



» LITERATURE LIST

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PREFACE

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

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



Higher Efficiency



Lower Energy



Small Lumen

1.1 LUNG-HEALTHY SUBJECTS

• 1.1.1 Clinical data

Weber et al., Acta Anaesthesiol Scand. 2019

The workgroup of Prof. Schumann performed a crossover randomized controlled trial in lung-healthy patients comparing FCV® to VCV. They revealed a higher efficiency of ventilation when using FCV®, even after short-term application. With similar ventilation settings, FCV® resulted in a 9% higher arterial oxygenation and 5% lower arterial CO₂ concentration (P<0.001). The mean tracheal pressure was higher during FCV® (+10 %; P<0.001), with comparable tidal volumes, inspiratory plateau pressure and end-expiratory pressure. This study indicates that FCV® shows potential benefits to allow lung protective ventilation.

Weber J, Schmidt J, Straka L, Wirth S, Schumann S. Flow-controlled ventilation improves gas exchange in lung-healthy patients – a randomised interventional cross-over study. Acta Anaesthesiol Scand. 2019;00:1–8



Sebrechts et al., Eur J Anaesthesiol. 2021

In this randomized cross-over pilot study, FCV® was compared to VCV in eight lung-healthy patients for 15 minutes of ventilation. Upon baseline ventilation with VCV, patients were either ventilated with FCV® followed by VCV, or the other way round. Ventilation settings were chosen to be comparable between FCV® and VCV, and recruitment maneuvers were performed before changing between modes. All patients were adequately ventilated, with respiratory and hemodynamic parameter within normal range. While no significant difference in arterial oxygenation was detected, the authors report an improved CO₂ removal during FCV® while using a comparable minute volume, indicating a higher ventilation efficiency. Furthermore, they state that recruitment maneuvers may have masked intrinsic differences between the ventilation modes, and that more data in larger patient groups is needed to evaluate the effects of FCV® compared to VCV.

Sebrechts T, Morrison SG, Schepens T, Saldien V. Flow-controlled ventilation with the Evone ventilator and Tritube versus volume-controlled ventilation. Eur J Anaesthesiol. 2021 Feb 1;38(2):209-211. doi: 10.1097/EJA.0000000000001326



• 1.1.2 Preclinical data

Spraider et al., Crit Care 2020

In a randomized porcine study, Spraidner and colleagues demonstrated that FCV® significantly improved gas exchange and maintained better lung aeration during 10 hours of ventilation, as compared to pressure controlled ventilation (PCV). Ventilation settings for FCV® were individually optimized through compliance-guided pressure settings, while PCV settings were chosen according to the standard of care for lung-protective ventilation. Results showed a significantly better oxygenation in the FCV® group (+24%, P=0.0097) while requiring a 53% lower minute volume (P <0.0001) to achieve normocapnia. Furthermore, in pigs ventilated with FCV® the fraction of non-aerated lung tissue including



atelectatic areas was reduced by 27% (P=0.032), with use of lower PEEP and comparable driving pressure, indicating an improved lung recruitment. This study demonstrates the applicability of compliance-guided individualization of FCV[®] settings, allowing the optimization of ventilation based on the precise measurement of dynamic lung mechanics.

Spraider P, Martini J, Abram J, Putzer G, Glodny B, Hell T, Barnes T, Enk D. Individualized flow-controlled ventilation compared to best clinical practice pressure controlled ventilation: a prospective randomized porcine study. Crit Care 2020 Nov 25;24(1):662. doi: 10.1186/s13054-020-03325-3

Schmidt et al. Eur J Anaesthesiol. 2018

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.

Schmidt J, Wenzel C, Mahn M, Spassov S, Schmitz HC, Borgmann S, Lin Z, Haberstroh J, Meckel S, Eiden S, Wirth S, Buerkle H, Schumann S. 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



1.2 ARDS

• 1.2.1 Clinical data

Grassetto et al., presentation ESAIC 2022

In this pilot study Dr. Grassetto and colleagues aimed to investigate their hypothesis that FCV[®] may reduce mechanical power and increase ventilatory efficiency in COVID-19 patients developing refractory hypoxemia despite optimization of conventional volume-targeted ventilation (controlled mechanical ventilation, CMV) and prone positioning. Seven ICU patients with ARDS secondary to COVID-19 (P/F ratio <150 mmHg) were included. Measurements of respiratory variables were obtained during CMV prior to switching to FCV[®] (CMV1), after four hours of FCV[®], and after four hours upon resuming CMV (CMV2). During FCV[®], the decreased inspiratory flow was associated with an overall decreased respiratory rate and minute ventilation in comparison with CMV. During FCV[®], despite similar driving pressure and compliance, the mechanical power was overall lower. Moreover, the authors observed an overall lower ventilatory ratio during FCV[®] compared to CMV. In conclusion, these findings suggest that FCV[®] may reduce mechanical power and increase ventilatory efficiency in patients who remain severely hypoxemic upon optimization of CMV.

Grassetto A, Pettenuzzo T, Badii F, Carlon R, Sella N, Navalesi P. Mechanical power and ventilatory efficiency during flow-controlled ventilation in severe COVID-19 ARDS. Poster 11AP03-10, presented at ESAIC 2022



Van Dessel et al., Intensive Care Med Exp.

This study represents the first prospective crossover trial in 11 patients with moderate ARDS from Covid-19, with the aim to compare the ventilatory efficiency of FCV[®] to VCV. Patients received a ventilation sequence of PCV (baseline), followed by 30 minutes FCV[®] and VCV. Ventilation settings were aimed to be kept comparable between the ventilation modes. With similar arterial CO₂ values, the applied minute volume was significantly lower (16%) in FCV[®] compared to VCV (6.6 L/min vs VCV 7.9 L/min; P<0.001), indicating a higher ventilation efficiency with FCV[®].

