Rescue ventilation using expiratory ventilation assistance : innovating while clutching at straws

Rescue ventilation using Expiratory Ventilation Assistance

Innovating while clutching at straws

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Traveller, your footprints
Are the road and nothing more;
Traveller, there is no road,
The road is made by walking.
By walking the road is made
And when you look back
You'll see the path
Never to be trodden again.
Traveller there is no road -
Only wakes upon the sea.

Fragment from "Proverbios y cantares" in *Campos de Castilla*. 1912, Antonio Machado

This PhD project was a fascinating journey with several unexpected turns, a lot of fun, many challenges, numerous opportunities to learn something new, some difficult decisions to make and a lot of delay, but moreover it was a journey with valuable encounters with wise, creative, passionate, inspiring and beautiful people. I would like to thank everybody that I met on this journey and who walked along for some time, whether it was just for a brief moment or from beginning to end. You all supported, advised, motivated, educated, guided or inspired me while I was creating my own path.

Thank you!!

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Prologue

An anaesthetist's nightmare

Case Report

3:00 am Monday August 9th 2010

A 55 year-old male was admitted to the emergency room with severe respiratory distress and a loud inspiratory stridor. He had been diagnosed with an untreatable oropharynx carcinoma a couple of days earlier. Although the airway was already clearly compromised at that time, the patient refused a tracheostomy and decided he only wanted palliative care at home. He was discharged from the hospital on Friday afternoon. Sunday evening he became progressively dyspnoeic and returned to the hospital. After obtaining informed consent from the patient the ENT surgeon decided to perform an emergency tracheostomy.

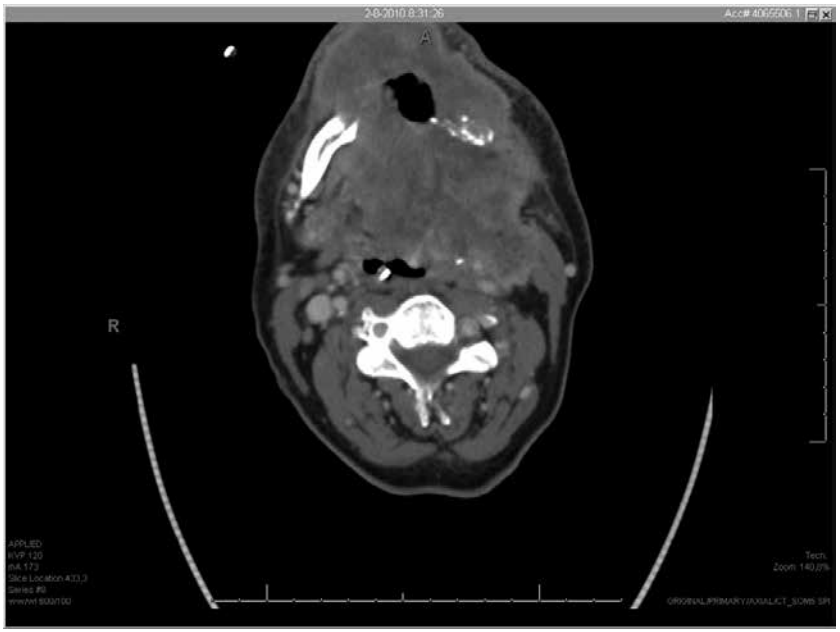

Figure 1 A prior CT scan showed a large tumour extending on the left side from the oropharynx, invading the mandible all the way down to the thyroid cartilage.

The patient arrived at the OR in an upright position with his head flexed to his chest. He could not extend his neck or obtain a supine position as this would make the airway to obstruct. He had a severe inspiratory stridor, was tachypnoeic and used his accessory breathing muscles. While breathing through a non-rebreathing-mask the pulse-oximetry reading was 92%. The patient was anxious and his blood pressure and heart rate were elevated. The external anatomy of the airway was distorted due to the tumour that ulcerated through the skin. The mouth opening was limited to 1.5 cm.

As a team, consisting of the ENT surgeon, ENT and anaesthetic resident, anaesthetic nurse, scrub nurses and anaesthesist, we devised a clear airway strategy. According to the ENT surgeon an awake tracheostomy was not possible as the neck couldn't be flexed and the anatomy was distorted. Our first choice was an awake flexible intubation. Plan B was a needle cricothyroidotomy with jet ventilation and subsequently a surgical tracheostomy.

After the application of local anaesthetic the airway obstructed and the patient desaturated quickly. Even by applying CPAP it wasn't possible to open up the airway. As the patient was chocking we induced anaesthesia, paralysed him and placed the patient in supine position. As expected mask ventilation was impossible. His mouth opening was too small to place a supraglottic airway or attempt direct laryngoscopy so as planned we immediately inserted a needle cricothyroidotomy cannula (Ravussin catheter). A manual jet ventilator was connected and oxygen was insufflated. Saturation improved quickly. However, the egress of air through the upper airway was severely compromised even with jaw trust and chin lift applied. The chest failed to fall after insufflation of oxygen and blood pressure decreased. The jet ventilator was repeatedly disconnected from the Ravussin catheter to allow egress of air through the catheter and to avoid barotrauma and limit hemodynamic instability. Within a couple of minutes the ENT surgeon had performed successfully an emergency tracheostomy. The patient woke up without neurologic sequelae and left the hospital after a few days.

The inability to maintain oxygenation by non-invasive means is one of the most pressing emergencies in anaesthesia and emergency care. To prevent hypoxic brain damage and death in a 'cannot intubate, cannot oxygenate' situation, emergency percutaneous airway access must be performed immediately. Even though this emergency is rare,

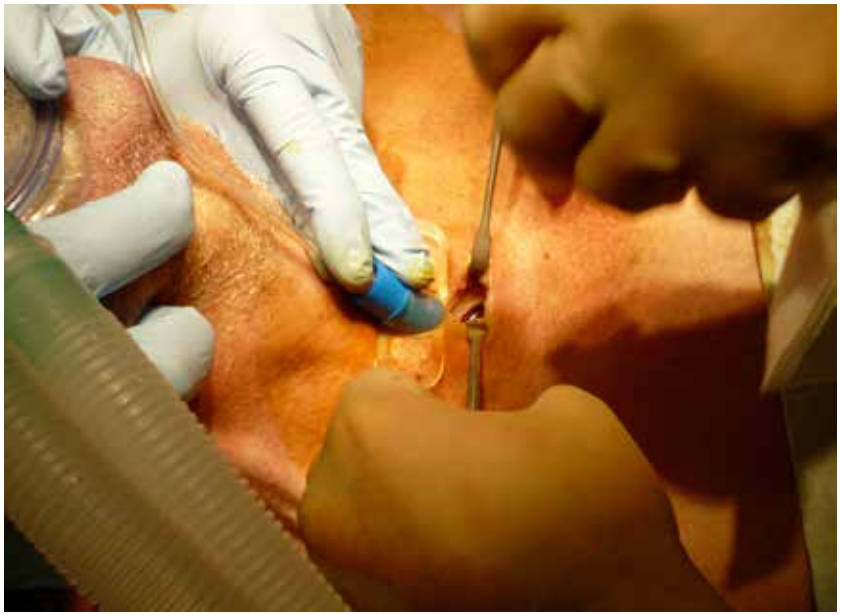

Figure 2 After successful re-oxygenation through the needle cricothyroidotomy an emergency tracheostomy was performed.

every anaesthetist should be capable of performing an emergency percutaneous airway as the situation may arise unexpectedly. Various techniques have been described for emergency oxygenation and several commercial emergency cricothyroidotomy sets are available. However, all available techniques have their limitations.

In the above case a narrow-bore catheter was successfully inserted in the airway and oxygen could be insufflated into the lungs. Unfortunately a new problem arose as it was impossible to provide an adequate outflow of the gas, which resulted in air trapping and haemodynamic instability. Although a narrow-bore cricothyroidotomy catheter is easy to insert, reoxygenation and ventilation through a narrow-bore catheter poses new challenges. The ideal rescue technique for a ‘cannot intubate, cannot oxygenate’ situation seems not yet to exist.

