VAPOTHERM®

Let Babies Be Babies First

High Velocity Therapy

A Gentler Alternative to nCPAP

Give Babies Developmental Care They Need with the Ease of Handling you Want

Developmental care is crucial for premature neonates and nCPAP is the gold standard primary respiratory support. However, it presents some difficulties when it comes to developmental care, especially skin-to-skin care, and nursing. Handling the baby creates a risk of leaking at the interface that could compromise the efficacy of the therapy. Additionally, the nCPAP interface hides a baby's face from its family and could cause nasal trauma in this vulnerable population.[1]

These well-known limitations of nCPAP are why many clinicians choose to use High Flow Nasal Cannula (HFNC) when possible. However, HFNC hasn't been shown to be a viable alternative to nCPAP when it comes to providing primary support.[2,3] Vapotherm® high velocity therapy offers a solution that combines the best of both modalities:

A viable alternative to nCPAP[4,5] that can provide primary respiratory support, but with the gentleness of HFNC.

- Give your babies gentle primary respiratory support so their metabolic energy can fuel their thriving
- Families can practice skin-to-skin and kangaroo care without worrying about leaking at the interface
- Mothers can breastfeed with a low risk of therapy disruption
- Families can see their baby's face and bond without bulky interfaces being in the way

1. Imbulana DI, Manley BJ, Dawson JA, Davis PG, Owen LS. Nasal injury in preterm infants receiving non-invasive respiratory support: a systematic review. Arch Dis Child Fetal Neonatal Ed. 2018 Jan;103(1):F29-F35. doi: 10.1136/archdischild-2017-313418. Epub 2017 Sep 28.
2. Roberts, Calum T., M.B., Ch.B., Louise S. Owen, M.D., Brett J. Manley, Ph.D., Dag H. Frøisland, Ph.D., Susan M. Donath, M.A., Kim M. Dalziel, Ph.D., Margo A. Pritchard, Ph.D., David W. Cartwright, M.B., B.S., Clare L. Collins, M.D., Atul Malhotra, M.D., and Peter G. Davis, M.D. for the HIPSTER Trial Investigators. "Nasal High-Flow Therapy for Primary Respiratory Support in Preterm Infants." New England Journal of Medicine. September 22, 2016; 375:1142-1151.
3. Manley, Brett J., et al. Nasal High-Flow Therapy for Newborn Infants in Special Care Nurseries. N Engl J Med 2019; 380:2031-2040. DOI: 10.1056/NEJMoa1812077

The Efficacy of nCPAP with the Comfort of High Flow

Vapotherm high velocity therapy is an innovation among NIV modalities as it uses a nasal cannula interface. It is the only mask-free and seal-free therapy clinically proven in randomized controlled trials as an alternative to CPAP for both:

- Primary respiratory support for RDS[4]
- Post-extubation support[5]

(Studies shown on page 7 in more detail)

High Velocity Therapy is a Viable, Gentler Alternative to nCPAP

High velocity therapy is non-inferior to nCPAP, meaning it delivers comparable clinical efficacy. But while the therapy may not be better than nCPAP, this modality does have some attractive advantages:

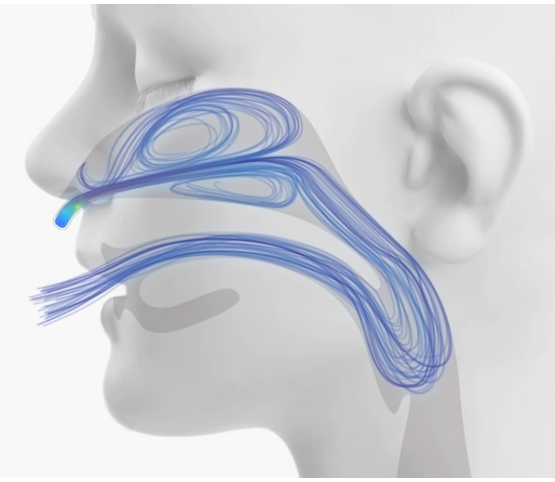
- Reduce the risk of nasal injury and skin breakdown. Nasal cannula interfaces are associated with significantly reduced rates of nasal injury by comparison to common nCPAP interfaces.[1]
- nCPAP carries known risk factors associated with pressure modalities, such as gastric distension—i.e. CPAP Belly—and pneumothorax[6]
- High velocity therapy doesn't use pressure as a primary mechanism of action and generates a low distending pressure

4. Lavizarri A, Colnaghi M, Ciuffini F, Veneroni C, Musumeci S, Cortinovis I, Mosca F. "Heated, humidified high-flow nasal cannula vs nasal continuous positive airway pressure for respiratory distress syndrome of prematurity – a randomized clinical noninferiority trial." JAMA Pediatr. 2016 Aug 8.

