

# A prototype small-bore ventilation catheter with a cuff: cuff inflation optimizes ventilation with the Ventrain

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## Conflicts of interest

Dietmar Enk is the inventor of the Ventrain and the Tritube (which is based on the prototype of the small-bore ventilation catheter) and receives royalty payments from Ventinova Medical. He is also a consultant for Ventinova Medical.

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**Background:** Ventilation through small-diameter tubes typically precludes use of a cuff as this will impede the necessary passive outflow of gas alongside the tube's outer surface. Ventrain assists expiration and enables oxygenation and normoventilation through small-bore cannulas or catheters, particularly in obstructed airways. A small-bore ventilation catheter (SBVC; 40 cm long, 2.2 mm inner diameter) with a separate pressure monitoring lumen and a cuff was developed. Efficacy of oxygenation and ventilation with Ventrain through this catheter was investigated in sealed and open airways in a porcine cross-over study.

**Methods:** Six pigs were ventilated with Ventrain (15 l/min oxygen, frequency 30 breaths per min, I : E-ratio 1 : 1) through the SBVC, both with the cuff inflated and deflated. Prior to each test they were ventilated conventionally until steady state was achieved.

**Results:** With an inflated cuff, PaO<sub>2</sub> rose instantly and remained elevated (median [range] PaO<sub>2</sub> 61 [52–69] kPa after 30 min;  $P = 0.027$  compared to baseline). PaCO<sub>2</sub> remained stable at 4.9 [4.2–6.2] kPa. After cuff deflation, PaO<sub>2</sub> was significantly lower (9 [5–28] kPa at 10 min,  $P = 0.028$ ) and interventional ventilation had to be stopped prematurely in five pigs as PaCO<sub>2</sub> exceeded 10.6 kPa. Pulmonary artery pressures increased markedly in these pigs. Intratracheal pressures were kept between 5 and 20 cmH<sub>2</sub>O with the cuff inflated, but never exceeded 2 cmH<sub>2</sub>O after cuff deflation.

**Conclusion:** The SBVC combines the benefits of a small diameter airway and a cuff. Cuff inflation optimizes oxygenation and ventilation with Ventrain.

## Editorial comment

For a small bore endotracheal catheter and the Ventrain ventilation system, an inflated cuff can improve ventilation and oxygenation effects. This large animal experimental assessment of the utility of an inflated cuff on the catheter validates this principle.

We describe the evaluation of a newly developed small-bore ventilation catheter (SBVC) with an inner diameter (ID) of 2.2 mm and a cuff.

Decreasing the diameter of an artificial airway offers several theoretical and practical advantages: It can improve the surgical view when

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the anatomical airway is shared between the anaesthetic and surgical team, and it might decrease the incidence and severity of well-known complications like post-operative sore throat, hoarseness, and injury to the laryngeal epithelium and vocal cords.<sup>1,2</sup> Also, severe narrowing of the anatomical airway may preclude the use of conventional size endotracheal tubes.

When ventilating through small diameter airways, resistance to flow is markedly increased and high pressure source jet ventilation is therefore commonly used to ventilate through small-bore catheters. However, exhalation is passive and requires sufficient expiratory time and a patent upper airway. Incomplete exhalation results in gas trapping which can lead to severe barotrauma and haemodynamic instability.<sup>3–5</sup>

Typically, ventilation through a small-bore catheter therefore precludes the use of a cuff. This has several disadvantages, including a higher risk of aspiration and entrainment of debris from the upper airway during laryngeal or tracheal surgery and inability to accurately control inspiratory volumes and composition of inspired gasses as well as to accurately measure end-tidal gas concentrations (e.g. capnometry).