Chapter 1

A General introduction

Part of this introduction has been published in:

Equipment and strategies for emergency tracheal access in the adult patient
Ankie Hamaekers & John Henderson

Anaesthesia 2011, 66 Suppl 2:65-80

Summary

The inability to maintain oxygenation by non-invasive means is one of the most pressing emergencies in anaesthesia and emergency care. To prevent hypoxic brain damage and death in a 'cannot intubate, cannot oxygenate' situation, emergency percutaneous airway access must be performed immediately. Even though this emergency is rare, every anaesthetist should be capable of performing an emergency percutaneous airway as the situation may arise unexpectedly. Clear knowledge of the anatomy and the insertion technique, and repeated skill training are essential to ensure completion of this procedure rapidly and successfully. Various techniques have been described for emergency oxygenation and several commercial emergency cricothyroidotomy sets are available. There is, however, no consensus on the best technique or device. As each has its limitations, it is recommended that all anaesthetists are skilled in more than one technique of emergency percutaneous airway. Avoiding delay in initiating rescue techniques is at least as important as device choice in determining outcome.

The 'cannot intubate, cannot oxygenate' (CICO) scenario describes the clinical situation where attempted tracheal intubation has failed and oxygenation cannot be maintained by non-invasive means. If not corrected rapidly CICO will inevitably lead to brain hypoxia and death. As emphasised in the Difficult Airway Society guidelines a percutaneous airway must be established without delay [1].

Incidence and causation of CICO

The incidence of CICO in general anaesthetic practice is low. Kheterpal et al. reported only 4 cases of impossible mask ventilation and intubation in 53,041 anaesthetics in a tertiary university hospital, only in one of which an EPA was performed [2]. The 4th National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society (NAP4) reported a calculated incidence of 1 in 50,000 general anaesthetics [3]. The incidence of EPA is strongly influenced by clinical setting and case-mix. In the emergency department incidences of 0.3% [4] and 0.8% [5] and in the pre-hospital setting as high as 11% [6] have been reported.

Risk factors for CICO include known risk factors for difficult mask ventilation [7] and difficult direct laryngoscopy [8]. Patients difficult to mask ventilate are more likely to be difficult or impossible to intubate compared to patients with easy mask ventilation [9]. Furthermore, multiple attempts at tracheal intubation can cause airway oedema and may change a 'cannot intubate, can oxygenate' situation into a CICO situation [10-12]. Cricoid pressure, especially when performed poorly, can hinder laryngoscopy [13] and may itself cause airway obstruction and hence CICO [14-16]. Laryngospasm in the non-paralysed patient can be an important factor in failure of mask ventilation. Use of narcotic anaesthesia without paralysis may cause ventilation difficulty with the likely mechanism being vocal cord closure [17, 18].

Diagnosed and undiagnosed laryngeal disease is a more frequent contributor to CICO than generally realised [19, 20]. Of the 58 cases of EPA in 133 anaesthetic patients reported to the NAP4 43 (74%) were head/neck cases [12], suggesting a significantly increased risk in this patient population.

Management of CICO

Anticipation of risk and preparing an optimum strategy to prevent CICO

Reducing the risk of CICO starts with assessment of the airway and use of awake flexible intubation in patients in whom difficulty with mask ventilation, direct laryngoscopy or cricothyroidotomy is anticipated. A clear airway strategy including back-up plans in case of failure, and availability of an anaesthetist skilled in alternative techniques of laryngoscopy (e.g. flexible laryngoscopy with or without a conduit and straight blade or rigid indirect laryngoscopy) may all reduce the risk of CICO [21]. Effective pre-oxygenation increases the time available to secure the airway before profound hypoxia occurs [22, 23]. Strictly limiting the number of intubation attempts makes better use of the available time and decreases the likelihood of airway trauma [10, 11].

Initial, non-invasive techniques for managing CICO

Standard airway clearing manoeuvres (head extension, jaw thrust, two-person mask ventilation, an oropharyngeal air-

way and a gently inserted nasopharyngeal airway) are the first steps in management of the obstructed airway [1]. Early insertion of a supraglottic airway device (SAD), as long as mouth opening is sufficient, is now standard practice. The SAD chosen should be familiar and easy to insert, but should also be reliable at achieving ventilation and ideally offer some protection against aspiration. While SADs have been effective in many cases of difficult or impossible mask ventilation [24] success is not guaranteed [24-27]. Cricoid pressure, if applied, should be reduced or withdrawn completely [28]. The Larson manoeuvre [29] (strong medial digital pressure between the angle of the mandible and the mastoid process) should be tried and is easily added to conventional jaw thrust. In the NAP4 report the probable value of neuromuscular blockade when CICO arises in a patient who is not paralysed has been emphasised [12]. If all these fail and the airway is still obstructed, the option of waking the patient should be strongly considered at this point.

Decision to proceed to emergency percutaneous airway (EPA)

Immediate EPA is indicated when maximal efforts at non-invasive techniques fail to relieve severe hypoxaemia [1]. It is not possible to define the oxygen saturation at which cricothyroidotomy *should* be performed. However, it should certainly have been started (rather than just considered) by the time bradycardia supervenes. In a life-threatening airway emergency there are no contra-indications to EPA. However, the presence of a large laryngeal tumour, neck pathology, obesity or coagulopathy will make the procedure more hazardous.

Cricothyroid membrane anatomy and advantages over other sites

Percutaneous (or transcutaneous) access to the trachea can be achieved by tracheostomy through the upper tracheal cartilages or by cricothyroidotomy. Tracheostomy involves incision through the skin and subcutaneous tissues, separation of the strap muscles, division of the isthmus of the thyroid gland, control of haemorrhage and incision through two tracheal cartilages. Access to the trachea can be difficult because of its depth in the neck and the vascularity of the thyroid gland. Good lighting, competent assistance and a range of surgical instruments are needed. Although elective tracheostomy has a high success rate and a low risk of complications, emergency tracheostomy is associated with a higher complication rate [30].

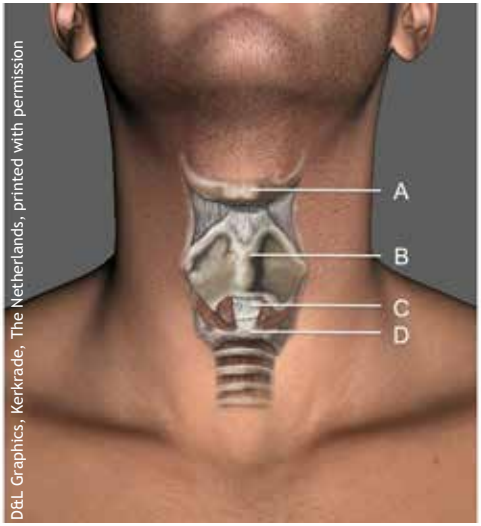

Figure 1 Relevant anatomical structures for cricothyroidotomy: A: hyoid bone, B: thyroid cartilage, C: cricothyroid membrane, and D: cricoid cartilage.

Cricothyroidotomy achieves percutaneous tracheal access through the cricothyroid membrane: a dense fibro-elastic membrane between the thyroid and cricoid cartilages with an average height of 10 mm and a width of 11 mm [31] (Figure 1). Transverse incision in the lower half of the cricothyroid membrane is recommended to avoid damaging the cricothyroid arteries and the vocal cords. The circumferential cricoid cartilage is partially resistant to compression [32] and its posterior lamina lies behind the cricothyroid membrane providing some protection against posterior wall and oesophagus injury during cricothyroidotomy. Failure to identify the cricothyroid membrane occurs frequently [33] and is the principal cause of failed cricothyroidotomy. We recommend its position should be confirmed before induction of anaesthesia in all patients using palpation of the hyoid bone and the thyroid and cricoid cartilages. The hyoid can be located by balloting the bone laterally between the thumb and index finger. The thyroid cartilage's superior notch is then identified in males as the greatest laryngeal prominence. In females the greatest prominence is usually the cricoid cartilage, which is best identified by moving the palpating finger upward from the sternal notch. Identification of the thyroid and cricoid cartilages leads to the cricothyroid membrane over which there is a slight depression. Cricothyroidotomy is the preferred route for EPA on account of the shorter duration required for its completion and its greater safety [34, 35].

Overview of types of cricothyroidotomy

Cricothyroidotomy can be performed by puncture or surgical incision of the cricothyroid membrane. Puncture may be achieved using a narrow-bore (usually an internal diameter (ID) of ≤2 mm) cannula-over-needle, a wide-bore (usually ID ≥4 mm) cannula-over-trocar or a wire-guided (Seldinger) technique, with dilation after cricothyroid membrane puncture. All techniques will be discussed briefly.