5. Collins C, Holberton J, Barfield C, Davis P. "A randomized controlled trial to compare heated humidified high-flow nasal cannulae with nasal continuous positive airway pressure postextubation in premature infants." J Pediatrics. 2013 May; 162: 949-54.

6. Bamat et. al. Duration of continuous positive airway pressure in premature infants. Semin Fetal Neonatal Med. 2016 Jun; 21(3): 189–195. Published online 2016 Mar 3. doi: 10.1016/j.siny.2016.02.005

How Does it Work? Mechanisms of Action



Unlike traditional forms of non-invasive ventilation that rely on pressure, high velocity therapy relies on washout as the primary mechanism of action. The Precision Flow® delivers high velocity therapy. The rapid flush through high velocity facilitates alveolar ventilation.

Alveolar Ventilation = (Tidal Volume – Dead Space) x Respiratory Rate

While traditional non-invasive positive pressure modalities, like CPAP, work by impacting the "Tidal Volume" aspect of the above equation by opening up more air sacs, high velocity therapy works by reducing the Dead Space.

There are some additional, but not primary, mechanisms of action that contribute to the clinical outcomes:

- Reduction of work of breathing (WOB) through provision of adequate flow
- Reduction of energy cost for conditioning (heating and humidifying) gas, which reduces metabolic expenditure, allowing the neonate to conserve energy
- Improvement of lung mechanics through optimally humidified and warmed gas
- A mild, distending pressure that is safe for neonates

An Open System

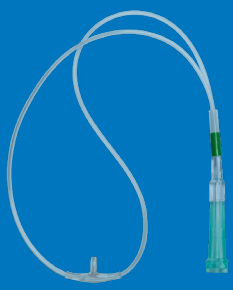
It is crucial to note that pressure is not the primary mechanism of action of high velocity therapy, which is an open system that requires that no more than 50% of the patients' nares are occluded. This enables dead space washout and CO_2 egress.

The loose-fitting interface is also what facilitates developmental care and greatly reduces the likelihood of skin erosion and nasal trauma in babies.

A Gentler Start in Life with the Precision Flow® System

Vapotherm Precision Flow Systems Help You Keep Your Babies Safe and Cared for.

- Mask-free interface facilitates comfortable skin-to-skin care and family bonding and reduces chance of nasal trauma[1]
- Large visual display shows at a glance what therapy parameters the baby is receiving
- Patient-focused alarms and alerts warn of disruption to therapy
- Easy-to-apply nasal cannula may improve workflow
- Control of L/min, $\%O_2$, and temperature with the touch of a button
- The Precision Flow Plus and Precision Flow Hi-VNI® systems come equipped with Nurse Call and EMR connectivity to improve hospital workflows and efficiency
- All components are safe to touch without burn risk
- Incubator safe



SOLO cannula effectively delivers high velocity therapy, but through one nare, allowing for easier NGI tube placement.

A Fully Mobile System

The Vapotherm Transfer Unit ensures high velocity therapy is mobile throughout the hospital:

- Delivery Room stabilization and transfer[7]
- Maintain the same level of respiratory support on the go

7. Reynolds P, Leontiadi S, Lawson T, et al. Stabilisation of premature infants in the delivery room with nasal high flow Archives of Disease in Childhood – Fetal and Neonatal Edition 2016;101:F284-F287.

A Chance at Greater Family Satisfaction by Keeping Families Local

A case report* of a community hospital with a Level II nursery showed that the hospital reduced neonatal transports by over 80% after implementing high velocity therapy. This allowed families to stay local—a factor often associated with greater patient satisfaction.

The hospital had a policy guideline that infants requiring pressure support beyond initial recruitment breaths were considered for transport to a Level III NICU.

The NICU Medical Director believed that NICU transports out can result in lower family satisfaction, increased patient risk during transport, and unfavorable economics.

Before High Velocity Therapy

35/year

Average Transports Out

After High Velocity Therapy

3/year

Average Transports Out

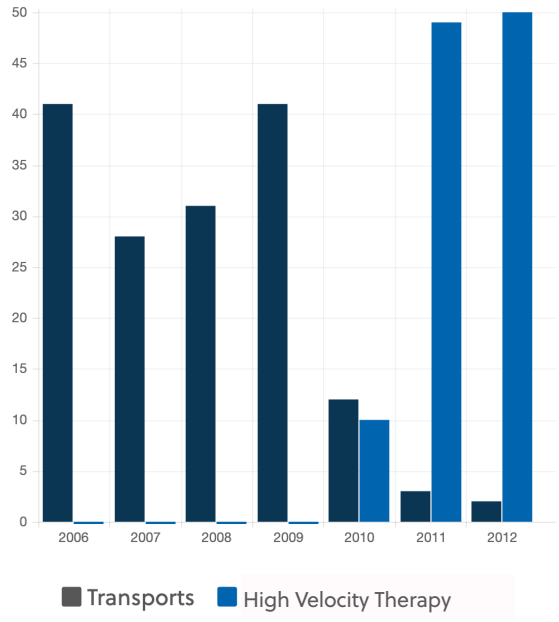


Figure 1: Level II Nursery Transports Out

Care Area: 10-Bed Level II Nursery
Setting: Community Hospital
Location: Greater Phoenix Metro
Deliveries per Year: 1,700 (approx.)

