

» Literature List

**Publications regarding Ventinova Medical's concepts and products are increasing. This list comprises published literature on clinical use, pre-clinical validation and technological development.**

Specific features of FCV® and EVA® described are indicated:



Higher Efficiency



Lower Energy



Small Lumen



## Upper Airway Surgery

### Evone® – Clinical Studies – Upper Airway Surgery

The first clinical study on FCV® using Evone in combination with the narrow-bore Tritube®, conducted at two German academic medical centers, showed adequate ventilation during ear-nose-throat surgery, with stable respiratory and hemodynamic parameters throughout the procedure. Online videos illustrate good visibility of the laryngeal structures during and after placement of Tritube and the linear intratracheal pressures displayed on the screen by Evone during ventilation in FCV® mode. With Tritube's cuff deflated, patients could comfortably breathe spontaneously after emergence from anesthesia. In one patient Tritube (with deflated cuff) was left in place until arrival in the post anesthesia care unit. The authors state that, "FCV® in combination with Tritube contributes to the armamentarium for airway management".



*J. Schmidt, F. Günther, J. Weber, S. Wirth, I. Brandes, T. Barnes, A. Zarbock, S. Schumann, D. Enk. Flow-controlled ventilation during ear, nose and throat surgery. A prospective observational study. Eur J Anaesthesiol. 2019 May;36(5):327-334*

---

The workgroup of Prof. Schumann demonstrated in a randomized controlled trial involving patients undergoing laryngeal surgery that Tritube improves surgical conditions for surgeons with a lower level of expertise by reducing concealment of laryngeal structures (-68%;  $P < 0.001$ ) compared to an MLT-6. Further, they showed that FCV<sup>®</sup> improves alveolar recruitment and consequently enhances respiratory system compliance compared to VCV ( $63 \pm 14$  vs.  $46 \pm 8$  mL/cmH<sub>2</sub>O;  $P < 0.001$ ), while using a lower inspiratory plateau pressure ( $14 \pm 2$  vs.  $17 \pm 2$  cmH<sub>2</sub>O;  $P < 0.001$ ).



*J. Schmidt, F. Günther, J. Weber, S. Wirth, S. Schumann. Improved airway management and ventilation with a cuffed endotracheal tube with an outer diameter of 4.4 mm for laryngeal surgery - a randomized controlled trial. Abstract #3269 presented at Euroanaesthesia 2019 - Manuscript submitted*

---

Drs. Kristensen and Abildstrøm showed in a randomized controlled trial in patients with predicted difficult laryngoscopy undergoing head/neck surgery that Tritube improves intubation and surgical conditions as compared to a standard MLT-6. Additionally, they demonstrated that, with a deflated cuff, Tritube is equally well tolerated as compared to a standard tube exchanger when left in situ postoperatively.



*M.S. Kristensen, H.H. Abildstrøm. Endotracheal video-laryngoscope guided intubation with a 2.4 mm cuff'ed tube and active expiration by a dedicated ventilator versus a standard tube/ventilator. A randomized single blinded study in patients with a predicted difficult airway. - A paradigm shift in airway management? Abstract #3755 presented at Euroanaesthesia 2019 - Manuscript in preparation*

## **Evone – Clinical Cases – Upper Airway Surgery**

---

Dr. Imran Ahmad is the first to describe a challenging airway case, in which Tritube and Evone were found of significant value. The patient, scheduled for panendoscopy, had an anticipated difficult airway combined with airway pathology and COPD. Dr. Ahmad therefore opted for awake tracheal intubation with Tritube. After awake placement of the flexible bronchoscope, Tritube was guided using a silk suture tied over the bronchoscope. The patient was anesthetized and adequately ventilated with Evone for 45 minutes. Tritube allowed adequate surgical access with the advantage of a definitive airway, whilst continuous ventilation was delivered.



*K. Jeyarajah and I. Ahmad. Awake tracheal placement of the Tritube under flexible bronchoscopic guidance. Anaesthesia Cases / 2018-0097 / ISSN 2396-8397 epub Jul 2018*

## General Surgery

### Evone – In-Vivo Study – General Surgery

The workgroup of Prof. Schumann was the first to execute a comparative study, evaluating a commonly applied VCV protocol with FCV® mode by Evone. This study in healthy pigs shows that FCV® improves lung aeration via elevated mean tracheal pressure and consequently improves arterial oxygenation (+10%,  $P=0.002$ ) at unaltered positive end-expiratory pressure (PEEP) and peak inspiratory pressure (PIP), while using a lower minute volume (-21%,  $P=0.04$ ). Moreover, these findings suggest the FCV® mode provided by Evone is a new approach for protective lung ventilation.

