Perinatal-Pediatrics Bulletin
May/June '00

2
Notes from the Co-Editor

Decentralization: *An Overview Both Professional and Personal*

3
An In Vitro Evaluation of Homemade Spacers for the Delivery of Albuteral by Metered Dose Inhaler

5
Specialty Practitioner of the Year

American Association for Respiratory Care

Notes from the Chair: Aerosol Medication Delivery to Infants

by Peter Betit, RRT

Recently, there have been discussions on the Perinatal-Pediatric Listserve regarding the delivery of aerosolized medications to infants. The common theme of the queries and comments posted on the listserve centered around the identification of the ideal delivery method. Some RTs indicated that a mask was key to adequate drug deposition, whereas others thought "blow-by" treatments were better tolerated. Some advocated the exclusive use of MDIs with holding chambers and masks, while others opined on the futility of aerosol delivery to these patients.

While reading these comments, I recalled the symposium on Pediatric Aerosol Delivery that was held at the 1999 AARC Congress in Las Vegas. Included in the symposium were presentations by David Geller, MD, from Nemours Children's Clinic in Winter Park, FL, and Bruce Rubin, MD, from Wake Forest University School of Medicine in Winston Salem, NC. Together, they highlighted some of the misconceptions and common pitfalls associated with aerosol delivery to infants. Two issues included in the discussions were the use of "blow-by" treatments and the notion that crying enhances drug delivery.

With respect to "blow-by" treatments (or "drive-by treatments," as they were referred to during the presentation), the following study was reviewed: Everard ML, Clark AR, Milner AD. Drug delivery from jet nebulisers. *Arch Dis Child* 1992;67:586-589. In this in vitro experiment, researchers studied the rate of drug delivery that occurred when the driving gas flow and drug concentration were altered and delivered to a mask system that simulated tidal breathing at volumes of 50 ml, thus simulating infant breathing. A driving gas flow rate of 8 L/min was used, and when the mask was moved back 1 cm from the collection filter ("face"), there was a >50% reduction in delivered medication. When it was moved back 2 cm there was an 85% reduction. It was suggested that the poor response to aerosolized medications in infants may be attributed to the "blow-by" delivery method.

The effect of crying on aerosol delivery was addressed first with an audience poll. The audience was asked, "Who thinks that crying produces a larger tidal volume and thus better drug deposition?" The majority of the audience raised their hands. Citing the following study – Iles R, Lister P, Edminds AT. Crying significantly reduces absorption of aerosolised drug in infants. *Arch Dis Child* 1999;81:163-165. – the speaker refuted this notion. In this study drug absorption was measured by urine concentrations. Infants who were crying and unsettled had significantly lower concentrations of drug than those who received their treatment while calm and asleep.

Following these presentations I was left with a sense that delivering aerosolized medications to infants is fairly ineffective. From my own experience, I know that it has taken many years to dispel the myth about "blow-by" treatments in our institution. They still occur, but not as frequently. Regarding intubated infants, we have adopted a practice of hand-ventilating treatments delivered via MDI and holding chamber. I often question if this is the most effective method for these situations.

The delivery of aerosolized medications to infants continues to be a prevalent practice in neonatal and pediatric care. What explains this prevalence if the limitations of drug delivery are fairly apparent? Are the drugs in this class (e.g., beta agonists) considered benign? How do we assess the effectiveness of these drugs on these small patients? The interpretation of breath sounds might be more of a culprit than a valuable tool. What may be a wheeze to caregiver A may be a minor squeak to caregiver B. Are we giving the correct dose and/or concentration? It seems that it is okay to be administering a "benign" class of drugs, but we are not willing to push the doses.

There continues to be uncertainty regarding the delivery of aerosolized medications to infants. I suppose the liberal approach would be to not bother, and the conservative approach would be to go ahead and give the treatment since it carries little risk and may be beneficial. ■

Notes from the Co-Editor

by Douglas Eric Petsinger, BS, RRT/RCP IV

Greetings, and happy spring. I have a few thoughts and a couple of updates to bring you this issue.

Since our last *Bulletin*, Claudia Schauffler, a colleague of mine here on the Egleston campus of Children's Healthcare of Atlanta, has been promoted to acting administrative director of the case management/utilization review department. I'd like to congratulate her on her new position and, more importantly for this audience, point her out as another great example of an RT thinking and working outside of the traditional role of a respiratory therapist. There is truly no limit to what we can accomplish with hard work and determination.