Van Dessel E, De Meyer GR, Morrison S, Jorens PG, Schepens T. Ventilatory efficiency is improved during flow-controlled ventilation in ARDS. Intensive Care Med Exp. 2020,9(1):001167



Bergold et al., Presentation WAMM 2019

Dr. Bergold and colleagues present the first application of FCV[®] to a 22-year old patient with traumatic brain injury and chest trauma who was admitted to the ICU with severe acute respiratory distress syndrome (ARDS; P/F ratio 49 mmHg). As ventilation parameters did not improve with volume controlled ventilation and continuous lateral rotational therapy, and extracorporeal membrane oxygenation was contraindicated, FCV[®] ventilation using Evone was considered as last alternative treatment option. FCV[®] was individually optimized based on the patient's respiratory system compliance, and led to a significant improved lung condition within a few hours (P/F ratio 177, 270 and 397 mmHg after 1, 12 and 24 hours, respectively). After 77 hours of FCV[®] ventilation the patient could enter a weaning procedure. He was discharged to a rehabilitation facility two weeks later in a favorable neurological condition.

Bergold M, Otterburg T, Woitzik J, Byhahn C. Flow-controlled ventilation – a novel approach to treating severe acute respiratory distress syndrome. Abstract presented at WAMM 2019



Spraider et al., BMC Anesthesiol. 2021

In this case report, Spraider et al. describe for the first time the ventilation of a Covid-19 ARDS patient with severely compromised lung function using FCV[®] by Evone[®]. Compared to best standard of care pressure-controlled ventilation (PCV), FCV[®] quickly led to an increase of the oxygenation index by 30%, and subsequently allowed the reduction of invasiveness of ventilation by applying a compliance-guided optimization approach. However, when further optimization became limited by the severe extent of lung damage and the patient's condition deteriorated, it was decided to switch back to PCV with highly invasive pressure settings. This publication elucidated the possibilities of a personalized ventilation approach uniquely offered by Evone[®], and at the same time describes its potential restrictions in the presence of massively compromised lung tissue.

Spraider P, Putzer G, Breikopf R, Abram J, Mathis S, Glodny B, Martini J. A case report of individualized ventilation in a COVID-19 patient – new possibilities and caveats to consider with flow-controlled ventilation. BMC Anesthesiol 2021. 21, 145. <https://doi.org/10.1186/s12871-021-01365-y>



Piowarczyk et al., presentation ESAIC 2022

This is the first case report describing the successful use of FCV[®] for weaning from extra-corporeal membrane oxygenation (ECMO) therapy. A 24-year-old parturient without comorbidities was admitted to the hospital for initiation of veno-venous ECMO due to



critical course of COVID-19. Mechanical ventilation was started on the day of caesarian section and ECMO two days later. Initially, ultraprotective ventilation with proning was applied. Daily ECMO weaning trials using pressure-released VCV mode and PEEP titration failed. On the 9th day of ECMO, FCV[®] was initiated (FiO₂ 0,6; Inspiration Flow 14 L/min; I:E ratio 1:1,1; Peak 28 mbar; EEP 9 mbar). PaO₂/FiO₂ increased from 96 to 154 and pCO₂ decreased from 63 to 44 mmHg. At 12th day ECMO therapy could be terminated under FCV[®]. Static compliance of the lungs increased from 13 ml/cm H₂O to 28 ml/cm H₂O. This case report shows that FCV[®] may be an effective method to improve ventilation parameters in patients undergoing ECMO, thereby shortening the duration of ECMO therapy.

Piwowarczyk P, Bialka S, Pituch-Sala K, Borys M, Palaczynski P, Czuczwar M. Flow controlled ventilation as a novel useful strategy in weaning from extracorporeal membrane oxygenation therapy in critical course of COVID-19 in parturient – case presentation. Poster 09AP02-06, presented at ESAIC 2022

- **1.2.2 Preclinical data**

Schmidt et al., Crit Care Med. 2020

This randomized controlled study by the workgroup of Prof. Schumann demonstrates an increased ventilation efficiency and lung protective effects by FCV[®] compared to VCV in an experimental model of acute respiratory distress syndrome (ARDS). With similar PEEP, peak pressures, tidal volumes and respiratory rates FCV[®] significantly improved oxygenation (PaO₂ +47%, P=0.035), while using a 26% lower minute volume (P<0.001). In the dependent lung parts FCV[®] resulted in more normally aerated lung tissue (24% vs 10%; P=0.004) and less non-aerated lung tissue (23% vs 38%; P=0.033) as compared to VCV. Furthermore, lung damage was reduced by FCV[®] as shown by the presence of thinner alveolar walls (5.5 μm vs 7.8 μm; P<0.001), a reduced amount of infiltrating inflammatory cells (20/field vs 32/field; P<0.001), and a higher concentration of surfactant protein A in the bronchoalveolar lavage fluid (1.1 vs 1.0; P=0.039). The authors state that they feel confident that their results 'provide evidence for an attenuated lung injury after FCV[®].' Further correspondence regarding this study by Prof. Enk and colleagues elaborates on pressure measurements during FCV[®] and the respective calculation of respiratory system compliance.

Schmidt J, Wenzel C, Spassov S, Borgmann S, Lin Z, Wollborn J, Weber J, Haberstroh J, Meckel S, Eiden S, Wirth S, Schumann S. Flow-Controlled Ventilation Attenuates Lung Injury in a Porcine Model of Acute Respiratory Distress Syndrome: A Preclinical Randomized Controlled Study. Crit Care Med 2020; 48:e241–e248

Commented by Enk D, Spraidner P, Abram J, Barnes T. Pressure Measurements in Flow-Controlled Ventilation. Crit Care Med. 2020 Dec;48(12):e1359-e1360. doi: 10.1097/CCM.0000000000004561. PMID: 33255124. Response by J. Schmidt, S. Schumann. The authors reply. Crit Care Med. 2020 Dec;48(12):e1360-e1361. doi: 10.1097/CCM.0000000000004653. PMID: 33255125



1.3 CARDIAC SURGERY

• 1.3.1 Clinical data

Wichelhaus et al., presentation ESAIC 2022

The presented data contains preliminary results of an ongoing, explorative, ancillary study integrated with the randomized controlled trial FLOWVENTIN HEARTSURG (see *Becker, S et al. Eur J Anaesthesiol 2021; 38(e-S 59):127*). The aim of this sub study is to assess the effect of individualized FCV[®] versus best clinical practice PCV on perioperative lung aeration in patients undergoing on-pump cardiac surgery by using electrical impedance tomography (EIT). EIT-data is recorded on six serial perioperative times. The percentage of aeration win and loss compared to baseline measurements was analyzed in 60 consecutive patients (n = 30 per group). Results show that preoperative median aeration win was higher and mean aeration loss lower in FCV[®] compared to PCV after onset of ventilation. However, group differences waned and aeration loss deteriorated in both groups during the postoperative period, respectively. Consequently, higher mean postoperative oxygenation indices measured in the FCV[®] group possibly not result from a sustained improvement of postoperative lung aeration, and thus deserve further analysis.