*J. Schmidt, C. Wenzel, M. Mahn, S. Spassov, H.C. Schmitz, S. Borgmann, Z. Lin, J. Haberstroh, S. Meckel, S. Eiden, S. Wirth, H. Buerkle and S. Schumann. Improved lung recruitment and oxygenation during mandatory ventilation with a new expiratory ventilation assistance device: A controlled interventional trial in healthy pigs. Eur J Anaesthesiol. 2018 Oct;35(10):736-744*



### Evone – Clinical Studies – General Surgery

The workgroup of Prof. Schumann revealed in a crossover randomized controlled trial in lung-healthy patients a higher efficiency of ventilation when using FCV® compared to VCV, even after short-term application. With similar ventilation settings, FCV® resulted in a 9% higher arterial oxygenation and 4% lower arterial CO<sub>2</sub> concentration ( $P<0.001$ ). The mean tracheal pressure was higher during FCV® (+10 %;  $P<0.001$ ). This study indicates that FCV® may help to prevent hypoxemia during mechanical ventilation.

*J. Weber, J. Schmidt, L.M.M. Straka, S. Wirth, S. Schumann. Flow-controlled ventilation improves oxygenation in mechanically ventilated lung-healthy patients - a crossover controlled interventional trial. Abstract #3301 presented at Euroanaesthesia 2019 - Manuscript submitted*



The workgroup of Prof. Schumann revealed in a crossover randomized controlled trial that in morbidly obese patients FCV® better maintains end-expiratory lung volume as compared to VCV ( $P<0.001$ ). The subsequent ventilation phases were applied for only 7 minutes, with similar tidal volumes, but lower peak inspiratory pressures for FCV®. This study indicates that FCV® may help to prevent atelectasis during mechanical ventilation.

*J. Weber, L.M.M. Straka, J. Schmidt, S. Borgmann, S. Wirth, S. Schumann. Flow-controlled ventilation improves end-expiratory lung volume in obese patients - a crossover controlled interventional trial. Abstract #3315 presented at Euroanaesthesia 2019 - Manuscript submitted*



## Intensive Care

### Evone – In-Vivo Study – Intensive Care

The workgroup of Prof. Schumann demonstrated in porcine ARDS, that FCV<sup>®</sup> ventilation stabilizes alveolar walls and shifts ventilation distribution from atelectatic to aerated lung tissue. Consequently, FCV<sup>®</sup> ventilation improves oxygenation (+53%, P=0.04) and facilitates CO<sub>2</sub> removal with a lower Minute Volume (-30%; P<0.001). This study illuminates the higher ventilation efficiency and lung protective potency of FCV<sup>®</sup> in ARDS.

*J. Schmidt, C. Wenzel, S. Spassov, S. Wirth and S. Schumann. Expiratory Ventilation Assistance during mandatory ventilation in porcine ARDS improves arterial oxygenation - a randomized controlled animal study. Abstract Euroanaesthesia 2018 - Manuscript submitted*



## FCV<sup>®</sup> and Lower Energy

### Evone – Theoretical Evidence – FCV<sup>®</sup> and Lower Energy

Prof. Barnes, together with Van Asseldonk and Enk, provides clear theoretical evidence for lower energy dissipation in the lungs by FCV<sup>®</sup> as compared to VCV or PCV. They present a simple analysis and numerical calculations indicating that energy dissipation may be substantially reduced by controlling the ventilation flow to be constant and continuous during both inspiration and expiration and by ventilating at an I:E ratio very close to 1:1 – that is by using FCV<sup>®</sup>.

*T. Barnes, D. van Asseldonk and D. Enk. Minimisation of dissipated energy in the airways during mechanical ventilation by using constant inspiratory and expiratory flows - flow controlled ventilation. Medical Hypotheses 121 (2018); 167-176*



### Evone – Clinical Proof of Concept – FCV<sup>®</sup> and Lower Energy

Profs Barnes and Enk are the first to actually determine pressure-volume (PV) loops and to show minimized energy dissipation in a patient ventilated with FCV<sup>®</sup> by Evone. During FCV<sup>®</sup> ventilation, both inspiratory and expiratory flows were kept nearly constant around 12 L/min and the I:E ratio was 1:1 resulting in a minute volume of 6.2 L/min. PV loops were recorded using pressure measured directly within the patient's trachea and the energy dissipated in the patient was calculated from the hysteresis area of the PV loops. The energy dissipation was 0.17 J/L, which is even lower than values quoted in literature



for spontaneous breathing (0.2-0.7 J/L). They state that FCV® may have implications for lung-protective ventilation.

*T. Barnes and D. Enk. Ventilation for low dissipated energy achieved using flow control during both inspiration and expiration. Trends in Anaesthesia and Critical Care 2019 (24); 5-12*

## › ventrain ◀

### Airway Management

#### Ventrain – Review Article – Airway Management

This review by Dr. Doyle sets out the clinical and technical perspectives on Ventrain®. A short explanation of the physical principles underlying the functional concept of Ventrain is followed by a summary of bench and animal studies that demonstrate its novelty and efficient performance. Dr. Doyle then highlights clinical cases and studies demonstrating clear advantages of Ventrain compared to conventional ventilation techniques through small lumen catheters. He describes the use of Ventrain during upper airway surgery, in emergency CICO ('Cannot Intubate, Cannot Oxygenate') situations, for critical pediatric airways and its potential value during extubation. In sum, all published data support an emerging and promising role of Ventrain in clinical airway management.