Narrow-bore cricothyroidotomy

Surveys have shown that for most anaesthetists the first-choice device for EPA is a narrow-bore cannula [36, 37], which was also used in the case described in the prologue. Insertion of a narrow-bore cannula is suggested to be simple, relatively safe and only minimally traumatic [38].
Although often it is suggested that in an emergency situation any type of available narrow-bore cannula is suitable, it is strongly recommended to use a kink-resistant cannula such as the Ravussin cannula (VBM Medizintechnik GmbH, Sulz, Germany) or the emergency transtracheal airway catheter (Cook Medical, Bloomington, IN, USA) (Figure 2). An intravenous catheter is widely available, but is not designed for percutaneous emergency ventilation. Several case reports have described problems with kinking or catheter dislodgement.

Figure 2 The Ravussin airway catheter (VBM Medizintechnik GmbH, Sulz, Germany) and emergency transtracheal airway catheter (ETAC, Cook Medical, Bloomington, IN, USA) are designed for needle cricothyroidotomy.

Once inserted a high-pressure ventilator is necessary to achieve normal tidal volumes via the narrow-bore cannula [39-41]. In 1967 Sanders introduced a hand-triggered oxygen injector using hospital oxygen pipeline pressure (4 bar) for ventilation through a narrow-bore cannula placed down the side arm of a rigid bronchoscope [42]. The modern oxygen injector, Manujet (VBM Medizintechnik GmbH, Sulz, Germany; Figure 3), allows adjustment of the driving pressure between 0.5 and 4 bar and is designed for emergency use. In a sheep model of CICO rescue with a narrow-bore cricothyroidotomy and manual injector was as efficient as with a surgical wide-bore cricothyroidotomy [43]. Various simple, self-assembled devices, consisting of a three-way stopcock or hole in the oxygen tubing, have also been proposed for emergency ventilation through a narrow-bore cannula [44-46]. Connected to an appropriate high-pressure oxygen source (e.g. a wall flow meter or oxygen cylinder set at 15 $l \cdot min^{-1}$ or higher), such self-assembled devices create an adequate inspiratory flow [47] and are capable of maintaining adequate oxygenation in a 36 kg pig model [45]. Many self-assembled devices, however, have been advocated without validation of their ability to achieve sufficient ventilation to restore oxygenation in the hypoxaemic patient. Such techniques are dangerous as they may be ineffective [48]. In addition, self-assembled devices are 'off-licence' use of equipment and might carry inherent risks. The Oxygen Flow Modulator (OFM; Cook Medical, Bloomington, IN, USA; Figure 4) is a single-use emergency device for use with a narrow-bore cannula. Connected to a flow meter set at 15 $l \cdot min^{-1}$ the OFM was as effective as the Manujet (at 1.5 bar) in restoring oxygenation in a 30 kg hypoxic pig model [49].

It is mandatory to maintain a patent upper airway for the egress of gas when ventilating through a narrow-bore cannula. Obstruction of the outflow tract or insufficient expiratory time results in air trapping [50] with subsequent barotrauma and haemodynamic instability. In a CICO situation partial obstruction of the upper airway, resulting from oedema, laryngospasm or distorted anatomy occurs frequently, so chest movements should be observed carefully and subsequent inspirations should not be initiated before complete fall of the chest wall. If the upper airway is completely obstructed and cannot be relieved from above (e.g. airway clearing manoeuvres, SAD) the injector must be detached from the cannula to allow egress of gas via the

Figure 3 The Manujet (VBM Medizintechnik GmbH, Sulz, Germany; http://www.vbm-medical.de/cms/files/p329_2.0_05.08_gb.pdf) is a hand-triggered oxygen injector.

Figure 4 The Oxygen flow Modulator (OFM; Cook Medical, Bloomington, IN, USA; http://www.cookmedical.com/cc/content/mmedia/C-EMB1004.pdf) is single use emergency ventilation device.

cannula. Unfortunately, even with manually compression of the chest to augment the exhalation the passive outflow through a narrow-bore cannula is very slow. Eger and Dunlap have suggested that expiration could be facilitated by applying suction in order to increase the achievable minute volume through a narrow-bore cannula and lower the risk of air trapping [51, 52]. However, none of the proposed techniques are available in clinical practice.

The success rate of emergency narrow-bore cannula cricothyroidotomy in clinical practice varies widely (from 37 to 79%) [12, 38]. Additionally, numerous case reports have described failures, severe complications and deaths as a consequence of the emergency use of high-pressure ventilation [53-56]. It is not clear whether the reason for these complications was poor insertion technique, use of inappropriate equipment, lack of training and practice or an inherently

NARROW-BORE CANNULA CRICOTHYROIDOTOMY AND HIGH PRESSURE VENTILATION	
1	position the patient (head and neck extended) and identify the landmarks
2	immobilise the cricoid cartilage between the thumb and middle finger of the non-dominant hand
3	puncture the cricothyroid membrane in the midline with a kink-resistant narrow-bore cannula attached to a 5 or 10 ml syringe
4	confirm needle placement in the trachea by aspiration of air; if time permits partial filling the syringe with saline makes the end-point of tracheal entry much easier to identify.
5	hold the needle in one hand and use the other to advance the cannula in a 45o caudad direction over the needle; remove needle only when cannula is fully inserted
6	aspirate air or saline through cannula to confirm correct placement; capnography may also be used to confirm tracheal entry
7	delegate one person to hold the cannula in position
8	connect high-pressure ventilation device and insufflate oxygen for 1 second; start at a driving pressure of 1 bar
9	watch (and palpate) chest rise and fall
10	do not insufflate until chest has fallen: adjust frequency to ensure there is sufficient time for expiration, in order to prevent air trapping
11	if there is inadequate egress of gas through the upper airway (as seen by chest wall not falling) place oral airway or supraglottic airway, perform jaw thrust if necessary. Consider administering neuromuscular blocking agent if not already done, manually compress chest to augment exhalation
12	discuss plan: wake the patient, intubate or convert to cuffed tracheostomy or cricothyroidotomy

Table 1 A step by step checklist for performing a narrow-bore cannula cricothyroidotomy and using high-pressure ventilation

greater risk involved in use of manual high-pressure ventilation. Experience with high-pressure ventilation and meticulous technique should reduce the risk of complications. The steps included in the technique are shown in Table 1. In case of an obstructed upper airway rescue ventilation through a narrow-bore cannula is inefficient and dangerous and should not be used.

Wide-bore cannula-over-trocar cricothyroidotomy

Insertion of a wide-bore cannula/tube (ID of ≥4 mm) offers advantages regarding ventilation. Adequate minute volume can be achieved using a conventional low-pressure breathing system with expiration via the cannula. However, reliable ventilation can only be guaranteed with a cuffed tube as use of an uncuffed tube may lead to gas leakage to the upper airway [57, 58]. The Quicktrach II (VBM; Medizintechnik GmbH, Sulz, Germany; Figure 5) and Portex® cricothyroidotomy kit (PCK; Smiths Medical Ltd, Hythe, UK; Figure 6) have cuffed cannulae and are designed and marketed for emergency cricothyroidotomy. When wide-bore cannula-over trocar devices are used there is a risk of compression of the airway as considerable force is sometimes required to push the device through the cricothyroid membrane with the consequence that the trocar enters the trachea with a high velocity and lack of control, increasing the risk of damage of perforation of the posterior tracheal wall [59]. An initial scalpel incision to reduce the force required [60] and insertion of the Quicktrach in a caudal direction minimises risks. The Quicktrach includes a red detachable stopper designed to limit initial insertion depth and thereby prevent posterior airway trauma. This mechanism does limit the utility in obese patients (patients with a thick neck) as the cannula might fail to reach the trachea: such failure was reported in NAP4 [3]. The PCK incorporates a Veres needle and signalling system that indicates tracheal entry and any subsequent contact with the posterior tracheal wall. Although designed to limit posterior wall damage a 70% incidence of such damage was reported in a pig larynx model [61].