Wichelhaus LM, Kurz CT, Poepping J, Timmesfeld N, Zahn PK, Becker s. Flow-controlled versus pressure-controlled ventilation in on-pump cardiac surgery procedures: An explorative study on perioperative lung aeration based on Electrical Impedance Tomography data. Poster 07AP01-02, presented at ESAIC 2022



Spraider et al., presentation ESAIC 2022

The presented data contains results of a sub study of a randomized controlled trial comparing individualized FCV[®] to best-practice PCV during cardiac surgery with cardiopulmonary bypass. The authors hypothesized that the functionally available lung tissue within the limits of individual lung mechanic, which is efficiently aerated upon compliance-based optimization of FCV[®], may differ between male and female patients. In 24 patients randomized to receive FCV[®] (female: n = 6; male: n = 18), sex related differences in respiratory parameters were analyzed. Whereas PEEP and peak pressure settings were comparable upon titration, the resulting tidal volume was significantly (15%) lower in female patients, reflected by a significantly lower compliance. Gas exchange parameters were comparable in either gender. These findings may indicate that the functionally available lung volume in women is lower, and use of the predicted body weight (PBW) - as suggested in common guidelines - does not adequately comply with sex related differences. This would support the use of a personalized ventilation strategy with FCV[®], which is based on the actual mechanic properties of the individual patient.

Spraider P, Abram J, Putzer G, Wagner J, Hell T, Martini J. Gender differences in applied tidal volume with compliance titrated flow-controlled ventilation during cardiac surgery. – a subgroup analysis of a randomized controlled trial. Poster 07AP01-11, presented at ESAIC 2022



1.4 ONE-LUNG VENTILATION

• 1.4.1 Clinical data

Abram et al., presentation ESAIC 2022

This randomized controlled trial is the first to investigate the effect of individually optimized FCV[®] compared to best clinical practice PCV on gas exchange during one-lung ventilation (OLV). In total 46 patients were randomized to receive FCV[®] or PCV for the duration of general anesthesia. The primary outcome parameter PaO₂/FiO₂ was significantly higher in the FCV[®] group (n = 21) compared to control (n = 22) (187 vs 136; p=0.047) after 30 minutes of initiation of OLV. Additionally, the required respiratory minute volume (MV) to obtain similar paCO₂ levels was significantly lower in FCV[®] (3.0 vs 4.5 L/min; p<0.001), reflecting improved CO₂ removal. Thus, in this study FCV[®] was found to be superior to current standard pressure-controlled ventilation after 30 minutes of OLV in terms of oxygenation and CO₂ removal, indicating a higher ventilation efficiency.

Abram J, Spraidler P, Putzer G, Dejaco H, Velik-Salchner C, Martini J. Flow-controlled ventilation in thoracic surgery requiring one-lung ventilation – a randomized, controlled, single-center trial. Poster 07AP05-03, presented at ESAIC 2022

• 1.4.2 Preclinical data

Wittenstein et al., Intensive Care Med Exp. 2020

This is the first study reporting the use of FCV[®] during one lung ventilation (OLV) in a clinically relevant model of thoracic surgery. The authors compared the effects of FCV[®] versus conventional VCV during OLV in normo- and hypovolemic pigs. While there was no measurable effect on oxygenation, FCV[®] allowed ventilation with higher efficiency during normovolemia, as a significantly lower minute volume could be applied. Furthermore, during FCV[®] the mechanical power applied to the porcine lungs was reduced, which might potentially lower the risk of postoperative pulmonary complications. Further correspondence on this publication by Prof. Enk and colleagues elaborates on critical aspects that should be considered when comparing dynamic compliance measurement during FCV[®] with conventional ventilation strategies.

Wittenstein J, Scharffenberg M, Ran X, Keller D, Michler P, Tauer S, Theilen R, Kiss T, Bluth T, Koch T, Gama de Abreu M, Huhle R. Comparative effects of flow vs. volume-controlled one-lung ventilation on gas exchange and respiratory system mechanics in pigs. Intensive Care Med Exp. 2020 Dec 18;8(Suppl 1):24. doi: 10.1186/s40635-020-00308-0

Commented by Enk D, Abram J, Spraidler P, Barnes T. Dynamic compliance in flow-controlled ventilation. Intensive Care Med Exp. 2021 May 31;9(1):26. doi: 10.1186/s40635-021-00392-w. PMID: 34056674; PMCID: PMC8164913



Diaper et al., presentation ESAIC 2022

This porcine study aimed to compare the effects of FCV[®] compared to pressure-regulated volume control ventilation (PRVC) on lung aeration, gas exchange and hemodynamics during one-lung ventilation (OLV). Ten pigs (n = 5 per group) were randomly assigned to FCV[®] or PRVC treatment and ventilated with comparable PEEP, respiratory frequency, and

tidal volumes during both two-lung and one-lung ventilation. Respiratory and hemodynamic parameters, as well as measurement of lung aeration using electric impedance tomography (EIT) were assessed at baseline and one hour after either FCV[®] or PRVC applied during OLV. The sequence was subsequently repeated in a crossover design. OLV led to a decrease in PaO₂ under both FCV[®] and PRVC, while an increase of PaCO₂ was only noted under PRVC (p <0.001) compared to whole lung ventilation. EIT demonstrated significant ventilation redistribution by the increased aeration of dependent and non-dependent regions during OLV with both modalities (p <0.05 for all) in a similar manner, while PIP was significantly lower under FCV[®] (p <0.001). Ventilating one lung with FCV[®] led to better gas exchange with higher PaO₂ and SvO₂ and lower PaCO₂ than with PRVC (170.6±15.8 vs 154.1±13.4 mmHg, 78.7± 5.0% vs 73.1±4.2% and 43.5±6.3 vs 52.6±11.7 mmHg, respectively; p<0.05). Hemodynamic parameters remained constant with both ventilation modalities and under OLV. The authors conclude that improved lung aeration and gas exchange was evidenced in FCV[®] during one-lung ventilation at lower airway pressure than with PRVC. They further suggest that FCV[®] may be considered a protective ventilation modality during one-lung ventilation.