*D.J. Doyle. Ventilation via Narrow-Bore Catheters: Clinical and Technical Perspectives on the Ventrain Ventilation System. The Open Anaesthesia Journal 2018, Volume 12*



### Upper Airway Surgery

#### Ventrain – Clinical Cases – Upper Airway Surgery

Dr. Kristensen and colleagues were the first to describe Tritube's clinical use in seven adult ear-nose-throat surgical patients with airway narrowing or whose surgical access was facilitated by this small-bore endotracheal tube. In combination with Ventrain, adequate ventilation was achieved in all patients and intratracheal pressure was kept between 5 and 20 cm H<sub>2</sub>O.

They concluded that: *"The 2.4 mm internal diameter Tritube seems to facilitate tracheal intubation and to provide unprecedented view of the intubated airway during oral, pharyngeal, laryngeal or tracheal procedures in adults."*



Additionally, they state that: *"This technique has the potential to replace temporary tracheostomy, jet-ventilation or extra-corporal membrane oxygenation in selected patients."*  
*M.S. Kristensen, M.W.P. de Wolf and L.S. Rasmussen. Ventilation via the 2.4 mm internal diameter Tritube® with cuff - new possibilities in airway management. Acta Anaesthesiol. Scand. 2017 Jul; 61(6):580-589*

---

Dr. Rodríguez and colleagues present a series of nine cases of laryngeal microsurgery to treat benign polyps. All patients were ventilated satisfactorily using Ventrain and Tritube, confirmed by blood gas analyses. Surgical satisfaction was excellent, mainly due to the greater exposure and better maneuverability provided by Tritube.

*L. Rodríguez, J.J. Sanchez Palomo, M.A. Lopez Salcedo, N.E. Pizarro, S. Fossati Puertas, L. Santé Serna. Cutting-edge ventilation method in laryngeal microsurgery. Abstract #3280 presented at Euroanaesthesia 2019*



---

Dr. Zuercher and colleagues report an innovative combination of Ventrain and S-Guide for airway management of a planned endoscopic dilation of a severe subglottic stenosis in an adult patient. They state that this new alternative may offer advantages over existing airway management techniques in similar cases.

*M. Zuercher, M. Pythoud-brügger, K. Sandu and P. Schoettker. Combined use of Ventrain and S-Guide for Airway Management of Severe Subglottic Stenosis. Turk J Anaesthesiol Reanim 2019 (epub ahead of print)*



---

Dr. Ahmad and colleagues present a case of a patient with severe upper airway obstruction undergoing surgical intervention, avoiding the need for tracheostomy. The patient sternly refused an awake elective tracheostomy or wide-bore cricothyroid cannula, so a 2-stage airway management technique was performed: an awake fiberoptic intubation with a small diameter endotracheal tube, followed by needle cricothyroidotomy with Cricath® after anesthetic induction. Ventrain was used to adequately ventilate the patient for 75 minutes (SpO<sub>2</sub> 100%, PaCO<sub>2</sub> 46 mmHg). Post-operatively Cricath was left in situ for 24 hours. No complications occurred. The patient was discharged home 2 days later. View this elegant two-stage airway management technique: <http://links.lww.com/AACR/A133>

*D.N. Onwochei, K. El-Boghdady and I. Ahmad. Two-Stage Technique Used to Manage Severe Upper Airway Obstruction and Avoid Surgical Tracheostomy: A Case Report. A A Pract 2018 Mar 1;10(5):118-120*



---

Dr. Fearnley and colleagues reported the elective use of Ventrain in a patient with post radiation fibrosis that had previously prevented passive expiration during attempted high frequency jet ventilation. Ventrain was found simple and easy to use and provided perfectly



adequate transtracheal ventilation for > 1 hour, allowing laser resection of the stenosis. They have used our transtracheal catheter Cricath, which was found kink resistant. Ventrain has now become their first choice device when emergency needle cricothyrotomy is performed.

*R.A. Fearnley, S. Badiger, R. Oakley and I. Ahmad. Elective use of the Ventrain for upper airway obstruction during high frequency jet ventilation. J Clin Case Rep 2016 (6):2*

---

Dr. Borg and colleagues reported the successful and uneventful elective use of Ventrain in combination with a transtracheal catheter (2 mm ID) with 20 min of adequate ventilation and oxygenation in a patient with partial obstruction of the laryngeal inlet.

*P.A. Borg, A.E.W. Hamaekers, M. Lacko, J. Jansen and D. Enk. Ventrain for ventilation of the lungs. Br J Anaesth. 2012 Nov;109(5):833-4*



---

Dr. Monnier and colleagues reported a new surgical technique in a patient with an early stage squamous cell carcinoma of the glottis with involvement of both vocal cords and impossible transoral access to the larynx, due to a medical history of head and neck radiation. While the larynx was accessed transthyrohyoidly, Ventrain was used for transtracheal ventilation during the first part of the surgery, followed by high frequency jet ventilation when the airway was patent. This setup proved to be extremely safe for securing the airway and allowed endoscopic resection of the tumor.

*Y. Monnier, P. Schoettker, B. Morisod, C. Ikonomidis and C. Simon. Transthyrohyoid access to the larynx for endoscopic resection of early-stage glottic cancer. Head Neck 2016 Aug;38(8):1286-9*



---

Dr. Kalkoff described the first successful use of Ventrain in combination with an intubating catheter in an elective setting, in a patient undergoing microlaryngoscopy with a partly obstructed airway.