A former colleague of mine and a dear friend to many in the extracorporeal community, Bert Kesser, has authored one of articles in this issue. Bert left the exciting world of ECMO almost two years ago and moved back to sunny Florida, eventually joining the Nemours Children's Clinic in Orlando to conduct aerosol research. I miss working with Bert in both the respiratory and ECMO arenas. He is responsible, through tireless mentoring, for developing me into the clinician that I am today.

Since the approval of inhaled nitric oxide (INO) for the treatment of respiratory failure in neonates, the respiratory community as a whole has been in an uproar over the new pricing strategy put into place by INO Therapeutics. Personally, I have mixed feelings concerning their new prices ($3000 per day, with a $12,000, four-day price cap). However, I understand the company's predicament.

First and foremost, INO Therapeutics gave away the drug for years during clinical trials – their own and everyone else's as well. They basically stuck their necks out, footing the bill for the majority of the studies by either supplying gas and/or INO Vents, or funding the studies directly. That was quite an expense, and I understand the company's need to recoup its losses. Also, let's be honest, the price increase did not come out of the blue. We were all forewarned many months before the increase took place. We all had the ability to factor the cost into the budgetary process for this year, as well as begin the process to create or increase the charge for INO usage.

The greatest concern at this time is "off label usage" of the therapy and the road ahead for Food and Drug Administration (FDA) approval for different patient populations. Do we go ahead and use INO for other indications, even though the patient is not a neonate with PPHN? Gone are the days of compassionate-use protocols. We, as a group, must strive to find measurable end-points when studying the use and benefit of INO for different disease states. If your institution does not have a large enough study base, can the study numbers be increased by a multi-center study? This is the route we took during the clinical trails that led to approval of the therapy for neonates, and the whole process can happen again.

With the spirit of a collaborative process in mind, the Medical University of South Carolina at Charleston, Duke University, and Children's Healthcare of Atlanta are proposing the formation of a South Eastern Society of Nitric Oxide. This group will allow us all to collaborate on protocols and, hopefully, broaden FDA approval for this important therapy. Already both Charleston and Children's of Atlanta are working on a cardiac protocol for INO use. We will split the duties and write different wings for one large protocol. A Glenn and Fontan study is being created with the end-points of reducing the transpulmonary gradient and increasing systemic saturations. The other wing will focus on postoperative pulmonary hypertension with several key measurable end-points. The only way we can obtain further FDA approval for INO is through collaboration that allows for increased study numbers.

So, please – if you have any comments about INO research or creating a collaborative society, do not hesitate to contact me. As always, my door is open for any discussion. I am also awaiting your responses to my call for first-hand accounts of "Accidental Extubations PI/CI." (See your March-April *Bulletin*.) Your data and experiences will be greatly appreciated. ■

Perinatal-Pediatrics Bulletin
is published by the
American Association for Respiratory Care
11030 Ables Lane • Dallas, TX 75229-4593
(972) 243-2272 • FAX (972) 484-2720
e-mail: info@aarc.org

Kelli Hagen
AARC communications coordinator

Debbie Bunch
Bulletin managing editor

Edwards Printing
Bulletin typesetting

Section Chair and Bulletin Co-Editor
Peter Betit, RRT
Children's Hospital
300 Longwood Avenue
Boston, MA 02118
(617) 355-6118
FAX (617) 738-0338
e-mail: betit@hub.tch.harvard.edu

Co-Editor
Doug Petsinger, BS, RRT/RCP IV
Children's Healthcare of Atlanta
Egleston Campus
Sibley Heart Center/CICU
1405 Clifton Rd. NE
Atlanta, Georgia 30322
(404) 325-6577
Pager (770) 353-7651
FAX (404) 315-2806
email: doug.petsinger@choa.org

Medical Advisor
Mark Wilson, MD (ACAI)
(402) 354-5624
FAX (402) 354-5725
email: mwilson@chsomaha.org

Consultant Panel
Mike Czervinske, RRT
University of Kansas Medical Center
Department of Respiratory Care Education
3901 Rainbow Blvd.
Kansas City, KS 66106-7606
(913) 588-4631
FAX (913) 588-4632
email: mczervin@kumc.edu

Decentralization: *An Overview Both Professional and Personal*

by Douglas Eric Petsinger, BS, RRT/RCP IV

In 1995 Egleston Children's Hospital was in fierce business conflict with its rival children's hospital in Atlanta, Scottish Rite Medical Center. The conflict caused by these two businesses battling over insurance benefactors would lead to the decentralization of a cutting edge respiratory care department – my own.