Diaper J, Schranc A, Habre W, Albu G. Flow-controlled ventilation improved gas exchange during one-lung ventilation: a randomized experimental cross over study. Poster 07AP05-08, presented at ESAIC 2022

1.5 OBESE PATIENTS

• 1.5.1 Clinical data

Weber et al., BMC Anesthesiol. 2020

The workgroup of Prof. Schumann published the first randomized controlled trial on the effect of FCV[®] during ventilation of obese and morbidly obese patients undergoing elective bariatric surgery. 23 patients were ventilated in a crossover design for seven minutes with FCV[®] and VCV. Even after this short application of FCV[®], notable differences could be detected: With comparable respiratory variables, FCV[®] improved lung recruitment, as demonstrated by a significantly reduced intraoperative loss of both end-expiratory lung volume (Δ EELV) and mean lung volume (Δ MLV) as compared to VCV (Δ EELV: FCV -126 ±207 ml; VCV -316 ±254 ml; p<0.001; Δ MLV: FCV: -108.2 ±198.6 ml; VCV -315.8 ±252.1 ml; p<0.001). These effects might be partially attributed to the increased mean tracheal pressure caused by the linearized pressure decline during FCV[®]. The authors conclude that 'the recruitment effect (...) and the elevated Pmean during FCV[®] may help prevent atelectasis and hypoxemia during mechanical ventilation in obese patients.'

Weber J, Straka L, Borgmann S, Schmidt J, Wirth S, Schumann S. Flow-controlled ventilation (FCV) improves regional ventilation in obese patients – a randomized controlled crossover trial. BMC Anesthesiol 2020;20(1):24



1.6 EX-VIVO LUNG PERFUSION

• 1.6.1 Preclinical data

Ordies et al., Intensive Care Med Exp. 2020

This randomized controlled study compared FCV[®] to conventional VCV for ventilation of porcine lungs during ex vivo lung perfusion (EVLV). Fourteen porcine lungs were mounted on EVLP after a warm ischemic interval and ventilated for six hours with VCV or FCV[®], respectively. FCV[®] led to improved oxygenation and alveolar recruitment, with a higher proportion of well-aerated lung tissue and less atelectatic areas. Thus, FCV[®] is a potential strategy to prolong EVLP over time, with less risk of volutrauma and atelectrauma and thus less risk of ventilator induced lung injury (VILI).

Ordies S, Orlitova M, Heigl T, Sacreas A, Van Herck A, Kaes J, Saez B, Vanstapel A, Ceulemans L, Vanaudenaerde BM, Vos R, Verschakelen J, Verleden GM, Verleden SE, Van Raemdonck DE, Neyrinck AP. Flow-controlled ventilation during EVLP improves oxygenation and preserves alveolar recruitment. Intensive Care Med Exp. 2020 Nov 25;8(1):70. doi: 10.1186/s40635-020-00360-w



1.7 REVIEW ARTICLES AND LETTERS

• 1.7.1 History and application of FCV[®]

Bialka et al., Anaesthesiol Intensive Ther. 2022

This narrative review focuses on the development and application of the FCV[®] concept, available (pre-)clinical data, and future outlook. The authors present an extensive evaluation of current evidence regarding FCV[®] in the clinic, along with a discussion of its lung-protective potential. Furthermore, they include individual case reports describing the successful use of Evone[®] in three distinct application areas: tracheal resection, thoracic surgery with one-lung ventilation, and ventilation of an ARDS patient on the intensive care unit.

Bialka S, Palaczynski P, Szuldrzynski K, et al. Flow-controlled ventilation – a new and promising method of ventilation presented with a review of the literature. Anaesthesiology Intensive Therapy. 2022;54(1): 62-70. doi:10.5114/ait.2022.112889



• 1.7.2 Lung-protective potential of FCV[®]

Silva et al., Annual Update in Intensive Care and Emergency Medicine 2022

In this book chapter on individualized mechanical ventilation approaches Prof. Pelosi and colleagues acknowledge FCV[®] as a potential strategy to improve respiratory function and reduce VILI. The authors elaborate on the fact that rapid changes of ventilatory variables in time, meaning a high strain rate, lower the threshold for stress injury and ventilator-induced lung damage, especially in heterogeneous lungs. This may be prevented during FCV[®], with its constant and relatively low flow applied throughout the ventilation cycle, without zero-flow phases. By actively controlling the expiratory phase, the appearance of intrinsic PEEP may be avoided, which in turn promotes better air exhalation among alveoli



with different time constants. Furthermore, the authors note that the direct intratracheal pressure measurements allow a much more precise analysis of individual lung mechanics than conventional strategies. Consequently, gradual increases of tidal volumes that may be applied during individualization of FCV[®] are directly related to individual dynamic compliance and reflect ventilation of the available aerated lung tissue, and simultaneously decrease the risk of atelectasis and/or overdistension.

Silva PL, Rocco PRM, Pelosi P. Personalized Mechanical Ventilation Settings: Slower Is Better!. In: Vincent, JL. (eds) Annual Update in Intensive Care and Emergency Medicine 2022. Springer, Cham. https://doi.org/10.1007/978-3-030-93433-0_9

Barnes et al., Medical Hypotheses 2018

Prof. Barnes, together with Van Asseldonk and Enk, provides clear theoretical evidence for lower energy dissipation in the lungs by FCV[®] 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[®].

Barnes T, van Asseldonk D, Enk D. 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



Barnes and Enk, TACC 2019

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[®] by Evone[®]. During FCV[®] 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.