We hypothesized that with the Ventrain we would be able to safely ventilate through a small-bore catheter in a (by inflation of a cuff) sealed airway. Originally devised for rescue ventilation through small-bore transtracheal catheters in 'cannot intubate, cannot oxygenate' situations, Ventrain establishes flow-controlled inspiration and facilitates expiration by jet flow generated suctioning, thereby permitting normoventilation through small-bore catheters even in highly or completely obstructed airways.<sup>6–9</sup> The term expiratory ventilation assistance (EVA) has been coined for this feature.<sup>10</sup> Importantly, airway obstruction and/or airway seal optimizes oxygenation and ventilation with the Ventrain.<sup>7,8</sup>

To combine the advantages of ventilation through a small-bore catheter with the advantages of an elective seal, a new, 40 cm long, small-bore ventilation catheter (SBVC) was developed (outer diameter (OD) = 4.0 mm, diameter of the ventilation lumen = 2.2 mm).<sup>11,12</sup> The catheter has a distal cuff for elective occlusion of the airway and a separate lumen to allow (continuous) intratracheal pressure monitoring.

The primary aim of the current study was to investigate if elective ventilation with the Ventrain through this SBVC is indeed efficient and safe. A porcine model was used, because of the similarity in lung anatomy to the human lung. Our secondary aim was to investigate differences in gas exchange between a sealed and an open airway. We hypothesized that the efficacy of oxygenation and ventilation would be optimized by electively creating a seal by cuff inflation.

## Methods

### Animal preparation

After approval of the local animal welfare committee (DECNR 2011-068) six female pigs weighing 38–45 kg were obtained from a local breeder. The experiments were conducted at the animal facilities of the Maastricht University Medical Centre and all relevant aspects of the ARRIVE guidelines were followed.<sup>13</sup> The animals were housed in groups with free access to water and were fed regularly. The night before the experiments they were fasted with free access to water. The pigs were pre-medicated with an intramuscular injection of tiletamine/zolazepam (6 mg/kg) and atropine (0.05 mg/kg) to allow placement of an 18 G catheter in an ear vein for introduction of intravenous medication and infusions. Prior to induction of anaesthesia, continuous electrocardiogram and pulse oximetry monitoring were established. Anaesthesia was then induced with propofol (4–8 mg/kg), sufentanil (0.4 µg/kg) and pancuronium (0.15 mg/kg). The trachea was intubated with a 9.0 mm ID cuffed ETT for conventional ventilation prior to and between the experimental runs and to facilitate expeditious insertion and removal of the SBVC. Intratracheal pressure was continuously measured using a stylet (made from 3 mm OD, 2 mm ID standard plastic tubing) with the tip (having multiple end ports) fiberoptically positioned 2 cm above the carina, connected to a transducer and a multichannel recorder.

Because in pigs the right upper lobe bronchus invariably arises several centimetres proximal to the carina, prior to the experimental runs the SBVC was passed into the ETT and fiberoptic

guidance was used to place the tip above the tracheal branch-off of the right upper lobe bronchus. The depth of insertion was marked and the SBVC then removed. This way it was easy to rapidly and reliably replace the SVBC in the same position during the experiment.

The pigs were then mechanically ventilated in supine position with intermittent positive pressure ventilation (IPPV) with a fractional inspired oxygen concentration ( $\text{FiO}_2$ ) of 0.4 and a positive end-expiratory pressure (PEEP) of 5  $\text{cmH}_2\text{O}$ . Tidal volumes were set at 10 ml/kg and respiratory frequency was adjusted aiming for a  $\text{PaCO}_2$  of 5.3–6.0 kPa.

A left femoral arterial catheter (Arrow, Reading, PA, USA) was placed for continuous intra-arterial pressure measurement and arterial blood sampling. A single lumen central venous catheter (Arrow, Reading, PA, USA) and a pulmonary artery catheter (Edwards Lifesciences Corporation, Irvine, CA, USA) were inserted via the right internal jugular vein for advanced haemodynamic monitoring. Anaesthesia was maintained by continuous infusion of propofol (9 mg/kg/h), sufentanil (8  $\mu\text{g}/\text{kg}/\text{h}$ ) and pancuronium (0.3 mg/kg/h). Throughout the experiments the animals received 10 ml/kg/h isotonic saline solution.