*M. Kalkoff. Ventilation through a small-bore intubating catheter using Ventrain in an elective procedure. Letter Br J Anaesth 2012*



---

In Ethiopia, Dr. Braga and colleagues electively used Ventrain in combination with a transtracheal catheter as a safe 'bridge to intubation' in a young patient presented for free flap surgery to cover a complex type IV NOMA defect.

*B.A.J. Braga, G. Rodey, G. Hotvedt, A.F.H. Taylor and D.R. Ball. Ventrain ejector ventilation as a bridge to tracheal intubation for complex NOMA pathology – Poster presented at the Difficult Airway Society 2014 and World Airway Management Meeting 2015*



## Ventrain – In-Vivo Studies – Upper Airway Surgery

The workgroup of Prof. Enk demonstrated with an early prototype of Tritube that small-bore ventilation with Ventrain is optimized in a cuffed airway. A pressure measurement line in the prototype Tritube enabled a reliable airway pressure monitoring using a cuff manometer. During the 30 minutes of ventilation with Ventrain (PaO<sub>2</sub> 61 [52-69] kPa; PaCO<sub>2</sub> 4.9 [4.2-6.2] kPa) hemodynamics were stable. This elegant study was executed in healthy pigs.

*M. W. P. de Wolf, T. van der Beek, A. E. Hamaekers, M. Theunissen and D. Enk. A prototype small-bore ventilation catheter with a cuff: cuff inflation optimizes ventilation with the Ventrain. Acta Anaesth Scand 2018 Mar 62(3):328-335*



Dr. Paxian and colleagues demonstrated that Ventrain can ensure sufficient oxygenation and ventilation through a small-bore transtracheal catheter in live pigs when the airway is open, partly obstructed, or completely closed. Additionally, the minute ventilation and avoidance of high airway pressures were superior in comparison with traditional hand-triggered jet ventilation, particularly in the event of complete upper airway obstruction.

*M. Paxian, N.P. Preussler, T. Reinz, A. Schlueter and R. Gottschall. Transtracheal ventilation with a novel ejector-based device (Ventrain) in open, partly obstructed, or totally closed upper airways in pigs. Br J Anaesth 2015 Aug;115(2):308-16. (Also referred in section "Emergency")*



## Ventilation during lung separation procedures

### Ventrain – Clinical Case – Ventilation during lung separation procedures

In a patient undergoing thoracoscopic esophagectomy and concomitant wedge resection, an iatrogenic lesion in the left main bronchus was observed following deflation of the right lung. Repair of the lesion required deflation of the bronchial cuff. This challenging situation was resolved by Dr. Evers. She used Ventrain to oxygenate the patient through an Arndt Endobronchial Blocker through the lumen beyond the bronchial defect. With the use of this technique, oxygenation was maintained at an acceptable level during repair.

*V.M. Evers, R.V. Immink, W.J.P. van Boven, M.I. van Berge Henegouwen, M.W. Hollmann and D.P. Veelo. Intraoperative Use of the Ventrain for Single Lung Ventilation After Iatrogenic Trauma to the Left Main Bronchus During Thoracoscopy: A Case Report. AA Case Rep 2017 Aug 15; 9(4):116-118 Commented by H.P. Grocott. Using the Ventrain With a Small-Bore Catheter: Ventilation or Just Oxygenation? Anesth Analg. 2018 Apr;126(4):1426-1427*



## Emergency

### Ventrain – Clinical Cases – Emergency

Dr. Morisson reported a case of a 71-year-old man with advanced vocal cord carcinoma, presenting with severe airway obstruction. Therapeutic anticoagulation with enoxaparin complicated management. Failure of an oral awake bronchoscopic intubation was rescued by passing a guidewire through the working channel and threading an Arndt exchange catheter into the trachea under videoscopic vision. Ventilation with Ventrain lasting 40 minutes (15 L/min, inspiration/expiration 1:1, 15 breaths/min), during IV anesthesia with muscle paralysis, resulted in excellent blood gas values until placement of the tracheal cannula. The authors state that: "This case report highlights the effectiveness of a novel ventilation technique that should be considered as back-up when bronchoscopic intubation fails."

*S. Morrison, S. Aerts, D. van Rompaey, O. Vanderveken. Awake Intubation for Critical Airway Obstruction Rescued With the Ventrain Device and an Arndt Exchange Catheter: A Case Report A A Pract. 2019 Feb 5 (epub ahead of print)*



Dr. Gerling and colleagues saved a patient's life using Cricath and Ventrain. Deteriorating respiratory distress, increasing hypoxia, and decreasing level of consciousness of a transported patient forced a ground ambulance to stop at the emergency department of the Meander Medical Center Amersfoort. Upon arrival the patient had a SpO<sub>2</sub> of 81%, which dropped to 37% within 5 minutes. Active ventilation was not possible. Quick intraoral inspection and fiberoptic evaluation revealed massive edema, secretions and no airway. Cricath was placed and ventilation with Ventrain was started. SpO<sub>2</sub> rapidly raised within 90 seconds to 99% and hemodynamics improved. Ventrain ventilation lasted for nearly 60 minutes before semi-elective surgical tracheotomy was safely performed.