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



2.1 UPPER AIRWAY SURGERY

• 2.1.1 Clinical studies

Meulemans et al., Front Surg. 2020

This is the first retrospective study critically assessing the perioperative use of Evone® and Tritube® during upper airway surgery from a surgeon's perspective. Prof. Vander Poorten and colleagues describe 15 consecutive difficult airway cases where FCV® ventilation has been replacing traditional high frequency jet ventilation (HFJV) or ventilation through a conventional endotracheal tube. Procedures included treatment of tracheal or (sub)glottic stenosis and microsurgery of laryngeal (pre)malignancies. Apart from supporting safety and feasibility of Evone® and Tritube®, the authors observed clear clinical benefits including a 'superior visualization and exposure of the surgical site' and a minimally traumatic airway access, while avoiding drawbacks frequently occurring during HFJV such as air-trapping, hypercapnia, desaturation and emphysema. Furthermore, they emphasize that application of FCV® through Tritube® likely reduces the duration of surgery by allowing stable ventilation with low oxygen concentrations and by offering the surgeon a calm working space. As a result, Evone® ventilation is nowadays their new standard of care in most cases of endoscopic airway surgery.

Meulemans J, Jans A, Vermeulen K, Vandommele J, Delaere P, Vander Porten V. Evone® Flow-Controlled Ventilation During Upper Airway Surgery: A Clinical Feasibility Study and Safety Assessment. Front. Surg. 2020; 7:6. doi: 10.3389/fsurg.2020.00006



Schmidt et al., Eur J Anaesthesiol. 2019

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® improves lung aeration and respiratory system compliance compared with VCV (63 ± 14 vs. 46 ± 8 mL/cmH₂O; $P < 0.001$), while using a lower inspiratory plateau pressure (14 ± 2 vs. 17 ± 2 cmH₂O; $P < 0.001$).

Schmidt J, Günther F, Weber J, Kehm V, Pfeiffer J, Becker C, Wenzel C, Borgmann S, Wirth S, Schumann S. Glottic visibility for laryngeal surgery: Tritube® vs. microlaryngeal tube - a randomized controlled trial. Eur J Anaesthesiol. 2019 Dec;36(12):963-971



Schmidt et al., Eur J Anaesthesiol. 2019

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'.

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

Kristensen and Abildstrøm, Abstract Euroanaesthesia 2019

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.

Kristensen MS, Abildstrøm HH. 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



● **2.1.2 Clinical cases**

Leow et al., J Laryngol Otol. 2022

In this case report, the authors describe the use of Tritube® and Evone® to facilitate local resection of a laryngeal chondrosarcoma through an anterior laryngofissure. Upon safe intubation of Tritube® past the major intralaryngeal obstruction, FCV® using Evone® was applied throughout the procedure. While adequate respiratory parameters were maintained, the small outer diameter of Tritube® provided unhampered surgical access and good surgical conditions. Thus, Tritube® and Evone® avoided the need for a peri-operative tracheostomy, thereby also decreasing the risk of post-operative discomfort for the patient.

Leow TYS, Van der Wal RAB, Marres HAM, Honings J. Intubation with a TriTube to avoid peri-operative tracheostomy in open airway surgery. J Laryngol Otol. 2022 Feb 23:1-16. doi: 10.1017/S002221512200024X. Epub ahead of print. PMID: 35193715



Martinez Botet et al., presentation ESAIC 2022

The authors present a case of laryngeal papilloma resection in a 12-year old girl, which was successfully managed using Evone® and Tritube®. A previous surgical approach had failed, as the outer diameter of the conventional endotracheal tube had prevented proper visualization and removal of the lesions. The patient was then re-scheduled for surgery using Tritube® in combination with Evone®, which provided adequate ventilation as well as an optimal visualization of the surgical field. This strategy allowed better access to the laryngeal lesions, increasing the possibility for complete resection.

Martinez Botet L, Siroki Borgonovo F, Mora Rivas E, Hinojal Olmedillo B. Tritube use in 12 year girl underwent scheduled laryngeal papilloma resection. Poster 11AP04-07, presented at ESAIC 2022



Mallam et al., Anaesthesia Reports 2022

Dr. Mallam and colleagues present the case of an emergent near total airway obstruction which was managed using Tritube® and Evone®. Given the severity of the obstruction, Tritube® was considered as first choice for airway management and facilitated a secure airway past the lesion. Subsequently, the authors describe device-related problems they were facing during the procedure, which are referred to in the corresponding publication by Ventinova (see Böttinger et al., *Anaesthesia Reports* 2022). Overall, the authors state that Tritube® in combination with FCV® still represents the most preferable strategy in patients with likewise pathology, precluding the need for HFJV or ECMO. This case report vividly demonstrates that adequate training is key to allow safe and efficient application of FCV®, including the importance to have a well-prepared rescue strategy as backup at hand.



Mallam L, Massingberd-Mundy D, Girgis M, De Zoysa N. Near total intrathoracic airway obstruction managed with a Tritube® and flow-controlled ventilation. Anaesth Rep. 2022 Feb 28;10(1):10.1002/anr3.12156. doi: 10.1002/anr3.12156. PMID: 35252872; PMCID: PMC8885748

Böttinger et al., Anaesthesia Reports 2022

In this correspondence, Ventinova Medical addresses the device-related complications described in the case report by Mallam et al. A brief recap is given on the voluntarily filed field safety notice which was handled to the satisfaction of involved competent authorities and led to the release of a software upgrade of Evone®. Furthermore, the authors emphasize that Ventrain – if applied correctly – represents the safest and most efficient device for ventilation in a (near) complete airway obstruction.



Böttinger L, Uriarte J, van der Hoorn JWA. Near total intrathoracic airway obstruction managed with a Tritube (R) and flow-controlled ventilation: a reply. Anaesth Rep. 2022 Mar 22;10(1):e12155. doi: 10.1002/anr3.12155. PMID: 35360362; PMCID: PMC8941302

Bailey et al., Anaesthesia Reports 2021

Dr. Bailey and colleagues present a case report in which Evone® combined with Tritube® enabled curative, en bloc resection of an advanced transglottic tumour (total laryngectomy) in a 43 year old patient who presented with acute lower airway obstruction. After the ultrathin Tritube® was advanced easily along the bulky tumor and secured the airway, resulting in a good surgical view, ventilation of the patient in FCV® mode by Evone® provided 'excellent gas exchange'. Continuous, closed ventilation provided with this combination helped avoid problems seen while using traditional laryngectomy tubes, i.e. multiple extubations, apneic periods, emergency tracheostomy and the associated possibility of tumor seeding. The authors mention to have used Evone® and Tritube® for management of several similar cases, which 'has facilitated debulking of the tumours in each case while minimising risk to the patient.'