The initiative began with "core" teams, which were developed in specific areas of the hospital with the idea of consistency of care as a common goal. Weekly group meetings were held with all the core team leaders and the director of respiratory care to discuss the future of the department. When our director tearfully announced that we would decentralize, a stunned silence and a dread of the unknown fell over the group. Shortly after the announcement, our director resigned.

When the core groups transferred to their respective cost centers, however, we were welcomed with opened arms by the physicians and nurses. The title of "team leader" quickly transformed to "Level IV," and slow integration into the existing management

"Decentralization" continued on page 3

"Decentralization" continued from page 2

teams ensued.

Early on, our input into the management structure (operations, fiscal, etc.) was not widely accepted. We were concerned, for example, about the effectiveness of having a nurse manager evaluate the performance of an RT. Even though the goals were the same (i.e., quality care for the patient), the approaches and philosophies were different.

Another concern was the budgetary process. RTs and their tools are expensive. Since there was no longer a respiratory department budget, equipment now had to be budgeted out of each respective cost center. It was difficult to explain why we needed $30,000 (each) to replace our antiquated ventilators with a newer model that would assist in decreasing length of stay and increase ventilator-free hours. We became song and dance specialists just for equipment's sake.

Successful decentralization depends on the commitment of the managers of the respective cost centers, as well as that of the administration of the institution. If the goal of decentralization is to decrease the overall numbers of FTEs through "cross-training," it will never work. Although I am in favor of RTs increasing their knowledge base and helping a teammate ease his or her workload, they are not able to handle a full triple assignment. An RT who is an ECMO specialist can and should be able to perform this arduous task, but that is the exception, not the rule. RTs are not qualified for total care for a paired or a triple assignment, even if the patients are respiratory patients.

Decentralization does provide an atmosphere conducive to consistency of care. It also allows the practitioner the ability to specialize in his or her respective areas of interest, with the premise that the more knowledge gained, the more a team's performance is enhanced.

I can only express my opinions on decentralization as it pertains to the CICU on the Egleston Campus of Children's Healthcare of Atlanta. Over the last five years, a successful collaborative multidisciplinary team has evolved. However, I believe my colleagues in the NICU, PICU, and ER would echo this sentiment about their respective areas. Personally, I found the road to be at times long and taxing, but at this point, I feel that something extremely good has come from decentralization.

Becoming an effective member of a managerial team proved to be the most difficult task of decentralization for me. Only in the last two years have I really started to become comfortable with all the nuances of managing people (win-win, coaching, conflict resolution, disciplining, delegating, etc.). Believe me – dealing with the idiosyncrasies of thoracic surgeons is a walk in the park compared to slowly learning managerial skills. What turned a position that I dreaded into one that I truly enjoy was the hiring of a new administrative director (AD) who did not rely on the traditions of the past.

Of course, that's not to say these last two years have been a "bed of roses." For example, we had to deal with inequalities in pay practices between RTs and RNs – from differentials to bonus pay – as well as tedious justifications for granting overtime pay for the RTs. The management team for the Sibley Heart Center's CICU is comprised of three RNs and myself, along with the AD. We have had to reapply for our positions twice due to restructuring – the latest being during a greatly needed reorganization. At that time, the unit manager position was created (actually, recreated). We now have a black and white, unbiased, and proactive individual to maintain our focus on day-to-day operations, consistent and effective managerial strategies, and collective team goals.

This was a giant step forward for the CICU, which historically has had the reputation of being a ruthless group of high maintenance prima donnas. Through our unit manager's leadership we have taken giant steps towards losing this reputation and have increased our professionalism and developed a shared governance model as well. The inequality issues have resolved, and both professions sit on the various councils in the shared governance model.

Clinically, throughout these last five years the RT's skills, knowledge, and degree of professionalism have risen to an impressive level. As stated earlier, we utilize a collaborative approach to patient care in the CICU. The entire multidisciplinary team rounds at the change of shift (0700) each morning. We get an overview of the events overnight and the game plan for the day: wean, wean to extubate, rest, increase support, change strategies, and so forth. It is then up to the RT and the RN to collaborate to meet the daily goals. This enables the RT to have free range in modality changes, titration of pressure support, pharmacological manipulations, CPAP/PEEP titration, and traditional respiratory modalities. This all occurs without the aid of protocols or a list of parameters. I am very proud of how this dedicated group of clinicians has striven over the years to earn the trust of the entire team to function in this professional manner.

My role has continued to grow over the last year and a half. Currently, I evaluate 19 clinicians, 15 RTs and four RNs. I have also become a relief charge person, which has allowed me to continue to broaden my scope of practice and enhance my daily operational skills. The respect for and consistency of the management team has continued to strengthen. The way we complement each other now is truly impressive. We have created a very unique atmosphere for a collaborative team approach in pediatric cardio-thoracic critical care.