*D.A. Heuveling, H.F. Mahieu, H.G. Jongsma-van Netten and V. Gerling. Transtracheal Use of the CriCath Cannula in Combination With the Ventrain Device for Prevention of Hypoxic Arrest due to Severe Upper Airway Obstruction: A Case Report. A A Pract. 2018 Dec 5;11(12):344-347*



Dr. Escribá presents the rescue of a difficult airway in a pediatric patient with subglottic stenosis with Ventrain. When the patient desaturated, the device enabled immediate ventilation during airway assessment through a rigid bronchoscope and restoration of normal oxygen saturation. Then, post intubation, ventilation with the Ventrain was valuable again,



when conventional mechanical PICU ventilation was very difficult due to elevated pressures. This case clearly indicates that the new ventilation device Ventrain offers advantages over devices available until now.

*F.J. Escrivá Alepuz, J. Alonso García, J.V. Cuchillo Sastriques, E. Alcalá and P. Argente Navarro. Emergency Ventilation of Infant Subglottic Stenosis Through Small Gauge Lumen Using the Ventrain®. A A Prac 2018 Mar 15;10(6):136-138*

---

Dr. Wahlen and colleagues described a case in which Ventrain in combination with a tube exchanger was used to ventilate a patient with life-threatening tracheal stenosis. After a failed initial intubation with an endotracheal tube (ID 5.0 mm) the tube exchanger was inserted allowing adequate ventilation with Ventrain until surgical tracheostomy was performed. Hemodynamic stability indicated that the active expiration induced by Ventrain prevented intrapulmonary pressure build-up by air trapping and subsequent barotrauma, which may be observed during traditional jet ventilation in a similar situation.

*B.M. Wahlen, H. Al-Thani and A. El-Menyar. Ventrain: from theory to practice. Bridging until re-tracheostomy BJM Case Rep 2017 Aug 16; 2017*



---

Dr. Willemsen and colleagues reported cases of ventilation through a small lumen intubating catheter (35 cm long; 1.6 mm ID) and an exchange catheter (45 cm long, 1.6 mm ID) using Ventrain to manage critical paediatric airways in babies of 2.1 kg and 4.3 kg, respectively.

*M.G. Willemsen, R. Noppens, A.L. Mulder and D. Enk. Ventilation with the Ventrain through a small lumen catheter in the failed paediatric airway: two case reports. Br J Anaest 2014 May;112(5):946-7*



---

Dr. J. López-Torres and colleagues present four case reports of Ventrain use: laryngeal microsurgery, foreign body in the airway emergency, subglottic stenosis and assistance to guide extubation in Pierre-Robin syndrome. They indicate that laryngospasm, edema or anatomical distortion, combined with over-vigorous jet insufflation can result in air trapping with subsequent barotrauma and hemodynamic instability. They state that Ventrain is the only ventilation device that provides full ventilation for these situations.

*J. López-Torres, F.J. Escrivá, J. Encarnación, J. Alonso, J.V. Cuchillo and P. Argente. Ventrain device for difficult or obstructed airways: 4 case report. Trends in Anaesthesia and Critical Care 2017 12:31*



---

Dr. Krapf demonstrated feasibility of using Ventrain in combination with needle cricothyrotomy in a pre-hospital CICV setting under reanimation conditions.

*M. Krapf, D. Gäumann, J. Jacquier and S. Graf. Cannot intubate, cannot ventilate: Beatmung über einen 2-mm-Katheter in der Präklinik. Notfallpraxis 2016 8(39); 792-794 (article in German)*



---

Dr. Nellgård underlined the importance of performing an early cricothyrotomy in a situation of CICV. After several failed attempts to intubate a patient with instable angina pectoris scheduled for coronary artery bypass surgery, bag and mask ventilation became unsuccessful. A transtracheal catheter (2 mm ID) was placed and ventilation with Ventrain increased saturation from <50% to ~80%. Then, cricothyrotomy was successfully performed using the Melker Cricothyroidotomy 5. Surgery was postponed and percutaneous coronary intervention was performed instead.

*P. Nellgård. Ventrain in a case of can't intubate can't ventilate situation. Orally presented at the European Society of Anaesthesiology 2013*



---

Dr. Kalsi and colleagues reported for the first time the use of Ventrain in combination with a transtracheal catheter (2 mm ID) in an emergency scenario. They demonstrated adequate ventilation with saturation levels >98%.

*A. Kalsi, K. Konieczny and M. Turner. Transtracheal jet ventilation using the Ventrain Device in a patient with severe upper airway obstruction. Poster presented at the Difficult Airway Society 2012*



## **Ventrain – In-Vivo Studies – Emergency**

---

Prof. Enk's workgroup demonstrated that Ventrain provided rapid reoxygenation and effective ventilation through a 100 cm long airway exchange catheter (ID 3 mm) in severe hypoxic pigs with an obstructed airway. This study clearly indicates potential clinical applicability and usefulness of Ventrain, not only in combination with short, transtracheal cannulas but also with long small lumen tubes/catheters when (re)intubation is difficult or has failed.

