

CONTINUOUS NEBULIZATION

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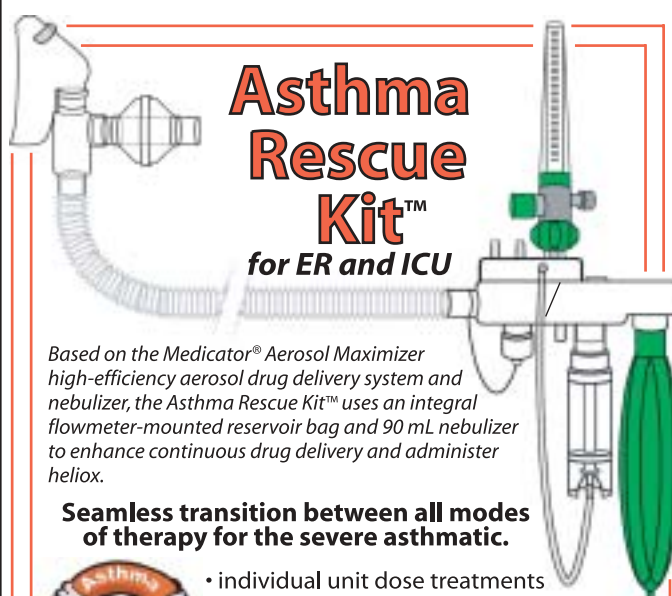
One of the nice things about getting to write a regular column is that you can complain about things that really bug you. Want proof? Just read Andy Rooney's columns in this journal and you'll see what I mean. So what am I going to complain about? I have been wanting to complain about "continuous nebulization" for a long time, and now is my chance.

Historically, before what we now call continuous nebulization first began, clinicians would refill small volume medication nebulizers with a fresh unit dose of drug, either albuterol or terbutaline, every 10-15 minutes or so for a few hours. That time interval between treatments was about how long it took for the nebulizer to empty. This procedure had the effect of nearly continuous bronchodilator therapy. This was done for the most seriously-ill patients with status asthmaticus. Clearly, this was a very time-consuming procedure and, in the United States, it became the job of respiratory therapists to conduct the procedure and expend the time. However, respiratory therapists also had a lot of other work to do and it became very difficult for them to stay at the bedside of such a patient continuously or to come back to the bedside repeatedly, right on schedule, to refill the nebulizer. So doctors and nurses would complain about the therapists. I think a lot of respiratory therapists began to complain about having to perform "nearly-continuous" nebulizer treatments. To circumvent this problem, which was actually more of a labor problem rather than a technical problem, a couple of different facilities began to develop technical ways to keep the nebulizer filled continuously.

These involved intravenous drips and motorized syringe pumps that continuously pumped a small amount of bronchodilator solution into the nebulizer through a needle inserted through a small hole in the plastic top cap of the nebulizer. Although it sounded good in theory, this was probably a difficult procedure to get just right; what more likely happened was the nebulizer was either underfilled or overfilled. And so it became the respiratory therapist's job to fix the problem. I suspect that many of them complained about it.

Then, in the mid-1990s, Vortran developed a large volume continuous nebulizer called the HEART (High Output Extended Aerosol Respiratory Therapy). This was the first commercially available large volume medication nebulizer. In the package literature that accompanied the HEART neb, instructions were provided for setting up the device to deliver either 5, 10, 15 or 20 mg/hour of medication. These supposed drug delivery rates were based upon the nebulization rate of the nebulizer and the amount of drug placed in it. The HEART nebulizer nebulized at a rate of 30 mL per hour. Suppose you put 104 mL of normal saline plus 16 mL of 0.5% albuterol solution, for a total of 120 mL, into the HEART neb. Therefore, at a rate of 30 mL/hr, 120 mL should last 4 hours. The 16 mL of 0.5% albuterol (5 mg/mL) renders 80 mg of albuterol (5 mg/mL X 16 mL = 80 mg). And, according to the prevailing logic, 80 mg/4 hours = 20 mg/hour. Therefore, every 30 mL of nebulized solution was supposed to contain 20 mg of albuterol. A similar calculation is available for 5, 10 and 15 mg/hour. The die was cast. The nomenclature of continuous nebulization was born and dosing scenarios of 5, 10, 15 and 20 mg/hour entered our professional lexicon. Unfortunately, I believe it has come to be assumed, by some at least, that the dose delivered to the patient under these conditions was 20 mg/hour.