Ultimately this hospital was able to drastically reduce their NICU transports of babies with mild to moderate RDS and keep families local. This was accomplished by implementing high velocity therapy which was able to offer the clinical efficacy of nCPAP, but without being a pressure support device.

*This is a story about one community hospital's positive experience using Vapotherm's high velocity therapy. Although individual results may vary, Vapotherm believes this story is a powerful testimonial in support of the use of high velocity therapy on patients experiencing respiratory distress.

Clarifying the Research HFNC vs High Velocity Therapy as Compared to nCPAP and NiPPV

High velocity therapy is non-inferior to nCPAP when it comes to primary respiratory support as well as post-extubation support.[4,5]

However, high velocity therapy often gets conflated with commodity high flow oxygen products, also commonly known as High Flow Nasal Cannula (HFNC), which have not shown these clinical outcomes. Many studies don't differentiate between the two, though this is slowly changing in the medical field as randomized controlled trial evidence showed high velocity therapy to have outcomes comparable to Non-Invasive Positive Pressure Ventilation (NiPPV) when treating adult emergency department patients in undifferentiated respiratory distress.[7]

Nevertheless, when reading existing research, clinicians often have to look closely to determine whether a study was conducted with high velocity therapy or with commodity high flow oxygen products. When sorted accurately, the clinical literature demonstrates the effectiveness of high velocity therapy, as shown in Figure 2.

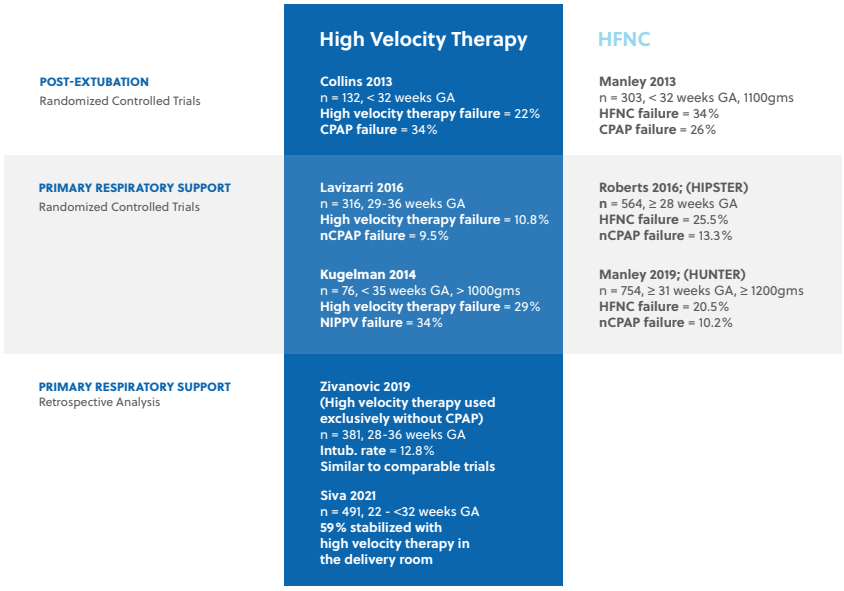


Figure 2: Trials with Vapotherm High Velocity Therapy Show Noninferiority to CPAP

A Category of One

Following substantial clinical evidence, the U.S. Food and Drug Administration created a new product code for the Precision Flow Hi-VNI system, placing the device into a different category from commodity high flow products altogether. The code is QAV.

8. Doshi, Pratik et al. High-Velocity Nasal Insufflation in the Treatment of Respiratory Failure: A Randomized Clinical Trial. Annals of Emergency Medicine, 2018. Published online ahead of print. https://www.ncbi.nlm.nih.gov/pubmed/29310868

More Ease for Your Patients and Their Families

- Families can see their baby's face
- Kangaroo care made easy
- Comfortable, well-tolerated
- Integrated safety alarms

"This kind of care is not care for a baby. It's care for a whole family and it makes such a difference to people's lives you know—to be able to see and feel their baby."
—Nadia Merhi, mother of premature twins supported on high velocity therapy

More Ease for You and Your Institution

- As effective as the gold standard CPAP, but with lower risks of complications and discomfort that come with a tight-fitting interface
- Fast set up—ready to go in less than 5 minutes
- Easy interface fitting

"We use Vapotherm in the NICU to wean our patients from the ventilator. The therapy is effective clinically and promotes bonding and enhances rates of breastfeeding."
—Diana, RN, describing her personal experience using Vapotherm

Visit **www.vapotherm.com** to learn more.

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