### Design of the SBVC

To make the SBVC we used a 40 cm long, 4 mm OD Laserjet catheter (Acutronic Medical Systems AG, Hirzel, Switzerland). The Laserjet catheter has two lumens: One for ventilation and the second for measuring intratracheal pressures. The cuff and pilot balloon were taken from a 4.0 mm ID microlaryngeal tube (Mallinckrodt, Dublin, Ireland). A 19 G epidural catheter (B. Braun Melsungen AG, Melsungen, Germany) was used to connect the cuff to the pilot balloon. The cuff was held securely in

place on the catheter using thin foil tape (Tegaderm; 3M Deutschland GmbH, Neuss, Germany). The resulting SBVC-prototype had thus three lumens: a ventilation lumen of approximately 2.2 mm ID, a lumen for continuous intratracheal pressure monitoring and the lumen of the epidural catheter (placed inside the ventilation lumen) to inflate and deflate the cuff (Fig. 1).

### Experimental design

Our experiments were designed as a cross-over study in which each pig underwent two ventilation runs of 30 min each. One was performed with a sealed airway with the cuff of the SBVC inflated and the other was done with an open airway (which, in this experimental set-up, consisted of the 9.0 mm ID ETT with the 4.0 mm OD SBVC within it) with the cuff of the SBVC deflated. The cuff of the 9.0 mm ID ETT was continuously kept inflated during the whole experiment. Half the animals began with the sealed trial and the other half with the unsealed trial, the order of which was randomized by manually drawing lots.

After steady state IPPV for 30 min the ETT was disconnected from the ventilator. Immediately the SBVC was placed through the ETT as a conduit at the predetermined depth and a cuff pressure manometer (VBM Medizintechnik GmbH, Sulz a. N., Germany) was attached to the intratracheal pressure monitoring lumen. Ventilation through the SBVC with Ventrain (Ventnova Medical, Eindhoven, the Netherlands) was then commenced with either an inflated cuff (= sealed airway run) or a deflated cuff (= open airway run) using an oxygen flow of 15 l/min (from a calibrated, pressure-compensated flowmeter; Draeger, Luebeck, Germany), a fixed frequency of 30 breaths per min and an I : E-ratio of approximately 1 : 1 (guided by a



**Fig. 1.** Prototype of the 40 cm long, small-bore ventilation catheter (SBVC) with the cuff inflated. For placement of the SBVC a removable, malleable metal stylet can be loaded in the ventilation lumen (approximately 2.2 mm inner diameter, blue Luer-lock connector with the loop of the loaded metal stylet). A (e.g. cuff pressure) manometer can be attached to the pressure monitoring channel (white Luer-lock), which has a side opening distally to the cuff.

metronome). During the ventilation cycles of the sealed airway trials, the I:E-ratio was slightly adjusted to maintain peak inspiratory pressure (PIP) below 20 cmH<sub>2</sub>O while aiming for a PEEP of 5 cmH<sub>2</sub>O. Between each ventilation run the ETT was reconnected to the ventilator and the pigs were ventilated with IPPV for at least 30 min until respiratory and haemodynamic variables had returned to baseline values.

Blood samples for arterial blood gas measurements as well as respiratory and haemodynamic data were collected at baseline, 5, 10, 15, 20, 25 and 30 min of both runs. Haemodynamic and intratracheal pressure data were recorded with a multichannel recorder system and processed with the IDEEQ Data Acquisition Program 2.5.0 build 2 (IDEE, Maastricht University Medical Centre, Maastricht, the Netherlands). Baseline haemodynamic measurements were done 5 min before the start of each run by calculating the mean over 2 min of each variable. To obtain correct and reliable haemodynamic measurements at the predefined times, the mean of the measured values over approximately 30 s around these points in time was calculated. In case of artefacts, values were sampled out of an interval of 1 min around the predefined times.

If at any point oxygen saturation (SaO<sub>2</sub>) dropped to 80% or lower and/or PaCO<sub>2</sub> reached 10.6 kPa or higher, the experiment was stopped and baseline IPPV was resumed.

At the end of the experiments the anaesthetized animals were euthanized by injection of an overdose of sodium pentobarbital.

### Statistical analysis

Our primary endpoints for statistical analysis were PaO<sub>2</sub> and PaCO<sub>2</sub> during ventilation with Ventrain both with the cuff of the SBVC inflated and deflated, compared to baseline PCV and to compare efficacy of oxygenation and ventilation between the two ventilation trials, reflected by PaO<sub>2</sub> and PaCO<sub>2</sub>, respectively. Secondly, we evaluated the effects on haemodynamic parameters during ventilation through the SBVC with the cuff inflated and deflated.