*M.W.P. de Wolf, R. Gottschall, M.P. Preussler, M. Paxian and D. Enk. Emergency ventilation with the Ventrain through an airway exchange catheter in a porcine model of complete upper airway obstruction. Can J Anaesth. 2017 Jan;64(1):37-44*



---

Dr. Paxian and colleagues demonstrated that Ventrain can ensure sufficient oxygenation and ventilation through a small-bore transtracheal catheter in live pigs when the airway is open, partly obstructed, or completely closed. Additionally, the minute ventilation and avoidance of high airway pressures were superior in comparison with traditional hand-triggered jet ventilation, particularly in the event of complete upper airway obstruction.

*M. Paxian, N.P. Preussler, T. Reinz, A. Schlueter and R. Gottschall. Transtracheal ventilation with a novel ejector-based device (Ventrain) in open, partly obstructed, or totally closed upper airways in pigs. Br J Anaesth 2015 Aug;115(2):308-16 (Also referred in section "Upper airway surgery")*



---

The workgroup of Prof. Enk showed quickly restored oxygenation after ventilation with Expiratory Ventilation Assistance (EVA®) in cases of a completely or partially obstructed upper airway in severe hypoxic pigs. Reoxygenation and ventilation were less efficient when the upper airway was completely unobstructed.

*A.E.W. Hamaekers, T. van der Beek, M. Theunissen and D. Enk. Rescue ventilation through a small-bore transtracheal cannula in severe hypoxic pigs using expiratory ventilation assistance. Anesth Analg. 2015 Apr;120(4):890-4*



---

In post-apnoeic sheep, Dr. Berry and colleagues demonstrated that Ventrain provided stable oxygenation and effective ventilation at low airway pressures during emergency percutaneous transtracheal ventilation in critically obstructed airways. Manujet provided effective temporizing oxygenation in this situation with hypoventilation necessary to minimize barotrauma risk.

*M. Berry, Y. Tzeng and C. Marsland. Percutaneous transtracheal ventilation in an obstructed airway model in post apnoeic sheep. Br J Anaesth. 2014 Dec;113(6):1039-45*



---

Dr. Ziebart and colleagues confirmed in a pig model with upper airway obstruction adequate ventilation using Ventrain in combination with a transtracheal catheter. Furthermore, they underline the importance of training and education of users and adherence to the instructions for use in order to use Ventrain safely.

*A. Ziebart, A. Garcia-Bardon, J. Kamuf, R. Thomas, T. Liu, A. Schad, B. Duenges, M. David and EK. Hartmann. Pulmonary effects of expiratory-assisted small-lumen ventilation during upper airway obstruction in pigs. Anaesthesia. 2015 Oct;70(10):1171-9*



---

In a small pilot study the workgroup of Prof. Rosenblatt demonstrated that Ventrain rapidly corrected hypoxemia in a large ovine model.

*S. Manoach, L. Paladino and W. Rosenblatt. Resuscitation from prolonged apnea and upper airway obstruction in a large ovine model: a pilot trial of transtracheal ventilation using 15 lpm with and without an entrainment assisted trans-catheter exhalation device. Poster presented at the Society for Airway Management 2011*



## Technology Development

### Concepts – Preclinical and bench studies – Technology Development

---

In a bench study the workgroup of Prof. Enk tested the efficacy of a prototype of Ventrain. Results of this study suggested that Ventrain is capable of achieving a normal minute volume for an average adult through a 2 mm ID transtracheal catheter.

*A.E.W. Hamaekers, P.A. Borg and D. Enk. Ventrain: an ejector ventilator for emergency use. Br J Anaesth. 2012 Jun;108(6):1017-21.*



---

Prof. Heerdt and co-workers showed in a porcine model that EVA ventilation with a Negative End Expiratory Pressure (NEEP; -8 mbar) improved hemodynamics during normovolemia and during hypovolemia after hemorrhage as compared with VCV with PEEP. Before hemorrhage EVA-NEEP increased stroke volume (+27%;  $p=0.003$ ) and cardiac output (+21%;  $p=0.023$ ), and reduced central venous pressure (-30%;  $p=0.013$ ) compared with Volume Controlled Ventilation with PEEP (4 mbar). After hemorrhage during hypovolemia the effects were more pronounced leading to an 41% increased cardiac output, higher mean arterial pressure and increased venous return for EVA-NEEP ventilation as compared with VCV-ZEEP (0 mbar). For this study a prototypical small automated ventilator based upon the EVA principle was used to generate a controlled period of negative EEP.

*D.A. Berlin, S. Manoach, C. Oromendia and P. Heerdt. Automated expiratory ventilation assistance through a small endotracheal tube can improve venous return and cardiac output. Intensive Care Med Exp 2019, 7(1), 22 Commented by L. Böttinger and J.W.A. van der Hoorn. Negative pressure ventilation – a special application of expiratory ventilation assistance. Intensive Care Med Exp 2019, 7(1), 22*

---

The importance of flow and pressure release in jet ventilation devices was demonstrated by Prof. Enk and his co-workers in a bench study where three previously described self-assembled jet devices and the Oxygen Flow Modulator were tested. In case of complete

upper airway obstruction the OFM provides sufficient flow and pressure release, whereas the self-assembled jet devices tested are inherently dangerous constructions.