As director of respiratory care, I had been asked to implement the HEART neb in our university hospital at the State University of New York at Stony Brook for the purpose of treating severely asthmatic children. When I took a close look at the device, something seemed intuitively very strange to me. Knowing that nebulizers were inherently inefficient devices, I questioned both the dosage and the logic behind it. I figured there was no way it could really administer 20 mg/hour, or even 15, 10 or 5. To do so would expose an adult, not to mention a child, to toxic amounts of albuterol. I already knew from my aerosol work with Dr. Gerald C. Saldone that typical SVN's deliver a patient dose (inhaled mass) of only about 10-20% of their "charge" or loading dose. This translates to about 0.25 to 0.50 mg of albuterol out of a 2.5 mg unit dose placed in the nebulizer. Further, expensive SVN's, in the \$6 - \$7 price range, could only deliver an inhaled mass of about 35%, or 0.875 mg out of a 2.5 mg unit dose. So what is with this 5, 10, 15 or 20 mg/hour claim for a large volume nebulizer? I really doubted that the HEART was able to give 100% of its loading dose (charge). Further, when I did a literature search and started reading what various investigators claimed they were giving with their continuous nebulizers or high frequency intermittent treatments, others were claiming the same thing. There were no qualifying statements to indicate that they were making a distinction between nebulizer



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loading dose and patient delivery. I became convinced that most of these clinicians, although well-intentioned, had a bad case of "nebulizer naiveté" and were confusing aerosol generation rate with drug delivery to the patient. So I studied the HEART neb in the aerosol lab and confirmed what I had postulated.

In 1997 we published a paper in *Chest* on this subject. It demonstrated that for the HEART nebulizer prepared for the 20 mg/hour albuterol delivery scenario, the actual delivery (inhaled mass) to a lung model was only 3.48 mg/hour with an adult breathing pattern and 1.83 mg/hour for a pediatric (rapid/shallow) breathing pattern. Nowhere near 20 mg/hour. However, this paper demonstrated on the test bench that the HEART neb is a reasonable labor-saving device inasmuch as it delivers almost the same amount of drug as back-to-back SVN treatments 10 minutes apart. An inexpensive SVN, refilled every 10 minutes with a 2.5 mg unit dose ampoule of albuterol, delivered 3.74 mg/hr for the adult breathing pattern and 2.48 mg/hr for the pediatric breathing pattern. This study also demonstrated the significant effect that breathing pattern, particularly a rapid/shallow breathing pattern, has on aerosol delivery. A rapid/shallow breathing pattern, typical of smaller pediatric patients, severely limits the amount of aerosol inhaled, even when a fairly concentrated amount of aerosol is available for inhalation. It is for that reason that I have been somewhat amused and dismayed at discussions about reducing the "dose" to 10 or even 5 mg/hour in pediatrics. I think I'll complain about pediatric dosing in a future article.

Let's now fast-forward to today. Currently on the market in the US, in addition to the HEART, are a number of large volume continuous nebulizers that have come on the market since the HEART was first introduced. All of these devices use the same

dosing convention as the original HEART neb; i.e., they state a "dosage" of so many mg/hour based upon the liquid nebulization rate of the nebulizer. In order to actually deliver to the patient that amount of drug per hour, these devices would have to be 100% efficient. There would have to be no losses in the system. They would have to nebulize and emit 100% of the nebulizer charge from the nebulizer and the patient would have to inhale it all. Clearly, that does not happen.

What has actually evolved is merely a convenient way of stating the drug preparation or dilution scenario, with which I have no complaint. In fact, I'm not sure there's a better alternative. And we know that continuous nebulization works; despite the disparity I have pointed out, it tends to be clinically effective. What I have a problem with is the implication, and I certainly hope it is not a widespread belief, that this is actually the patient dose, or drug delivery rate, which it is clearly not. I guess I am also complaining about the imprecision of this convention and the fact that manufactures and clinicians have so willingly accepted it without so much as a whimper (my 1997 publication notwithstanding). Subsequent work that I have done on the bench suggests that all continuous nebulization devices, when prepared for the same delivery scenario, deliver differing amounts to the same lung model. I could continue to complain about it, but it would not help. I just hope that most clinicians fully understand that the delivery scenarios included in the labeling of continuous nebulization devices are not the patient delivery.

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