And in retrospect, I know that the entire evolutionary process was made possible by decentralization and the dedication of the entire team to make the concept work. ■

An In Vitro Evaluation of Homemade Spacers for the Delivery of Albuterol by Metered Dose Inhaler

by B. Kesser, N. Kissoon, S. Teelucksingh, K. Blake, S. Murphy, and D. Geller

The delivery of inhaled medications to young children can be particularly challenging. Spacers and valved holding chambers (VHCs) improve the delivery of inhaled medications when used with pressurized meter dose inhalers (pMDIs).[1] Spacers reduce the impaction of larger particles in the oropharynx that can cause unwanted side effects and may improve the distribution of the aerosol in the airways.[2]

While there is widespread use of commercial spacers and VHCs in North America and Europe, they remain unavailable to a large population of children and adults elsewhere around the world. This has led to the use of alternate, more readily available items as surrogates for the commercially produced spacers. Plastic cups and soft drink bottles are commonly used as spacers since they are readily available, inexpensive, and easily adapted to accommodate a pMDI.

On the islands of Trinidad and Tobago in the West Indies, empty soft drink bottles with holes cut out of the bottom to accept an MDI serve as homemade spacer devices. However, the ability of these homemade devices to deliver a high percentage of particles in the size range that will deposit in the lower airways is unknown. This information is important to clinicians in these countries, since a poor response to inhaled therapy may be due to either lack of drug efficacy, or poor deposition of drug in the target airways. Therefore, we evaluated three plastic bottles, with volumes of 280cc, 320cc, and 500cc, respectively, that are typically used as spacers. We compared their respective drug outputs to those of

"Homemade Spacers" continued on page 4

"Homemade Spacers" continued from page 3

a commercially available VHC, the OptiChamber (Healthscan Products, Inc., NJ.) with a 218cc volume, and to a pMDI alone. Of principal interest was the amount of drug delivered in the respirable range, as well as the amount of drug in the larger, non-respirable range that would likely be deposited in the upper airway. We also compared the amount of drug retained within the OptiChamber to that retained in each of the three sizes of study bottles.

Methods

Sizing measurements were made with an Anderson 8 stage cascade impactor (Atlanta, GA). The cascade impactor utilizes a series of collection plates that separate and collect sampled drug within pre-determined size ranges at each stage. The sample is aspirated through the impactor at a calibrated flow rate of 28.3 (+/- 0.5) liters per minute. After sampling, the amount of drug present on each stage can be individually assayed, and the total amount of delivered drug within a particular range may be calculated. Particle sizes of ≤4.7 microns are generally considered respirable in the child and adult, while sizes of ≤3.3 microns may correlate better with in vivo estimates of lower airway deposition. Drugs with a particle size of ≤4.7 microns are most likely deposited in the upper airway.

Three different sizes of soft drink bottles which are available and used as spacer devices in Trinidad and Tobago were used. Holes were cut into the bottoms of each to accommodate an MDI actuator. The actuators were tight-fitting into the holes in the bottles, but no attempt was made to completely seal the actuator to the bottle. Albuterol with CFC propellant, 90 mcg/actuation (Schering Corporation, NJ) was used for all studies. The spacers and VHCs were washed in a commercially available liquid detergent and allowed to air dry overnight to reduce static charge on the inside wall.

Prior to each measurement, the pMDI canister was vigorously shaken, and 10 actuations were fired to waste to prime the canister. For each of the spacer studies, the pMDI was then inserted into the spacer inlet, the mouthpiece of the spacer was inserted into the inlet of the cascade impactor, and a dose was delivered. For the pMDI alone, the pMDI was primed as per above, and connected directly to the inlet of the impactor.

Five actuations were delivered to the impactor for each device at 30-second intervals. The pMDI was shaken vigorously for 10 seconds between each actuation. After sampling, the stages were disassembled and individually washed in 0.1N HCL to recover the drug. The deposited drug was also recovered from the spacer device and actuator. The total amount of drug on the individual components was then assayed with a spectrophotometer at 228 nanometers. Reproducibility was assessed by repeating this procedure four times for each device.

Results

The respirable (≤3.3 microns and ≤4.7 microns) amount of drug, in micrograms, delivered from all three bottles was greater than that which was delivered from both the OptiChamber (Op T) and the pMDI alone. The respirable dose was remarkably similar between the homemade spacers, despite an almost twofold difference in spacer volume between the smallest and largest bottle. The amount of drug delivered that was ≤4.7 µm was similar in the OptiChamber (Op T) and pMDI. The amount of drug delivered as large particles (≤4.7 microns) with the pMDI alone was greater than that which was seen in all other devices. Large particle fraction was similar among the three spacers and the Op T, at <10% of the nominal dose. The amount of drug retained within the device was greater in the OptiChamber than in any of the three bottles. (Table 1.)