Figure 5 Quicktrach II (VBM; Medizintechnik GmbH, Sulz, Germany) http://www.hospitecnica.com.mx/productos/VBM/cricotomia.pdf

Figure 6 Portex cricothyroidotomy kit (PCK; Smiths Medical Ltd, Hythe, UK) http://www.smiths-medical.com/catalog/cricothyroidotomy-kits/

Seldinger cricothyroidotomy

A guide wire is placed in the trachea through a narrow-bore needle and the tract is then dilated for the passage of a larger cannula (Figure 4), a sequence familiar to anaesthetists. The separation of the puncture and dilatation steps minimizes the risk of trauma [62]. Although several anaesthetists have attempted to use the Portex® Mini-Trach II device (Smiths Medical; http://www.smiths-medical.com/catalog/cricothyrotomy-kits/), which is widely available, during CICO, this is not recommended by the manufacturer. It was designed for sputum aspiration, is uncuffed and several failures to restore oxygenation have been reported [63, 64]. The Melker emergency cricothyroidotomy set (Cook Medical; http://www.cookmedical.com/cc/content/mmedia/C-EMB1004.pdf) is Seldinger-based and sizes 3.0 to 6.0 mm ID are available. Only the 5.0 mm ID cannula has a cuff. In general, anaesthetists prefer the wire-guided cricothyroidotomy technique above the surgical and wide-bore cannula-over-trocar techniques [61]. In a manikin study the Seldinger technique was considered more intuitive and 75% of anaesthetists felt confident with the Melker wire-guided technique [65]. While good results have been achieved with the Seldinger technique in human cadavers and manikin studies by those well trained, inexperienced operators have low success rates and a long performance time [66]. The most frequent technical problems are kinking of the guide wire [65] and attempts to place the cannula without using the dilator [67, 68]. Guide wire kinking prevents passage of

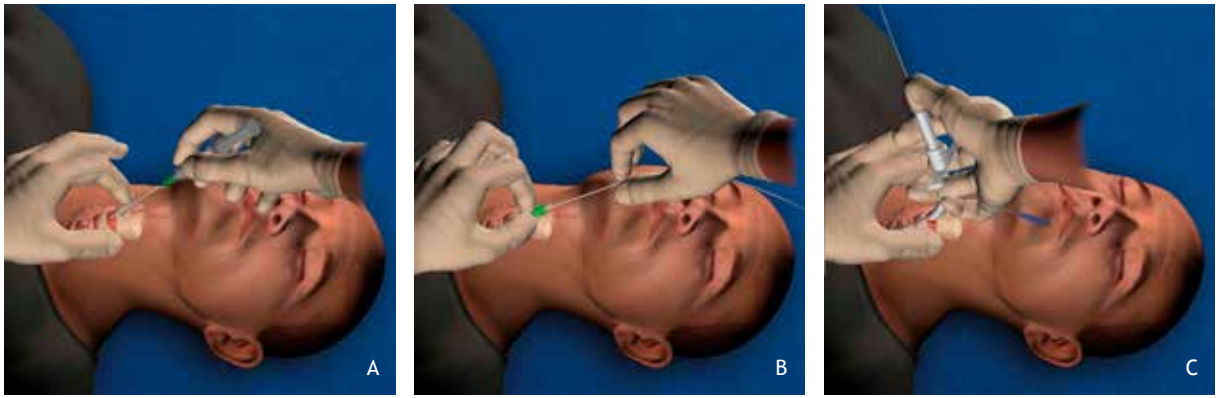

Figure 7 Illustrated procedure for Seldinger cricothyroidotomy:

1 position the patient (head and neck extended) and identify the landmarks
2 immobilise the cricoid cartilage between the thumb and middle finger of the non-dominant hand and puncture the cricothyroid membrane in the midline with the puncture needle attached to a 5 or 10 ml syringe while aspirating (figure 7A)
3 confirm needle placement in the trachea by aspiration of air, disconnect the syringe and insert guide wire through the needle in a caudad direction; to confirm the wire is not kinked check it can be withdrawn and advanced 1-2 cm without resistance (figure 7B)
4 incise the skin and membrane close to the guide wire and remove the needle
5 insert the dilator and cannula over the guide wire into the trachea in the same direction as the needle was inserted; a single advancement is ideal and lessens the risk of kinking the wire (figure 7C)
6 remove the guide wire and dilator, leaving the cannula in place
7 inflate the cuff, ventilate the patient, check correct placement (capnography and auscultation) and secure the cannula

a dilator and increases risk of misplacement by creation of a false passage. If identified it is safer to convert immediately to a surgical cricothyroidotomy.

Surgical cricothyroidotomy

Although many anaesthetists are reluctant to use this technique the skills are basic and all should be capable of this procedure. In the rapid four step cricothyroidotomy technique the steps are palpation, horizontal incision through both skin and cricothyroid membrane, insertion of a tracheal hook while the blade is within the larynx, retraction of the cricoid cartilage anteriorly and caudally with the hook, and passage of the tube (Figure 4) [69]. A no. 20 blade is used to minimise extension required for passage of a 6 mm ID tube and the risk of damage to the posterior wall of the larynx. Holding a blade between thumb and index finger to limit insertion depth also reduces this risk. Many techniques use an initial vertical midline skin incision: although the standard rapid four step technique does not, this is an essential first step in patients (e.g. obesity) in whom cricothyroid membrane identification is difficult. In many techniques the incision is kept maximally patent during tube insertion by a dilator, speculum or tracheal hook. If there is difficulty advancing the tube through the incision, the incision should be extended with a blunt rather than sharp instrument (surgical forceps, an appropriate dilator or a digit) and initial passage of an introducer (e.g. bougie or exchange catheter) should be used to facilitate tube placement [70]. Whatever procedure is used, gentle technique should minimise the risk of complications. Where a tracheostomy tube is immediately available, a tracheal tube should be inserted until its cuff is just beyond the incision to minimise the risk of endobronchi-

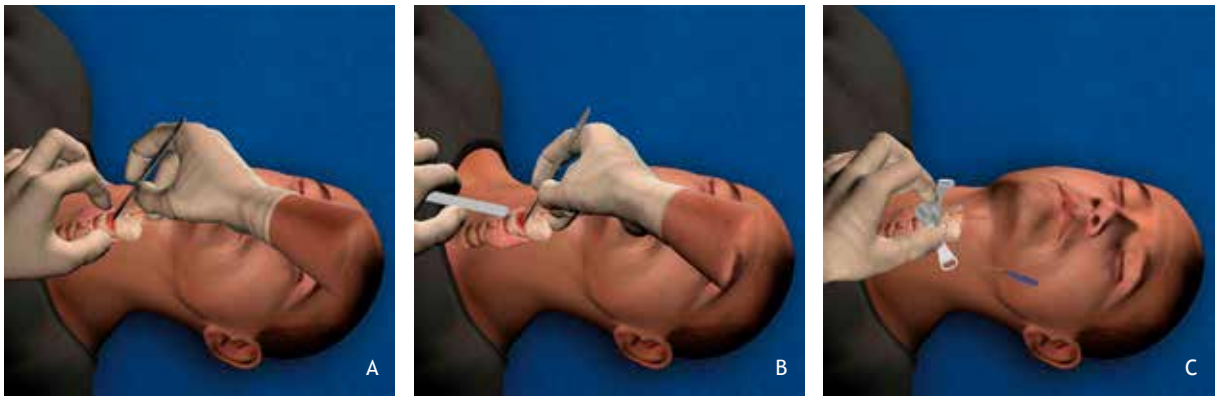

Figure 8 Illustrated procedure for surgical cricothyroidotomy (rapid four step cricothyroidotomy):

1. position the patient (head and neck extended) and identify the landmarks
2. immobilise the trachea with non-dominant hand and make a horizontal 25 mm stab incision through the skin and cricothyroid membrane with a no. 20 scalpel blade; keep the scalpel blade in place (figure 8A)
3. place the tracheal hook in the incision before removing the blade and apply caudal and ventral traction on the cricoid cartilage (figure 8B)
4. remove scalpel blade and insert 6.0 ID tracheal tube gently (figure 8C)
5. inflate the cuff, ventilate the patient, check correct placement (capnography and auscultation) and secure the tube

al intubation. Although some bleeding is normal, life-threatening haemorrhage is exceptionally rare and can normally be controlled by pressure after passage of the tube.

Complications of EPA

Reported complication rates of cricothyroidotomy vary from 0 to 52%, depending on the technique, the experience level of the operator, the patient population and the clinical situation [30, 34, 71-73]. The main complication is initial misplacement, (e.g. paratracheal, superior or inferior to the cricothyroid membrane or through the posterior tracheal wall) and is the principal cause of failure. This underlines the importance of taking care to identify the cricothyroid membrane. Inferior placement through the crico-tracheal space increases the risk of airway injury [32] and bleeding, but can still result in effective re-oxygenation.