The Wilcoxon signed-rank test was used to (1) compare PaO<sub>2</sub> and PaCO<sub>2</sub> baseline levels of the open and sealed airway runs to explore potential carry-over effects caused by the cross-

over design, (2) compare PaO<sub>2</sub> and PaCO<sub>2</sub> during ventilation through the SBVC to baseline in both the open and sealed airway runs, and (3) compare PaO<sub>2</sub> and PaCO<sub>2</sub> during the open airway run to the closed airway run. Data are presented as median [range]. Analyses were performed using SPSS Statistics for Windows, version 23.0 (IBM, Armonk, NY, USA).

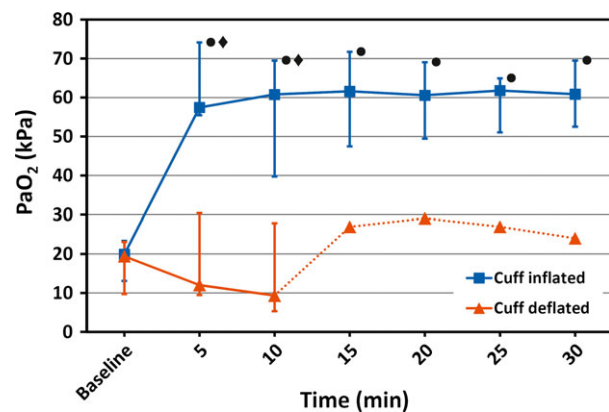
## Results

### Oxygenation and ventilation

At baseline, minute volume was 8.0 [4.8–9.0] l/min with a tidal volume of 400 [400–500] ml and a frequency of 19 [12–20] breaths per min. The compliance calculated from the peak inspiratory pressure setting and volume measurements on the ventilator during IPPV was 21 [16–22] ml per cmH<sub>2</sub>O.

There were no significant differences in baseline PaO<sub>2</sub> and PaCO<sub>2</sub> levels prior to the open and sealed airway experiments.

In the sealed airway runs, efficient oxygenation of all pigs was achieved throughout ventilation with Ventrain. PaO<sub>2</sub> increased to 61 [52–69] kPa after 30 min (Fig. 2,  $P = 0.027$  compared to baseline). Ventilation was adequate with stable PaCO<sub>2</sub> levels during ventilation



**Fig. 2.** PaO<sub>2</sub> during ventilation through the small-bore ventilation catheter in the sealed (cuff inflated) and open airway (cuff deflated) runs. Data are presented as median [range]. In only one pig ventilation with a deflated cuff could be continued from 12.5 min and onwards (dotted line with values measured in this pig). ● =  $P < 0.05$  compared to baseline, ◆ =  $P < 0.05$  sealed airway (cuff inflated) vs. open airway (cuff deflated).



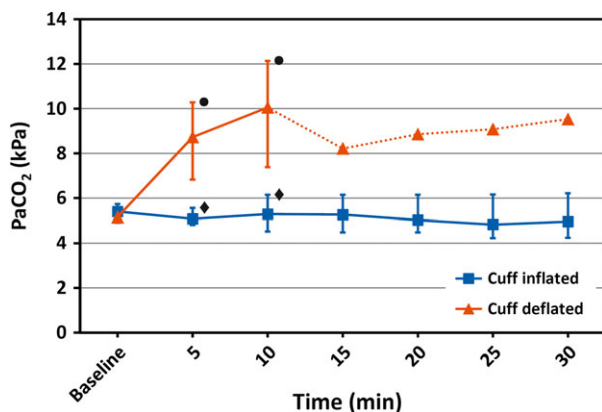
with inflated cuff and a PaCO<sub>2</sub> of 4.9 [4.2–6.2] kPa after 30 min (Fig. 3,  $P = 0.528$  compared to baseline).