Bailey JR, Lee C, Nouraei R, Chapman J, Edmond M, Girgis M, De Zoysa N. Laryngectomy with a Tritube® and flow-controlled ventilation. Anaesthesia Reports 2021, 9: 86-89. <https://doi.org/10.1002/anr3.12114>

Yilbas et al., Turk J Anaesthesiol Reanim. 2021

The authors describe a series of clinical cases involving Evone® and Tritube® to facilitate upper airway surgery in difficult airway patients. First, Tritube® was successfully used in a patient requiring emergency surgery for debulking of a massive laryngeal mass which obstructed nearly 80% of the tracheal lumen. Second, Tritube® was uniquely used for both airway management and tracheal dilatation in a patient with progressive dyspnea upon tracheal resection surgery, avoiding the need for tracheotomy. The third case describes an obese patient scheduled for uvulopalatoplasty due to severe obstructive sleep apnea. In all patients intubation with Tritube® was uneventful, and ventilation of patients using Evone® resulted in adequate respiratory parameters. The authors highlight the advantage of Tritube® to allow 'sufficient ventilation through a continuously secured airway without an increased risk on barotrauma.'



Yilbas AA, Melek A, Canbay O, Kanbak M. Experience with Tritube and Flow-Controlled Ventilation During Airway Surgery. Turk J Anaesthesiol Reanim. 2021;49(3):269-270

Shallik et al., Qatar Med J. 2021

Dr. Shallik and colleagues present the use of Evone® and Tritube® to manage a challenging case of thyroidectomy. The patient presented with an invasive thyroid carcinoma causing a significant tracheal stenosis with the narrowest part of only 4 mm, limiting the options for airway management. Upon initiation of anesthesia with the STRIVE-Hi technique the airway was secured by intubation with Tritube®, and the patient was optimally ventilated throughout the six hours procedure in the FCV® mode by Evone®. The authors stress that Evone® in combination with Tritube® represents an improved method to safely ventilate patients with a difficult airway, reducing the risk of barotrauma compared to high-frequency jet ventilation, and potentially eliminating the need for ECMO.



Shallik N, Elarref M, Khamash O, Abdelaal A, Radi Alkhafaji M, Makki H, Abusabeib A, Moustafa A, Menon A. Management of critical tracheal stenosis with a straw sized tube (Tritube): Case report. Qatar Med J. 2021 Jan 28;2020(3):48. doi: 10.5339/qmj.2020.48. PMID: 33598418; PMCID: PMC7842837

Jeyarajah and Ahmad, Anaesthesia Cases 2018

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.



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

Piosik et al., TACC 2018

Piosik and colleagues report the successful use of Evone® and Tritube® for surgery of a severe glottic stenosis. The patient, with a history of laryngeal papillomatosis, suffered from a fixated and thickened laryngeal inlet after several treatment procedures and had a previously abandoned jet ventilation. She presented with stridor and poor voice and was scheduled for surgical reduction of the stenosis and Mitomycin C treatment for symptomatic improvement. Ultrathin Tritube® was intubated easily and provided excellent surgical working conditions, while Evone® facilitated normoventilation with low airway pressures throughout the procedure. The authors state that this case demonstrates 'promising perspectives of treatment options for laryngeal surgery'.

Piosik ZM, Todsén T, Balle JS, Abildstrøm H, Kristensen MS. Ultra-narrow 2.4 mm id Tritube® together with Evone® ventilation allows surgical access and controlled ventilation even in case of severe stenosis. Trends in Anaesthesia and Critical Care 2018 (23); 20



2.2 TRACHEOSTOMY

• 2.2.1 Clinical data

Magasich-Airola et al., Int J Clin Pract. 2020

In this letter the authors describe the use of Evone® in combination with Tritube® to allow safe surgical tracheostomy with minimized aerosol generation while providing continuous ventilation. In the face of the Covid-19 pandemic, approaches to reduce the risk of virus spreading are urgently needed. While conventional tracheostomy is a highly aerosol generating procedure, introduction of Tritube® and FCV® ventilation using Evone® uniquely allows the placement of a transtracheal cannula in a sealed airway. Thereby, virus spread by air droplets is contained, and adequate ventilation of potentially severely hypoxic patients without apneic periods is ensured. The small outer diameter of Tritube® additionally provides a good working space for the surgeon.

Magasich-Airola NP, Martins MR, Desuter GR, Van Boven MJ. Novel technique for safe tracheostomy during COVID-19 pandemic using Evone® flow-controlled ventilation system. Int J Clin Pract. 2020 Nov 27;e13863. doi: 10.1111/ijcp.13863. Online ahead of print.



2.3 REVIEW ARTICLES

Nouraei et al., Oper Tech Otolaryngol Head Neck Surg. 2020

This article provides a common framework for multidisciplinary shared-airway management in difficult airway patients with infraglottic obstructions. The authors present devices and strategies that have improved airway management safety and may prove useful in the setting of the novel Coronavirus Disease 2019 (COVID-19). In patients requiring mechanical ventilation with general anesthesia, the introduction of Evone® and Tritube® increases the safety of endotracheal intubation and surgical options in the settings of an acutely obstructed airway. Manual ventilator Ventrain® is presented as valid option in cases where front-of



neck access is favorable. Furthermore, the authors emphasize that FCV® via Tritube® aids in minimizing aerosol generation when managing patients with airway compromise due to laryngotracheal stenosis. Overall, Evone® and Tritube® offer new solutions for shared airway situations that might be suitable for patients otherwise indicated for ECMO or cardiopulmonary bypass therapy.