Some complications are technique-related. Narrow-bore cannula techniques are associated with ventilation-related complications such as barotrauma [38, 39], (e.g. subcutaneous emphysema, pneumothorax, pneumomediastinum and circulatory arrest due to impaired venous return), and cannula obstruction due to kinking. Kinking of the guide wire is a common problem peculiar to the Seldinger technique and increases the risk of tube misplacement [65, 74]. The surgical method is associated with complications of tube insertion (e.g. bleeding, laryngeal fracture). Damage to the larynx is normally a consequence of excessive pressure during device insertion and is reduced by use of small tubes and gentle technique [59]. Long-term complications are subglottic stenosis, scarring and voice changes [34].

Which cricothyroidotomy technique should we use?

The ideal EPA technique is readily available, can be completed rapidly, has few steps and is easy to master and retain, has a high success and low complication rate, allows adequate ventilation independent of upper airway resistance and provides protection against aspiration [75]. While recent technical developments likely make EPA simpler, faster and more precise, delayed decision-making in CICO is often a reason for bad outcome. Retrospective studies of pre-hospital airway management show that most patients were already in cardiac arrest prior to EPA [76, 77]. In two thirds of the claims included in a closed claims analysis where an airway emergency occurred, EPA was performed too late to prevent poor outcome [11]. A reluctance to perform EPA (ie, human factors reasons) is likely the commonest cause of delay [78, 79]. The ideal EPA technique, therefore, should also be familiar to the anaesthetist.

Recently, NAP4 reported a success rate of only 37% for narrow-bore cannula-over-needle cricothyroidotomy, 57% for wide-bore cannula techniques and 100% for surgical cricothyroidotomy [12]. In a recent meta-analysis the pooled success rates of pre-hospital puncture cricothyroidotomy (27 patients included) and surgical cricothyroidotomy (485 patients included) were 66% and 91%, respectively [80] and retrospective cohorts from emergency departments confirmed the high success rate of surgical cricothyroidotomy [6, 81]. While it is tempting to conclude from these data that surgical cricothyroidotomy should be our preferred technique, we need to realise that although these studies provide valuable data they cannot be used to directly compare the effectiveness and safety of different EPA techniques. Randomised control trials (RCTs) are normally required to

find the best management. For obvious reasons, which have been recently discussed by Cook and Bogod [82], no RCT exists or is likely to be completed in the CICO setting. Although several RCTs have been performed on manikins, isolated pig larynxes, animals or human cadavers, these studies vary in anatomic validity, outcome measures used and in the qualifications, prior experience and training of those performing EPA (Tables 2-4). Consequently, conflicting results have been published. For example, in a pig trachea model paramedics were faster and more successful with the surgical technique than the Seldinger technique [83]. Other studies in larynx models or manikins also reported greater speed with the surgical technique [61, 67, 84]. However, in three out of four human cadaver studies the performance time of the Seldinger technique was as fast [74, 85] or faster [86] as the surgical technique. Reported success rates of the different techniques vary widely and range for surgical cricothyroidotomy from 55% to 100%, for wide-bore cannula-over-trocar from 30 to 100% and for Seldinger technique from 60% to 100% [32, 60-62, 65-67, 74, 83-94]. The differences in success rates may reflect varying definition of success (e.g. only one attempt allowed, or a certain time limit) and operator experience, but the study model likely has also an important influence on the outcome [95]. Due to lack of fidelity the results obtained from plastic models are likely biased towards wide-bore cannula-over-trocar and surgical techniques [96]. Overall the strength of current evidence does not justify recommending one technique over others.

It is however clear from NAP4 that we need to improve our clinical practice. The success rate of cricothyroidotomies performed by anaesthetists was only 39%. So, in 61% of the cases our final back-up plan fails. In the NAP4 report there are several recommendation on how to improve the logistics, having all equipment available, training and decision-making. There might also be room for technical improvement as we have the dilemma that anaesthetists generally feel more comfortable inserting a narrow-bore cannula (needle cricothyroidotomy) compared to a large-bore cannula [99], but a safe and efficient ventilation technique for rescue ventilation through a narrow-bore cannula is still lacking [100].

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AUTHORS [REF]	TECHNIQUES STUDIED	NUMBER OF CADAVERS	OPERATOR
Benkhadra et al. [93]	• Melker • Portex	n=40	Anaesthetists (n=2)
Chan et al. [85]	• Melker • surgical	n=15	EM attendings /residents (n=15)
Davis et al. [87]	• RFSC • standard surgical	n=30	EM residents (n=2)
Davis et al. [88]	• RFSC, Bair Claw • standard surgical	n=33	Emergency physicians (n=5)
Eisenburger et al. [74]	• Melker • surgical	n=40	ICU physicians (n=20)
Holmes et al. [90]	• RFSC • standard surgical	n=64	EM interns, residents, students (n=32)
Johnson et al. [91]	• Pertrach • surgical	n=44	students (n=44)
Schaumann et al. [86]	• Arndt • surgical	n=200	emergency physicians (n=20)
Schober et al. [66]	• Crico-scissor • Melker • Quicktrach • surgical	n=63	students (n=63)

Table 2 An overview of the randomised control trials on cricothyroidotomy insertion in human cadavers.

	OUTCOME MEASURES	RESULTS
	insertion time: from incision /puncture of the skin to inflation of the cuff	Melker 71s vs Portex 54s (p=0.01)
	success rate: device in the correct position in < 300 s	Melker 95% vs Portex 80% (NS)
	incidence of major tracheal and laryngeal injury	Melker 0% vs Portex 20% (p=0.003)
	insertion time: initial incision to final placement of cannula	Melker 75s vs surgical 73s (p=0.86)
	accuracy of placement	Melker 93% vs surgical 87% (p=0.05)
	complication rate	Melker 7% vs surgical 15%
	operator preference	93% preferred the Melker
	incidence of tissue damage or balloon rupture	RFSC 16.7% vs standard surgical 0% (<0.05)
	size of largest tube able to pass	both 7.0 mm ID
	time to definitive airway: not defined	RFSC 33s vs standard surgical 52s (p=0.037)
	size of largest tube able to pass	RFSC 7.7 mm ID vs surgical 7.8 mm ID (NS)
	complication rate	both 0%
	operator preference: numeric scale 1 to 4	Melker least preferred by 78%
	procedure time: from start to first ventilation	Melker 100s vs surgical 102s (NS)
	rate of tracheal placement	Melker 60% vs surgical 70% (NS)
	incidence of laryngotracheal injury	Melker 10% vs surgical 15% (NS)
	ease of use: from 1 (easiest) to 5 (worst)	Melker 2.4 vs surgical 2.2 (NS)
	insertion time: from incision to removal trocar from the Shiley tube	RFSC 43s vs standard 134s (p<0.001)
	success rate: within 1st attempt	RFSC 88% vs standard 94% (p=0.16)
	incidence of major complications	RFSC 9% vs standard 3% (p=0.32)
	insertion time: from palpation to first ventilation	Pertrach 148s vs surgical 55s (p<0.01)
	tracheal placement in the 1st attempt	Pertrach 78% vs surgical 86% (p=0.186)
	ease of insertion: 0 (very easy) to 10 (impossible)	Pertrach 5.1 vs surgical 3.0 (p<0.01)
	time from start of procedure to first ventilation	Arndt 109s vs surgical 137s (p<0.001)
	success rate: through cricothyroid membrane within 1 attempt	Arndt 88% vs surgical 84% (NS)
	incidence of injury	Arndt 0% vs surgical 6% (p<0.05)
	insertion time: from beginning of inspection until complete termination of procedure	Crico-scissor 60s vs Melker 135s vs Quicktrach 74s vs surgical 78s (Melker vs surgical p<0.05)
	success rate	Crico-scissor 100% vs Melker 71% vs Quicktrach 82% vs surgical 94% (Melker vs surgical p<0.05)
	complication rate	Crico-scissor 36% vs Melker 64% vs Quicktrach 71% vs surgical 0% (Melker vs surgical p<0.05)