In the open airway trials, the results were substantially different. PaCO<sub>2</sub> increased compared to baseline ( $P = 0.028$  at T5 and T10), and PaO<sub>2</sub> dropped, albeit not significantly at T5 and T10. Compared to ventilation with an inflated cuff, in the first 10 min PaCO<sub>2</sub> was significantly higher and PaO<sub>2</sub> was significantly lower ( $P = 0.043$  at T5 and  $P = 0.028$  at T10 for both PaO<sub>2</sub> and PaCO<sub>2</sub>). Afterwards, experiment termination criteria were reached in five of the six pigs: SaO<sub>2</sub> dropped below 80% in one pig and in five pigs PaCO<sub>2</sub> levels exceeded 10.6 kPa. As a result only one pig completed the open airway run which is shown as a dotted line in Figs 2 and 3.

### Intratracheal pressure

Intratracheal pressure could be easily monitored by the cuff pressure manometer attached to the pressure monitoring lumen of the SBVC.

The fixed flow of oxygen of 15 l/min resulted in a linear pressure increase during inspiration and a linear pressure decrease during expiration during the sealed airway runs (Fig. 4). In contrast, only unmeasurably low intratracheal



**Fig. 3.** PaCO<sub>2</sub> during ventilation through the small-bore ventilation catheter in the sealed (cuff inflated) and open airway (cuff deflated) runs. Data are presented as median [range]. In only one pig ventilation with a deflated cuff could be continued from 12.5 min and onwards (dotted line with values measured in this pig). ● =  $P < 0.05$  compared to baseline, ◆ =  $P < 0.05$  sealed airway (cuff inflated) vs. open airway (cuff deflated).

pressure changes ( $< \pm 2$  cmH<sub>2</sub>O) were observed in the open airway runs.

### Haemodynamics

Haemodynamic data are provided in Tables 1 and 2.

In the sealed airway runs all pigs remained haemodynamically stable.

However, in the open airway runs pulmonary artery pressure increased markedly within 10 min. Comparisons afterwards cannot be made as five pigs did not complete the open airway trial, although there might be a trend to an increase in heart rate.

### Discussion

This proof-of-concept study shows that efficient oxygenation and normoventilation of adolescent pigs could be achieved through the SBVC with expiratory ventilation assistance provided by the Ventrain device, by simply inflating the cuff of the SBVC and thereby sealing the airway. This differs from conventional approaches to ventilation through small-bore catheters where sealing the airway is contraindicated when using high pressure source ventilation.<sup>3,4</sup>

Heart rate, arterial blood pressure, and pulmonary artery pressure were maintained at a physiological level during the sealed airway runs, comparable to baseline values. In contrast, during the open airway runs, oxygenation was much less efficient and ventilation was inadequate. In addition, pulmonary artery pressure rose markedly, most likely because of subsequent hypoxic vasoconstriction.

A degree of hyperoxygenation was observed in the sealed airway runs. This could be reasonably expected, because the pigs were then ventilated with an FiO<sub>2</sub> of 1.0 compared to 0.4 during IPPV. In contrast, during open airway trials PaO<sub>2</sub> decreased despite the higher FiO<sub>2</sub>. This could be explained by airway leak, leading to inadequate tidal volumes and inadequate intrapulmonary pressure build-up as well as by entrainment of ambient air lowering the FiO<sub>2</sub>.

During the sealed airway runs, PaCO<sub>2</sub> levels decreased slightly, but were more variable compared to baseline. During IPPV, minute volume ranged between 4.8 and 9 l/min, whereas



**Fig. 4.** Typical graph of intratracheal pressure (ITP) course as measured through the stylet placed 2 cm above the carina during ventilation with Ventrain in a sealed airway run (screen shot from the data acquisition system). Note the linear inspiratory pressure increase as well as the linear expiratory pressure decrease.

**Table 1** Haemodynamic data in the sealed airway runs.

	Baseline	10 min	20 min	30 min
Heart rate (per min)	88 [65–111]	89 [68–103]	86 [66–93]	83 [62–90]
ABP systolic (mmHg)	144 [106–169]	133 [106–163]	136 [105–167]	135 [105–166]
ABP diastolic (mmHg)	86 [59–121]	80 [54–119]	77 [52–121]	78 [52–117]
PAP systolic (mmHg)	23 [20–30]	22 [20–27]	22 [20–31]	22 [18–31]
PAP diastolic (mmHg)	11 [8–17]	10 [7–20]	10 [6–19]	12 [6–19]

ABP, arterial blood pressure; PAP, pulmonary artery pressure. Data are presented as median [range].