Table 1

	mcg ≤ 3.3 µm mean ± sd	mcg ≤ 4.7 µm mean ± sd	mcg > 4.7 µm mean ± sd	Dose Retained by Spacer
280cc	57.3 ± 3.7	66.3 ± 4.1	7.5 ± 1.0	34.9 ± 4.8
320cc	56.5 ± 1.0	65.9 ± 1.7	7.6 ± 0.8	32.7 ± 4.2
500cc	57.8 ± 2.3	67.4 ± 2.8	7.0 ± 1.0	29.1 ± 2.1
pMDI	**41.4 ± 1.9	*46.9 ± 2.6	**51.2 ± 2.8	N/A
Op T	**47.6 ± 2.6	*52.8 ± 2.5	5.5 ± 0.5	**51.4 ± 5.0

*p < 0.05 compared to all †bottles **p < 0.05 compared to all others

Discussion

Under these controlled conditions, homemade spacer devices were capable of delivering a greater proportion of respirable drug than a pMDI alone or the OptiChamber. The use of these spacers without valves significantly reduced the amount of larger particles of drug as well as the valved Op T.

For this study we controlled two variables that may greatly affect drug delivery. First, each of the study devices was pre-washed in a liquid detergent prior to each measurement. Washing has been shown to reduce the electrostatic charge that is present on the surface of plastic spacer devices.[3] The presence of a high electrostatic charge may cause a greater percentage of drug to adhere to the spacer device, thereby decreasing the delivered dose.[3, 4] Second, there was no time delay between actuation of the pMDI and sampling through the impactor. Vacuum was applied to the impactor continuously, and the drug delivered in five separate "puffs." This technique simulates the method of dosing with a spacer and pMDI in a well-trained subject with good coordination, but frequently, particularly with infants and young children, there is poor coordination between the beginning of inhalation and the pMDI actuation. This results in an increased dwell time of drug within the spacer, leading to a greater loss of drug within the device[4]. We did not attempt to evaluate the effect of a time delay on the function of these devices.

Conclusions

VHCs improve the delivery of inhaled medications by increasing the percentage of respirable drug and decreasing the percentage of larger, non-respirable particles. The unavailability of commercially produced VHCs in some areas of the world has led to the use of alternate spacer devices that are more readily available to serve this need. The devices studied here are inexpensive, easy to use, and simple to modify for this purpose. Under these test conditions, they are able to deliver a higher respirable dose of albuterol than either the Op T or the pMDI alone.

References

1. Barry PW, O'Callaghan C. Inhalational drug delivery from seven different spacer devices. Thorax 1996;51:835-840.
2. O'Callaghan C, Cant M, Delivery of Beclomethosone dipropionate from a spacer device: what dose is available for inhalation? Thorax 1994;49:961-964.
3. Pierart F, Wildhaber JH, Vrancken I, Devadason SG, Le Souef PN. Washing plastic spacers in household detergent reduces electrostatic charge and greatly improves delivery. Eur Respir J 1999;13:673-678.
4. Wildhaber JH, Devadason SG, Eber E, Hayden MJ, Everard ML, Summers QA, LeSouef PN. Effect of electrostatic charge, flow, delay, and multiple actuations on the in vitro delivery of salbutamol from different small volume spacers for infants. Thorax 1996;51:985-988.■

Specialty Practitioner of the Year

Don't forget to make your nominations for the 2000 Perinatal-Pediatrics *Specialty Practitioner of the Year*. This honor is given to an outstanding practitioner from this section each year at the AARC's Annual Convention.

The recipient of this award will be determined by the section chair or a selection committee appointed by the chair. Each nominee must be a member of the AARC and a member of the section.

Use the following form to send in your nominations for this important award:

I would like to nominate ____________________________ for Perinatal-Pediatrics *Specialty Practitioner of the Year* because

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

Nominee	***Your Name***
Hospital	Hospital
Address	Address
City State,Zip	Your Name
Phone	Phone

Mail or FAX your nominee to the section chair at the address/number listed on page 2 of this issue.

American Association for Respiratory Care
11030 Ables Lane
Dallas, TX 75229-4593

Non-Profit Org.
U.S. Postage
PAID
Permit No. 7607
Dallas, TX