AUTHORS	TECHNIQUES STUDIED	STUDY MODEL	OPERATOR
Assmann et al. [65]	○ Melker ○ Portex	manikin	anaesthetists (n=64)
Dimitriadis et al. [67]	○ Melker ○ Mini-Trach ○ Quicktrach ○ surgical	manikin	EM physicians (n=23)
Fikkers et al. [60]	○ Mini-Trach ○ Quicktrach	pig-larynx model	anaesthesia and ENT residents (n=20)
Hill et al. [89]	○ RFSC ○ RFSC with bougie	sheep (n=21)	residents and students (n=21)
Keane et al. [83]	○ Melker ○ surgical	pig-larynx model	paramedics (n=22)
Mariappa et al. [92]	○ Melker ○ Portex ○ surgical	pig-larynx model	intensivist (n=3)
Metterlein et al. [62]	○ Melker ○ Quicktrach	sheep cadaver (n=16)	anaesthetists (n=2)
Salah et al. [32]	○ Mini-Trach ○ Quicktrac ○ Ravussin ○ surgical	pig-larynx model	anaesthetic trainees (n=10)

Table 3 An overview of the randomised control trials comparing cricothyroidotomy insertion techniques in non-human material (ie, manikins or animal models)

	OUTCOME MEASURES	RESULTS
	insertion time: from palpation of skin to ventilation	Melker 42s vs 33s (p<0.001)
	success rate: insertion of the device in the correct position	Melker 95% vs Portex 93% (NS)
	operator preference	59% of the operators preferred the Melker
	time to first ventilation	Melker 126s, Mini-Trach 48s, Quicktrach 48s, surgical 34s (p<0.0001)
	success rate: correct placement within 210	Melker 74%, Mini-Trach, Quicktrach and surgical 100%
	operator preference: numeric scale 1 to 4	Melker least preferred by 78%
	Insertion time: from inspection of instruments to first ventilation	Mini-Trach 149.7 s vs Quicktrach 47.9 s (p <0.001)
	success rate: correct position within 240 s	Mini-Trach 85% vs Quicktrach 95% (NS)
	ease of procedure: VAS 0-10	Mini-Trach 5.5 vs Quicktrach 2.1 (p<0.001)
	insertion time: from palpation to cuff inflation	RFSC 149s vs with bougie 67s (p=0.002)
	success rate: 1 attempt, within 180 s in correct position	RFSC 73% vs with bougie 90%
	ease of use: 1 (very easy) to 5 (very hard)	RFSC 3 vs with bougie 2 (p=0.04)
	procedure time: puncture/incision of the skin to completion of procedure	Melker 123s vs surgical 29s (p<0.001)
	success rate	Melker 91% vs surgical 100% (p=0.1)
	time to achieve patent airway: from location of cricothyroid membrane to first ventilation	Melker 47s vs Portex 63s vs surgical 50s (NS)
	success rate: intraluminal placement with resistance free ventilation	Melker 100% vs Portex 30% vs surgical 55% (p≤0.001)
	incidence of posterior wall injury	Melker 0% vs Portex 55% vs surgical 20% (p<0.001)
	time from the decision to start of procedure and time from incision/puncture to first successful ventilation	Melker 53s vs Quicktrach 32s (p<0.05)
	success rate: within 180 seconds	Melker 100% vs Quicktrach 63% (p<0.05)
	incidence injury posterior wall	Melker 13% vs Quicktrach 63%
	incidence and severity of tissue damage tracheal site or CTM	tissue injury more frequent when procedure is performed at tracheal site compared to CTM with Quicktrach and surgical rank order: surgical=Quicktrach>Mini-Trach=Ravussin
	maximum tracheal compression	compression more common at tracheal site compared to cricothyroid membrane rank order: Quicktrach>surgical>Mini-Trach>Ravussin

AUTHORS	TECHNIQUES STUDIED	STUDY MODEL	OPERATOR	
Manoach et al. [43]	○ narrow-bore cannula ○ surgical	sheep (n=12)	researchers (n=2)	
Murphy et al. [61]	○ Melker ○ Portex ○ Quicktrach ○ surgical	pig-larynx model	anaesthetists (n=20)	
Sulaiman et al. [57]	○ Melker (cuffed and uncuffed) ○ surgical	manikin	anaesthetists (27)	
Vadodaria et al. [94]	○ Melker ○ Quicktrach ○ Patil ○ narrow-bore cannula	human patient simulator	anaesthetists (10)	

Table 4 An overview of the randomised control trials concerning cricothyroidotomy insertion and ventilation.

	OUTCOME MEASURES	RESULTS
	procedure time: start procedure (at oxygen saturation of 80%) to initiation of ventilation	narrow-bore cannula 20s vs surgical 24s (p=0.69)
	respiratory and hemodynamic parameters	no significant differences
	insertion time: from opening the cricothyroidotomy kit until placement of device in the trachea	Melker 94s vs Portex 182s vs Quicktrach 52s vs surgical 59s
	success rate: placement in the trachea within 300s	Melker 100% vs Portex 60% vs Quicktrach 95% vs surgical 95%
	ease of use: 0 (very easy) to 10 (very difficult)	Melker 2.8 vs Portex 5.7 vs Quicktrach 4.8 vs surgical 3.1
	operator preference: ranking 1 to 4	Melker was most preferred technique
	Incidence of posterior wall damage	Melker 40% vs Portex 70% vs Quicktrach 15%, vs surgical 45%
	tidal volumes	no significant difference
	success rate: placement in the trachea within 300s	Melker 100% vs Portex 60% vs Quicktrach 95% vs surgical 95%
	ease of use: 0 (very easy) to 10 (very difficult)	Melker 2.8 vs Portex 5.7 vs Quicktrach 4.8 vs surgical 3.1
	operator preference: ranking 1 to 4	Melker was most preferred technique
	minute volume	Melker cuffed 6.6 $l.min^{-1}$ vs Melker uncuffed 0.3 $l.min^{-1}$ vs surgical 6.5 $l.min^{-1}$
	time required to achieve a patent airway	Melker 38s vs Quicktrach 51s vs Patil 123s vs narrow-bore cannula 102s
	time required to achieve a PaO_2 exceeding 13.3 kPa	Melker 130s vs Quicktrach 58s vs Patil 140s vs narrow-bore cannula 185s
	success rate: correct tracheal placement within 300s and achieving PaO_2 > 13.3 kPa	Melker 100% vs Quicktrach 100% vs Patil 60% vs narrow-bore cannula 40%
	incidence of posterior wall injury	20% for each technique
	operator preference	60% preferred Quicktrach and 40% Melker

Chapter 1

B Aims of this thesis

In this thesis the potential negative side effects of emergency ventilation through a narrow-bore cannula are discussed and a new ventilation mode, expiratory ventilation assistance (EVA), is developed and studied from bench to in vivo evaluation.

Aim 1: Are self-assembled emergency jet-ventilation devices safe?

Several self-assembled devices, usually consisting of a three-way stopcock connected to a high-pressure oxygen source, have been used for percutaneous rescue ventilation through a narrow-bore cannula. Combined with a high oxygen flow, these devices are generally supposed to provide emergency re-oxygenation. However, as a three-way stopcock acts as a 'flow splitter' it will never ensure total flow and pressure release through the open side port. When connected to a patient with an obstructed upper airway, this technique can result in airtrapping and barotrauma. In chapter 2 of this thesis, the results of a bench study on the efficacy of flow and pressure release of three currently used self-assembled ventilation devices and one commercially available tool, are described.

Aim 2: Which emergency jet-ventilation device can act as a bidirectional airway?

When used in case of an obstructed upper airway, an emergency ventilator connected to a percutaneous airway cannula has to allow both the insufflation of oxygen and the egress of gas to be used safely. In chapter 3, the capability to allow bidirectional airflow of two self-assembled, three-way stopcock based ventilation devices and the Oxygen Flow Modulator are studied.

Aim 3: Feasibilty of expiration through a narrow-bore airway catheter

Our group developed a new ventilation concept: Expiratory Ventilation Assistance (EVA). In Chapter 4 the concept of EVA is introduced and first results of a feasibility study are described and critically discussed.

Aim 4: Technical features to optimize the entrainment effect for Expiratory Ventilation Assistance (EVA)

The technical features and abilities of two novel ejector-based ventilation devices are described in chapter 5. The features to optimize the entrainment effect for EVA are discussed.

Aim 5: The efficiency of EVA to restore oxygenation and ventilation

In vitro EVA seemed promising and therefore in vivo evaluation was the next logical step. The efficiency of EVA on restoring oxygenation and ventilation in a pig model of acute hypoxia was studied and is presented and discussed in chapter 6.

Aim 6: Evaluation of the efficacy of a commercially available emergency EVA ventilator (Ventrain®)

Based on the optimized prototype for EVA (chapter 5), a portable, flow-regulated, manually operated, and ergonomically shaped ventilation device was developed: Ventrain® (Dolphys Medical BV, Eindhoven, The Netherlands). The results of a bench study of the Ventrain® are presented in chapter 7.