**Table 2** Haemodynamic data in the open airway runs.

	Baseline	10 min	20 min	30 min
Heart rate (per min)	83 [61–102]	88 [69–104]	109	96
ABP systolic (mmHg)	140 [113–161]	150 [116–164]	122	127
ABP diastolic (mmHg)	87 [61–124]	76 [52–89]	65	72
PAP systolic (mmHg)	25 [19–30]	42 [21–45]	22	29
PAP diastolic (mmHg)	13 [6–17]	21 [7–24]	8	10

ABP, arterial blood pressure; PAP, pulmonary artery pressure. Data are presented as median [range]. Only one animal remained after 12.5 min and onward. Data at 20 and 30 min are the values measured in this pig.

minute volumes were likely to vary between 7 and (theoretically) 7.5 l/min when ventilating through the SBVC.<sup>6</sup> Given this narrow range, both hypoventilation and hyperventilation could be reasonably anticipated in some pigs.

The pressure monitoring lumen of the SBVC permits continuous measurement of intratracheal pressure using a simple (e.g. cuff

pressure) manometer. So PEEP can easily be adjusted to the desired level.

Continuous (intratracheal) positive pressure was maintained throughout the respiratory cycle, when the cuff was inflated, notwithstanding the fact that the Ventrain continuously applies suction to the proximal end of the SVBC during expiration.

A weakness of our study is that we did not individualize ventilation through the SBVC. Instead we chose to ventilate all pigs with the same settings. However, in clinical practice, end-tidal CO<sub>2</sub> monitoring is also possible during ventilation with Ventrain to establish normoventilation using side stream capnometry attached to its side port. To measure end-tidal CO<sub>2</sub>, following inflation to the desired peak pressure, both apertures of the Ventrain should be released resulting in a slow passive expiration (thus without expiratory ventilation assistance) down to PEEP level. In this 'equilibration mode' a side stream capnometer will display the value with a delay of some seconds. This is caused by the dead space volume of the capnometry tubing and also depends on the suction flow of the capnometer pump.

The small sample size limits interpretation of our results. However, the large differences seen in the two groups indicate an important benefit of ventilation through the SBVC with an inflated over a deflated cuff, especially as the majority of the pigs could not be ventilated safely when the cuff was deflated.

A flaw of the open airway runs is the patent 9.0 mm ID ETT. We chose not to remove the ETT during ventilation with the SBVC to avoid unnecessary airway manipulation and to minimize apnoea time prior to the experimental runs. The larynx (and especially the glottis) must be considered a physiological stenosis of the upper airway. The 9.0 mm ID ETT with the 4.0 mm OD shaft of the SBVC inside is equivalent to an 8.0 mm ID ETT with a cross-section of approximately 50 mm<sup>2</sup>. In most cases this exceeds the cross-section of the upper airway of a paralysed patient. The results of the open airway runs therefore do not necessarily reflect what might be observed in an anaesthetized patient with an anatomically normal airway.

In conclusion, there are several advantages in using a small diameter airway, sealing the lungs with a cuff and establishing continuous control of intrapulmonary pressure throughout the ventilation cycle. The SBVC described here combines all these advantages. Our results show that expiratory ventilation assistance applied by Ventrain can be used to achieve adequate and precisely controlled ventilation by inflation of the cuff of the SBVC.

The results of this proof-of-concept study have triggered the development of the so called Tritube (Ventivova Medical B.V., Eindhoven, the Netherlands), a cuffed, small-bore endotracheal tube based on the prototype SBVC described here. We have already used the Tritube in several ENT cases. Our own and also experiences from other hospitals are equally promising.<sup>14</sup>

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### Authors' contribution

M. W. P. d. W.: None.

T. v. d. B.: None.

A. E.H., A. E. H.: was a member of the medical advisory board of Ambu and has received free samples of airway equipment for teaching and clinical evaluation from several companies. She has no financial interest in any company.

M. T.: None.

D. E., D. E.: is the inventor of the Ventrain and the Tritube (which is based on the prototype of the small-bore ventilation catheter) and receives royalty payments from Ventivova Medical. He is also a consultant for Ventivova Medical.

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