinical practicality of the 2 nebulizers in question is not due to their use of heliox but to their design as high-flow oxygen-delivery devices, designed to match patient peak inspiratory flow to avoid dilution of the inhaled gas with entrained ambient air.^{2,3} The use of 2 gas sources allows delivery of high inspiratory flows and control of the fraction of inspired oxygen (F_{IO_2}) without the use of more expensive blenders. In this case, the same total flow is required for proper operation of these nebulizers, whether using air or heliox.

The use of high-flow during delivery of aerosolized bronchodilators is a clinician decision based on practicality beyond any consideration of whether or not to use heliox. This is more of a judgment as to whether aerosol delivery with a high flow through an open mask is more comfortable for the patient than a tight-fitting valved reservoir mask for a dyspneic patient during an exacerbation of asthma or chronic obstructive pulmonary disease. In a busy emergency department, where continuous nebulization may be administered for 3 or more hours, the patient's ability

to tolerate the device is a key issue.⁴ In addition, the ability to use an FDA-cleared off-the-shelf device can save time and reduce delay in administering the therapy. Such considerations may offset the cost of heliox.

The FDA cleared these continuous high-volume nebulizers based on data that they do not change particle size or (as important) aerosol output at similar total flows as the predicate device without heliox. The FDA process did not deal with whether the use of heliox is clinically advantageous.

That said, a clinician might reason that a low-flow closed delivery system to administer heliox could reduce gas-related costs. Such a system was not available commercially prior to the introduction of the Aptair device (GE Healthcare), which uses a closed mask, pressure support, and a demand valve to meet the patient's inspiratory flow while reducing the volume of heliox required (compared to a high-flow system). I would suggest that the Aptair was designed to be a rapidly set-up first line of therapy. In environments in which severe life-threatening airway obstruction is not commonly seen, the ability to bring a device to the bedside, plug it in, open the gas cylinder, and begin therapy may be more clinically expedient than chasing around trying to find the necessary parts to jury-rig a solution.

As we began the symposium in San Antonio ["Heliox Therapy: Practice, Evidence, Risk, and Opportunities," at the 51st International Respiratory Congress of the American Association for Respiratory Care, held December 3–6, 2005, in San Antonio, Texas], we asked the audience for a show of hands of those who used heliox in their clinical practice. The sea of hands confirmed my impression that this type of therapy is widely used. Based on the review of the evidence presented by our speakers (and authors in the June issue), the role of heliox has been better demonstrated in some patient populations (upper-airway obstruction) than in others (bronchodilator delivery in severe asthmatics). In many areas, evidence suggests potential benefit, with the need for further study. These studies would greatly benefit from use of standardized, safe, well characterized, and effective devices.

This dialog should serve as a call to the medical device industry to meet the challenge of producing such devices that the