*A.E.W. Hamaekers, P.A. Borg, T. Götz and D. Enk. The importance of flow and pressure release in emergency jet ventilation devices. Paediatr Anaesth. 2009 May;19(5):452-7*

To reduce the risk of air trapping and to increase oxygenation efficacy an emergency transtracheal ventilation device needs to allow both inspiration and expiration. In absence of such a device Prof. Enk and his co-workers determined the capability of two self-assembled, three-way stopcock based jet devices and the Oxygen Flow Modulator to function as a bidirectional airway in conjunction with a small lumen catheter.

*A.E.W. Hamaekers, P.A. Borg and D. Enk. A bench study of ventilation via two self-assembled jet devices and the Oxygen Flow Modulator in simulated upper airway obstruction. Anaesthesia. 2009 Dec;64(12):1353-8*



The ineffectiveness and danger of using transtracheal jet ventilation in cases of complete upper airway obstruction motivated Prof. Enk to search for a better solution. Prof. Enk's workgroup transformed a small, industrial ejector into a simple, manual ventilator providing expiratory ventilation assistance (EVA®). They showed that EVA® shortened the expiration time and that a minute volume up to 6.6 L/min could be achieved through a 2 mm ID transtracheal catheter in a simulated obstructed airway.

*A.E.W. Hamaekers, T. Götz, P.A. Borg and D. Enk. Achieving an adequate minute volume through a 2 mm transtracheal catheter in simulated upper airway obstruction using a modified industrial ejector. Br J Anaesth. 2010 Mar;104(3):382-6*



A functional model of Ventrain, based on EVA® technology was build by Prof. Enk: the DE5. In laboratory tests the workgroup of Prof. Enk showed that the DE 5 is an optimized ventilation ejector suitable for applying expiratory ventilation assistance.

*A.E.W. Hamaekers, P.A. Borg, T. Götz and D. Enk. Ventilation through a small-bore catheter: optimizing expiratory ventilation assistance. Br J Anaesth. 2011 Mar;106(3):403-9*



The workgroup of Prof. Enk showed in a bench study that Ventrain is capable of achieving adequate minute volume ventilation through a 100 cm long, 3 mm ID Airway Exchange Catheter by applying EVA® in a simulated completely obstructed airway.

*E.M. Dias, A.E.W. Hamaekers, P.A.J. Borg and D. Enk. Adequate minute volume ventilation through a 100 cm long, 3 mm inner diameter airway exchange catheter by expiratory ventilation assistance (EVA®). Poster presented at the European society of Anaesthesiology 2012*



---

In this bench study Prof. Enk demonstrated that Ventrain in combination with a prototype cuffed jet ventilator catheter should allow adequate minute volume ventilation in adult patients.

*D. Enk and S. Enk. Small Lumen Ventilation through a Cuffed Jet Ventilation Catheter: Efficiency and Safety. Poster presented at the Society for Airway Management 2012*



---

In a bench study Dr. Calderon and colleagues compared passive expiration with EVA® using Ventrain in a Totally Obstructed Airway model. They demonstrated that, in contrast to passive expiration, EVA® maintained an acceptable Minute Volume, avoiding auto-PEEP.

*L.G.M.B Calderon, M.M. Moreira, G.L. Emídio, E.P. Corrêa, M.A. Carvalho-Filho and R.G.G. Terzi. Expiratory ventilation assistance (EVA®) through a 14G catheter (2mm) in a Totally Obstructed Airway (TOA). Poster presented at Society for Airway Management 2013*



---

In a bench study Dr. Schmidt and colleagues show that not every oxygen delivery device will generate enough driving pressure to deliver a predictable flow through Ventrain and a 2 mm (ID) 75 mm long transtracheal catheter. They confirmed that while using the prescribed oxygen supply system with a pressure compensated flow regulator, flow and tidal volume were predictable enabling adequate ventilation through a small lumen.

*A.R. Schmidt, K. Ruetzler, T. Haas, A. Schmitz and M. Weiss. Impact of oxygen sources on performance of the Ventrain® ventilation device in an in vitro set-up. Acta Anaesthesiol Scand. 2016 Feb;60(2):241-9. Rebuttal by de Wolf MW, Schutzer-Weissmann JM. Acta Anaesthesiol Scand. 2016 Nov;60(10):1477-1478.*



---

In a bench study Dr. Wirth and colleagues showed that active expiration assistance (using Ventrain) provided better maintenance of minute ventilation without intrinsic PEEP compared to conventional mechanical ventilation (passive expiration), when using a small endotracheal tube or cricothyrotomy catheter.

*S. Wirth, L. Seywert, J. Spaeth and S. Schumann. Compensating Artificial Airway Resistance via Active Expiration Assistance. Respir Care. 2016 Dec;61(12):1597-1604*



---

Dr. Schmidt and colleagues showed that a Respiration Function Monitor is capable of monitoring ventilation with Ventrain, which could make its use even safer.