Nouraei SAR, Girgis M, Shorthouse J, El-Boghdadly K, Ahmad I. A multidisciplinary approach for managing the infraglottic difficult airway in the setting of the Coronavirus pandemic. Oper Tech Otolaryngol Head Neck Surg. 2020 Jun;31(2):128-137. doi: 10.1016/j.otot.2020.04.009. Epub 2020 May 30. PMID: 32572325; PMCID: PMC7260599.

Schleicher and Groeben, J Thorac Dis. 2020

In this short review on techniques for tracheobronchial surgery the authors highlight Evone® and Tritube® as future perspective to provide controlled small lumen ventilation with active expiration. As opposed to high frequency jet ventilation, FCV® reduces the risk of barotrauma and pneumothorax by preventing intrapulmonary pressure buildup.

Schleicher A, Groeben H. Anesthetic considerations for tracheobronchial surgery. J Thorac Dis. 2020 Oct;12(10):6138-6142. doi: 10.21037/jtd.2020.02.52.



3.1 REVIEW ARTICLES

De Wolf et al., Paediatr Anaesth. 2022

In this educational review, Prof. Enk and colleagues elaborate on the use of manual ventilator Ventrain®, with a special focus on pediatric anesthesia. Besides giving a thorough explanation on its design and working principle, they highlight the application of Ventrain® for both management of airway emergencies, and for pediatric airway management to allow elective interventional procedures. Required equipment, technical prerequisites, and clinical safety measures are explained in detail. This review represents an exhaustive piece of education for users of the Ventrain® device.



de Wolf M, Enk D, Jagannathan N. Ventilation through small-bore airways in children by implementing active expiration. Paediatr Anaesth. 2022 Feb;32(2):312-320. doi: 10.1111/pan.14379. Epub 2021 Dec 22. PMID: 34902197

Dos Santos Rocha et al., Paediatr Anaesth. 2021

In this educational review, the authors elaborate on recent progresses that have been made in the field of pediatric anesthesia, with focus on adapted and novel ventilation strategies. They highlight Ventrain® with its EVA® functionality as a simple, but innovative ventilation tool likely to become a valuable addition to the armamentarium in pediatric emergency and difficult airway situations. Furthermore, the authors present FCV® by Evone® as a novel concept to potentially lower the risk of ventilator induced lung injury (VILI) by reducing energy dissipation in the lungs. They conclude that further research is needed to evaluate the advantages of FCV® for the pediatric population.



Dos Santos Rocha A, Habre W, Albu G. Novel ventilation techniques in children. Paediatr Anaesth. 2022 Feb;32(2):286-294. doi: 10.1111/pan.14344. Epub 2021 Dec 5. PMID: 34837438

Morrison et al., A A Pract. 2019

In this article Dr. Morrison and colleagues set out the structure and function of the Ventrain® device, and speculate on whether it may have a future role in difficult airway algorithms. The authors provide a detailed explanation on the working mechanism of Ventrain® and how it has been applied safely in the clinic, and elucidate the theoretical advantages expiratory ventilation assistance has over transtracheal jet ventilation. They advocate 'for regular simulation training and the detailed reporting of clinical experience with this encouraging new tool'.



Morrison S, Aerts S, Saldien V. The Ventrain Device: A Future Role in Difficult Airway Algorithms? A A Pract. 2019;13:362-365

Doyle, The Open Anaesthesia Journal 2018

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.

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

3.2 SMALL LUMEN VENTILATION

• 3.2.1 Clinical data – Upper airway surgery

Kristensen et al., Acta Anesthesiol Scand. 2017

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 H₂O. 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.“

Kristensen MS, de Wolf MWP, Rasmussen LS. Ventilation via the 2.4 mm internal diameter Tritube® with cuff - new possibilities in airway management. Acta Anesthesiol. Scand. 2017 Jul; 61(6):580-589



Rodríguez et al., Abstract Euroanaesthesia 2019

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®.

Rodríguez L, Sanchez Palomo JJ, Lopez Salcedo MA, Pizarro NE, Fossati Puertas S, Santé Serna L. Cutting-edge ventilation method in laryngeal microsurgery. Abstract #3280 presented at Euroanaesthesia 2019



Lee et al., TACC 2020

Dr. Lee and colleagues report the elective use of Ventrain® and Cricath® to safely facilitate the resection of significant pharyngeal fibrotic tissue due to radiotherapy. Previously, insertion attempts of a laser jet catheter and supraglottic devices had failed and surgery was abandoned. The patient returned for an elective insertion of Cricath®, followed by manually controlled ventilation with Ventrain® throughout the procedure. The authors appreciate that this 'elegant, minimally invasive technique' offers certain advantages over jet ventilation, as 'the risks of gas trapping and barotrauma are reduced.'

Lee S, Yeow D, Molena E, Pitkin L, Patel B. The Ventrain - An elegant way to facilitate elective surgery in upper airway obstruction. Trends in Anaesthesia and Critical Care 2020 (30) e13



Zuercher et al., Turk J Anaesthesiol Reanim. 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.

Zuercher M, Pythoud-brügger M, Sandu K, Schoettker P. Combined use of Ventrain and S-Guide for Airway Management of Severe Subglottic Stenosis. Turk J Anaesthesiol Reanim 2019 Jun;47(3):238-241



Onwochei et al., A A Pract. 2018

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 (SpO₂ 100%, PaCO₂ 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>

Onwochei DN, El-Boghdadly K, I. Ahmad I. 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



Fearnley et al., J Clin Case Rep. 2016

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.



Borg et al., Br J Anaesth. 2012

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.

Borg PA, Hamaekers AEW, Lacko M, Jansen J, Enk D. Ventrain for ventilation of the lungs. Br J Anaesth. 2012 Nov;109(5):833-4



Monnier et al., Head Neck 2016

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.

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

Kalkoff, Br J Anaesth. 2012

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.

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



Braga et al., DAS 2014/WAMM 2015

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.

Braga BAJ, Rodeny G, Hotvedt G, Taylor AFH, Ball DR. 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



● **3.2.2 Preclinical data**

De Wolf et al., Acta Anaesth Scand. 2018

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® (PaO₂ 61 [52-69] kPa; PaCO₂ 4.9 [4.2-6.2] kPa) hemodynamics were stable. This elegant study was executed in healthy pigs.

de Wolf MWP, van der Beek T, Hamaekers AE, Theunissen M, Enk D. 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



Paxian et al., Br J Anaesth. 2015

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.