Chapter 8, the general discussion, focuses on the possible role of expiratory ventilation assistance (EVA) by Ventrain® in emergency ventilation and on potential future applications of EVA as a new ventilation mode.

Chapter 2

Potential hazard unrevealed

The importance of flow and pressure release in emergency jet ventilation devices

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Summary

Several self-assembled devices, consisting of a three-way stopcock connected to a high-pressure oxygen source, have been proposed for transtracheal jet ventilation in an emergency situation. As a three-way stopcock acts as a 'flow splitter' it will, when connected to a continuous oxygen flow, never ensure total flow and pressure release through its side port. The aim of the present study was to measure the efficacy of flow and pressure release of three previously described self-assembled jet devices and one commercially available tool.

In a laboratory setting simulating an obstructed upper airway the generated pressure at the cannula tip (PACT) during the expiration phase was measured in three self-assembled jet devices consisting of a three-way stopcock with an inner diameter of 2 mm (device A), 2.5 mm (device B), and 3 mm (device C), respectively, and in the Oxygen Flow Modulator (OFM) at oxygen flows of 6, 9, 12, and 15 $l \cdot min^{-1}$.

The PACT of device A at on oxygen flow of 15 l $l \cdot min^{-1}$ was 71.1 (±0.08) cmH_2O. At a reduced flow of 9 $l \cdot min^{-1}$ the PACT of device A was still 25.8 (±0.08) cmH_2O. In device B and C the PACT was 35.6 (±0.04) and 17.6 (±0.04) cmH_2O, respectively, at an oxygen flow of 15 $l \cdot min^{-1}$. In contrast, the PACT in the OFM (five side holes open) was 4.4 (±0.02) cmH_2O at the same flow.

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.

Introduction

Transtracheal jet ventilation (TTJV) is a generally accepted technique to oxygenate a patient in case bag-mask ventilation, supraglottic airway devices and / or endotracheal intubation attempts have failed [1,2]. In order to overcome the resistance of a narrow cannula, a high-pressure oxygen source is necessary for TTJV. Because an automated or hand-triggered jet injector may not be immediately available, various simple, self-assembled devices made of a three-way stopcock and oxygen tubing have been proposed for emergency jet ventilation [3,4]. When connected to a high-pressure flow-regulated oxygen source these devices are supposed to transmit sufficient pressure and flow to allow effective low frequent jet ventilation by intermittent occlusion of the side port of the three-way stopcock [4,5].

Based on its geometry, however, a three-way stopcock acts as a 'flow splitter'. This means that when this self-assembled device is connected to a continuous oxygen flow the three-way stopcock, even with the side port completely opened, will never ensure total flow and pressure release through this side port. Consequently, a relevant flow of oxygen to the lungs of the patient cannot be avoided [6]. In a completely obstructed upper airway, this oxygen flow will inevitably create a positive end-expiratory pressure (PEEP) that can lead to barotrauma [7] and hemodynamic instability [8].

Sufficient gas flow and pressure release via the side port of the jet ventilation device is crucial to avoid high levels of PEEP. The ability of flow and pressure release via the side port of the jet device thus determines whether a self-assembled device can be used safely for TTJV. Therefore, the aim of our study was to measure the efficacy of flow and pressure release in three previously described self-assembled emergency devices and one commercially available emergency tool.

Methods

Four devices were tested in the laboratory. Self-assembled device A, as described by Schaefer et al. [5], consisted of a three-way stopcock with an inner diameter of 2 mm (Discofix® C, B. Braun Melsungen AG, Melsungen, Germany) connected in-line to a transtracheal airway cannula and a noncompliant oxygen tubing (Figure 1). In device B and C the standard three-way stopcock was replaced by a modified stopcock with all passages drilled to an inner diameter of 2.5 and 3 mm, respectively. The Oxygen Flow Modulator (OFM; Cook Medical, Bloomington, IN, USA) is a short, noncompliant 5 mm tubing having five openings with a diameter of 4 mm each (Figure 2).

All devices were tested separately with three different, currently and widely available transtracheal cannulas: a 16 G (50 mm long with an inner diameter of 1.3 mm) and a 13 G (78 mm long with an inner diameter of 1.7 mm) Ravussin needle (VBM Medizintechnik GmbH, Sulz, Germany) and a 6 Fr (80 mm long with an inner diameter of 2 mm) transtracheal catheter (TTC; Cook Medical, Bloomington, IN, USA). The same 4 mm oxygen tubing was used to connect all devices to a calibrated, pressure-compensated oxygen flow meter (Dräger Medical AG &Co. KG, Lübeck, Germany) attached to a wall outlet delivering oxygen at a maximum pressure of 5 bar (±73 psi).

In devices A, B, and C the pressure was measured at the tip of the transtracheal cannula with the side port of the three-way stopcock in the open position. We shall refer to this as the 'pressure at cannula tip' (PACT). In the OFM

the PACT was first determined with only one 4 mm opening released, then again with all five side holes opened.

Pressure measurements were obtained using the Calibration Analyzer series RT-200 (Timeter Instrument Corporation, St. Louis, MO, USA). In order to prevent gas leakage, care was taken to keep a tight fit of the transtracheal airway cannula in the aperture of the Calibration Analyzer (Figure 3). Prior to every measurement the flow meter reading was checked. After calibration, the generated PACT of all devices in combination with the three different catheters was determined at oxygen flows of 6, 9, 12, and 15 l·min^{-1}, respectively. Five repetitive measurements were performed. The mean and the standard deviation of these five pressure values were calculated and used for further analysis.

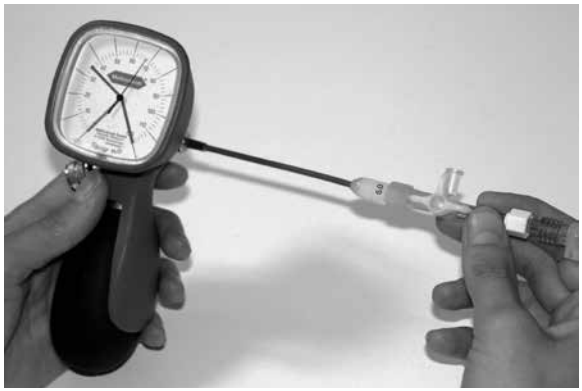

Figure 1 The pressure at the cannula tip can easily be checked with a conventional manometer for cuff pressure measurement.

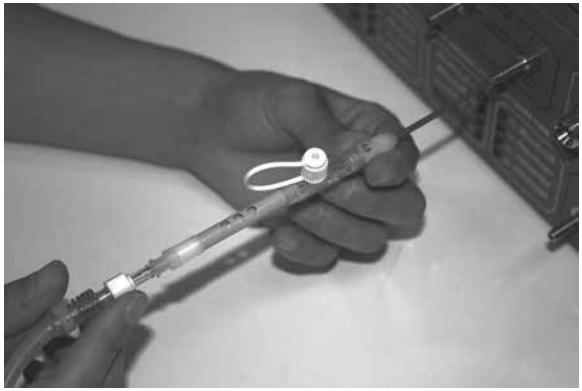

Figure 2 The oxygen flow modulator connected to a transtracheal catheter with all five openings released during measurements in the experimental setting. In the shadow the two openings at the bottom of the device can be seen.

Figure 3 Use of a conventional three-way stopcock (ID 2 mm) for emergency jet ventilation at a flow of 15 l·min^{-1} results with the side port open in a pressure at the catheter tip of about 70 cmH_2O.

Results

The generated PACT for each device in combination with the three catheters at the four different oxygen flows is listed in Table 1.

An oxygen flow of 15 l·min^{-1} applied to device A with the side port of the three-way stopcock (cross sectional area 3.14 mm^2) in the open position resulted in a pressure of 71.1 (±0.8) cmH_2O at the tip of the TTC (Figure 4). Although lowering the oxygen flow attenuated this pressure, a reduced oxygen flow of 9 l·min^{-1} still generated a PACT of 25.8 (±0.09) cmH_2O.

A larger cross sectional area of the side port as in device B (4.91 mm^2) and device C (7.07 mm^2) led to a better flow release and subsequently a lower PACT. In device B the pressure measured at the tip of the TTC at an oxygen flow of 15 l·min^{-1} was 35.6 (±0.04) cmH_2O. The PACT of device C in combination with the TTC was 17.6 (±0.04) cmH_2O.