*A.R. Schmidt, K. Ruetzler, T. Haas, A. Schmitz and M. Weiss. Monitoring der Tidalvolumina bei Verwendung des Ventrain® Notfallbeatmungsgerätes. Anaesthesist 65:514-520. Rebuttal by de Wolf, Gottschall and Enk. Anaesthesist 2017 · 66:207-208*

## Editorials, Correspondence

Dr. Noppens deliberated Ventrain's clinical significance:

*"The idea and working principle behind the Ventrain are very promising and have the potential to change the way we look at ventilation through small-bore cannulae, not only in emergency situations."*

*"For the benefit of patients in critical situations, it will be necessary to train and educate as many anesthetists as possible in this novel ventilation technique, not only to avoid inappropriate use, but to allow its incorporation into routine airway management in the future."*

This editorial refers to the study of Paxian and colleagues, which elegantly demonstrates that Ventrain ensures sufficient oxygenation and ventilation through a small-bore transtracheal catheter in cases of an open, partly obstructed, or completely closed airway.

*R.R. Noppens. Ventilation through a 'straw': the final answer in a totally closed upper airway? Br J Anaesth. 2015 Aug; 115 (2): 168-170*

Drs. Timmermann, Chrimes and Hagberg responded to the published 2015 Guidelines of the Difficult Airway Society (DAS), which endorse scalpel cricothyroidotomy as the sole method for emergency front-of-neck access:

*"This sole recommendation of a scalpel technique may increase the psychological barriers to successful achievement of front-of-neck access in an appropriate time frame when a CICO situation occurs. Training in both (scalpel-based and cannula-based) techniques remains warranted, and the option to use either technique should continue to be advocated."*

In addition to airway management techniques, they advised on ventilation techniques to be used after obtaining front-of-neck access. They recommend a.o. Ventrain:

*"These provide, in contrast to a jet ventilator, an affordable, simple mechanism for oxygen insufflation via a cannula that can be connected to a standard oxygen outlet and allows for passive or even active expiration via the cannula between breaths. Techniques have been developed for use of these devices, intended to minimize the risk of complications from volutrauma and barotrauma, even when the upper airway is completely obstructed."*

This editorial emphasizes the multiple options for saving a patient's life in an emergency CICO situation.

*A. Timmermann, N. Chrimes and C.A. Hagberg. Need to consider human factors when determining first-line technique for emergency front-of-neck access. Br J Anaesth. 2016 Jul;117(1):5-7*

Dr. Lang also responded to the DAS guidelines expressing his concerns that the DAS Plan D amount to 'wishful thinking' as it aims to avoid life-threatening consequences of barotrauma:

*"It focuses on attaining and then maintaining proficiency using an invasive technique (i.e., surgical cricothyroidotomy) with which many anesthesiologists are not comfortable and do not have an opportunity to practice."*

He underlines that Ventrain is based on concepts and skills familiar to most anesthesia practitioners and that it can be used in routine cases in order to gain clinical experience. As such the technique is trainable. Dr. Lang concludes:

*"I also believe, most importantly, that awareness of, familiarity and proficiency with, and dissemination of the device will certainly be easier and quicker to achieve than a cultural shift that would be necessary to ensure maintaining competence with surgical cricothyroidotomy."*

*S.A. Lang. Emergency airway management: What are the roles for surgical cricothyroidotomy and the Ventrain® device? Can J Anaesth. 2016 Aug;63(8):997-8*

## Handbooks

- C. Hagberg. Benumof & Hagberg's Airway Management, 4<sup>th</sup> ed. Elsevier (publisher); 2018; p.106-107; p. 865-866.
- C. Hagberg. Benumof & Hagberg's Airway Management, 3<sup>rd</sup> ed. Elsevier (publisher); 2013; p.595-6.
- P.G. Barash, B.F. Cullen, R.K. Stoelting, M. Cahalan, M.C. Stock and R. Ortega. Clinical Anesthesia, 7<sup>th</sup> ed., Wolters Kluwer Health (publisher); 2013; p.798.
- C. Spies, M. Kastrup, T. Kerner, C. Melzer-Gartzke, H. Zielke and W.J. Kox. SOPs in Anästhesiologie und Schmerztherapie. Thieme (publisher); 2013; p.94.
- Dornberger. Schwieriges Atemwegsmanagement bei Erwachsenen und Kindern. Thieme (publisher); 2013; p.251-2.
- W. Rosenblatt and W. Popescu. Master techniques in Upper and Lower Airway Management. Wolters Kluwer Health (publisher); 2015; Chapter 44 (ePub).

## » Adressess

### **Ventinova Medical B.V.**

**A** Meerenakkerplein 7  
5652 BJ Eindhoven  
The Netherlands  
**T** +31 (0)40 751 60 20  
**E** info@ventinova.nl

### **Ventinova Deutschland GmbH**

**A** Siemensstraße 31  
47533 Kleve  
Germany  
**T** +49 (0)282 1975 02 73  
**E** info@ventinova.de

MC012.07 May 2019

*FCV® is initially developed in its most basic form as EVA® (Expiratory Ventilation Assistance)*

© 2019 Ventinova, Eindhoven The Netherlands, all rights reserved.

® Ventinova, EVA, FCV, Evone, Tritube, Ventrain and Cricath are registered trademarks of Ventinova Medical.



**www.ventinovamedical.com**