Paxian M, Preussler NP, Reinz T, Schlueter A, Gottschall R. 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.



3.3 EMERGENCY

• 3.3.1 Clinical data

Morrison et al., A A Pract. 2019

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.“

Morrison S, Aerts S, van Rompaey S, Vanderveken O. Failed Awake Intubation for Critical Airway Obstruction Rescued With the Ventrain Device and an Arndt Exchange Catheter: A Case Report A A Pract. 2019 Jul 1;13(1):23-26



Heuveling et al., A A Pract. 2018

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 SpO₂ 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. SpO₂ 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.

Heuveling DA, Mahieu HF, Jongma-van Netten HG, Gerling V. 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



Wahlen et al., BJM Case Rep. 2017

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.

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



López-Torres et al., TACC 2017

Dr. 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.



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

Krapf et al., Notfallpraxis 2016

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



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

Nellgård, Presentation Euroanaesthesia 2013

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.



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

Kalsi et al., Presentation DAS 2012

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%.



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

● 3.3.2 Preclinical data

Mann et al., Paediatr Anaesth. 2021

Consistency and safety in airway emergencies - A comparative study of 6 cannula insufflation devices on test lung models of adult, pediatric and infant models found Ventrain® to be the sole device that insufflated oxygen with acceptable pressures and volumes with variable degrees of airway obstruction (complete, partial, open). Other devices were found to be either unsuccessful, or generating variable and excessive values.



Mann CM, Baker PA, Sainsbury DM, Taylor R. A comparison of cannula insufflation device performance for emergency front of neck airway. Paediatr Anaesth. 2021 Jan 11. doi: 10.1111/pan.14128. Epub ahead of print. PMID: 33432628

De Wolf et al., Can J Anaesth. 2017

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.

de Wolf MWP, Gottschall R, Preussler MP, Paxian M, Enk D. 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



Hamaekers et al., Anesth Analg. 2015

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.

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



Berry et al., Br J Anaesth. 2014

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.

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



Ziebart et al., Anaesthesia 2015

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.

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



Manoach et al., Presentation SAM 2011

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

Manoach S, Paladino L, Rosenblatt W. 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



3.4 PEDIATRIC VENTILATION

• 3.4.1 Clinical data

Escribá-Alepuz et al., A A Pract. 2018

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.

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



Willemsen et al., Br J Anaesth. 2014

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.

Willemsen MG, Noppens R, Mulder AL, Enk D. 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



3.5 ONE LUNG VENTILATION

• 3.5.1 Clinical data

Piccioni et al., J Cardiothorac Vasc Anesth. 2021

Dr. Piccioni and colleagues describe the use of Ventrain in combination with an airway exchange catheter to successfully manage hypoxemia during one lung ventilation. A 52-year-old female patient with normal preoperative lung function was scheduled for thoracoscopic pleural biopsies and talc pleurodesis. Two minutes upon initiation of one lung ventilation of the left lung, SpO₂ decreased quickly from 98% to 84%, which could not be adequately restored by subsequent increase of FiO₂, alveolar recruitment maneuver, or PEEP titration. An shortened airway exchange catheter was inserted through the tracheal lumen adapter of the double lumen tube and connected to Ventrain. EVA ventilation of the right lung was started using an oxygen flow of 6 L/min with a respiratory rate of about 20/min, which restored SpO₂ to 98% within one minute. As the lung movements did not interfere with the surgeon's work, the procedure could be finished without further problems. According to the authors, Ventrain is easier and safer to use compared to jet ventilation systems, which require a more specific training and carry a higher risk of barotrauma.

Piccioni F, Caccioppola A, Rosboch GL, Templeton W, Valenza F. Use of the Ventrain Ventilation Device and an Airway Exchange Catheter to Manage Hypoxemia During Thoracic Surgery and One-Lung Ventilation. J Cardiothorac Vasc Anesth. 2021 Jun 25:S1053-0770(21)00529-2. doi: 10.1053/j.jvca.2021.06.023. Epub ahead of print. PMID: 34294514.



Evers et al., A A Case Rep. 2017

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.

Evers VM, Immink RV, van Boven WJP, van Berge Henegouwen MI, Hollmann MW, and Veelo DP. 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 Grocott HP. Using the Ventrain With a Small-Bore Catheter: Ventilation or Just Oxygenation? Anesth Analg. 2018 Apr;126(4):1426-1427



3.6 TECHNOLOGY DEVELOPMENT

Hamaekers et al., Br J Anaesth. 2012

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.

Hamaekers AEW, Borg PA, Enk D. Ventrain: an ejector ventilator for emergency use. Br J Anaesth. 2012 Jun;108(6):1017-21



Berlin et al., Int Care Med Exp. 2019

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 a 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.

Berlin DA, Manoach S, Oromendia C, Heerdt P. 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. Response to letter by Drs Böttinger and van der Hoorn. D.A. Berlin, S. Manoach, P.M. Heerdt. Intensive Care Med Exp 2019 Jun6;7(1):31

Hamaekers et al., Paediatr Anaesth. 2009

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.

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

Hamaekers et al., Anaesthesia 2009

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.

Hamaekers AEW, Borg PA, Enk D. 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



Hamaekers et al., Br J Anaesth. 2010

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.

Hamaekers AEW, Götz T, Borg PA, Enk D. 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



Hamaekers et al., Br J Anaesth. 2011

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.

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



Calderon et al., Presentation SAM 2013

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.

Calderon LGMB, Moreira MM, Emídio GL, Corrêa EP, Carvalho-Filho MA, Terzi RGG. Expiratory ventilation assistance (EVA®) through a 14G catheter (2mm) in a Totally Obstructed Airway (TOA). Poster presented at Society for Airway Management 2013



Schmidt et al., Acta Anaesthesiol Scand. 2016

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.

Schmidt AR, Ruetzler K, Haas T, Schmitz A, Weiss M. 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.

Wirth et al., Respir Care. 2016

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.

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



Schmidt et al., Anaesthesist 2017

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

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



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