	6 L·MIN^{-1}	9 L·MIN^{-1}	12 L·MIN^{-1}	15 L·MIN^{-1}
Device A (ID 2 mm)				
Ravussin 16 G	10.62 (± 0.04)	23.60 (± 0.10)	44.08 (± 0.16)	66.86 (± 0.68)
Ravussin 13 G	10.84 (± 0.05)	23.68 (± 0.04)	44.18 (± 0.04)	66.36 (± 0.05)
TTC 6 Fr	12.33 (± 0.09)	25.84 (± 0.09)	47.14 (± 0.11)	71.08 (± 0.76)
Device B (ID 2.5 mm)				
Ravussin 16 G	5.48 (± 0.04)	11.98 (± 0.04)	22.34 (± 0.05)	33.74 (± 0.05)
Ravussin 13 G	5.18 (± 0.04)	12.04 (± 0.05)	22.38 (± 0.04)	33.78 (± 0.04)
TTC 6 Fr	5.72 (± 0.11)	12.70 (± 0.00)	23.76 (± 0.05)	35.58 (± 0.04)
Device C (ID 3 mm)				
Ravussin 16 G	2.56 (± 0.05)	6.04 (± 0.05)	11.52 (± 0.04)	18.52 (± 0.08)
Ravussin 13 G	2.52 (± 0.04)	6.02 (± 0.04)	11.42 (± 0.04)	18.16 (± 0.11)
TTC 6 Fr	2.74 (± 0.05)	6.18 (± 0.04)	11.44 (± 0.05)	17.56 (± 0.04)
OFM (1 hole open)				
Ravussin 16 G	1.06 (± 0.01)	2.40 (± 0.00)	4.44 (± 0.01)	7.00 (± 0.02)
Ravussin 13 G	1.07 (± 0.01)	2.40 (± 0.01)	4.43 (± 0.01)	6.81 (± 0.02)
TTC 6 Fr	1.10 (± 0.01)	2.50 (± 0.01)	4.86 (± 0.02)	6.79 (± 0.05)
OFM (5 holes open)				
Ravussin 16 G	0.50 (± 0.01)	1.15 (± 0.01)	2.12 (± 0.01)	3.38 (± 0.01)
Ravussin 13 G	0.49 (± 0.00)	1.14 (± 0.00)	2.09 (± 0.01)	3.29 (± 0.00)
TTC 6 Fr	0.74 (± 0.02)	1.58 (± 0.01)	3.02 (± 0.02)	4.40 (± 0.02)

Table 1 Pressure measured at the tip of a 16 G and 13 G Ravussin needle and a 6 Fr transtracheal catheter in cmH_2O (mean ± standard deviation) at different oxygen flows.

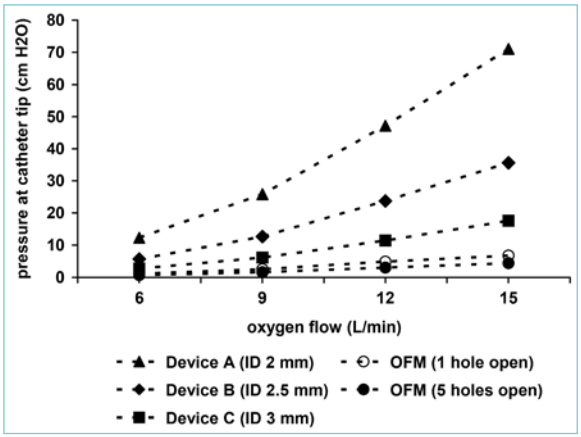

Figure 4 Pressure measured at the tip of a 16 G and 13 G Ravussin needle and a 6 Fr transtracheal catheter using three self-assembled devices consisting of a three-way stopcock with different inner diameters (device A, B, and C) and the oxygen flow modulator.

Release of one 4 mm opening (cross sectional area 12.56 mm^2) of the OFM at a flow of 15 $l \cdot min^{-1}$ resulted in a PACT of 6.8 (±0.05) cmH_2O and with all side holes open (total cross sectional area 62.80 mm^2) the pressure fell to 4.4 (±0.02) cmH_2O.

As could be expected from the static situation the pressure measurements with both the 16 G and 13 G Ravussin needle did not differ in a clinically relevant way from the PACT of the jet devices in combination with the TTC.

Discussion

The present study shows that the use of a three-way stopcock as a device to control the oxygen flow during emergency jet ventilation has a potentially dangerous drawback. Connecting a high-pressure oxygen flow to a conventional three-way stopcock with a released side port results in a high PACT, which in case of a completely obstructed upper airway will inevitably lead to hazardous levels of PEEP.

Jet ventilation should never be used if the egress of gas is not secured. In an emergency situation one can never be sure whether an obstructed upper airway will open up after initiation of TTJV or will stay blocked. It is mandatory that when using TTJV, the flow coming from the oxygen source either is stopped or adequately released through the side port of the emergency jet device during the expiration phase. In contrast to devices that allow a complete stop of the oxygen flow (e.g. the Manujet®; VBM Medizintechnik GmbH, Sulz, Germany), a three-way stopcock can only act as a 'flow splitter'.

Inadequate flow release via the open side port of the three-way stopcock causes a relevant gas flow to the patient. The PACT resulting from this flow to the patient for a given 'flow splitter' jet device is determined by the set flow rate and the resistance of the open side port of the three-way stopcock (essentially defined by its inner diameter) whereas the resistance of the transtracheal cannula (defined by its inner diameter and length) does not influence the PACT in a static situation as in our setting.

The present study reveals that high PACT in jet devices made of a three-way stopcock can be avoided by reducing the oxygen flow rate to 6 $l \cdot min^{-1}$. However, Bould et al. recently showed that in adults a flow rate of at least 15 $l \cdot min^{-1}$ was necessary to achieve adequate flow and pressure for low-frequency jet ventilation using a three-way stopcock [4]. Thus, although a reduced flow rate will minimize the risk of hazardous levels of PEEP, ventilation may become inefficient.

The flow and pressure release in a 'flow splitter' jet device is proportionally related to the cross-sectional area and length of its side port or side holes. The results of the

present study show that only a jet device having at least a 4 mm side port (like the OFM with one side hole open) can assure adequate flow release when connected to oxygen flows up to 15 $l \cdot min^{-1}$.

Our study has several limitations. Although the stability of the model is confirmed by the low variability between repeated measurements, we appreciate the limitations of applying results from this static model of complete upper airway obstruction to clinical practice. In the individual patient airway patency is variable. Due to the positive intrapulmonary pressure resulting from TTJV, an obstructed upper airway may open up thereby allowing the egress of gas. However, in up to 14% of the 'cannot intubate, cannot ventilate' (CICV) crises the upper airway remains obstructed and exhalation is compromised due to the distorted anatomy, oedema, or laryngospasm [9]. Another limitation is that this is not a clinical study. Only the PACT of the tested devices, but not the resulting PEEP, was measured in a laboratory setting. Nevertheless, in a completely obstructed upper airway PEEP will approach the PACT at equilibration.

High levels of PEEP have been shown to produce barotrauma [7] and to be detrimental to haemodynamics [8]. Increased intrathoracic pressure can decrease venous return and restrict cardiac filling, which may result in reduced cardiac output and hypotension. In a controlled trial of graded airway obstruction in dogs with 45 psi inflation pressure through a 13 G catheter, tracheal pressures of 24 cmH_2O were already associated with decreasing blood pressure and increased central venous pressure [10].

Because of the small size of the cricothyroid space a surgical cricothyroidotomy should not be attempted in children under the age of 5 years [11]. A needle cricothyroidotomy, however, is considered to be an option in emergency situations even in neonates, provided the landmarks can be correctly identified and the procedure is converted to a tracheostomy as soon as possible [12]. In elective surgical cases complications with the use of jet ventilation are well known [13]. Due to the narrow upper airway children are more prone to air trapping and their smaller lung volumes increase the risk of subsequent barotrauma following injection of oxygen. The results of our study unmask an additional, underestimated risk of self-assembled jet devices: By merely connecting these to a high-pressure oxygen source set at a continuous oxygen flow of more than 9 $l \cdot min^{-1}$ dangerously high airway pressures are inevitable in the event of upper airway obstruction. This automatism will be disastrous in children even quicker.

Although a CICV situation is very rare, every anaesthetist must be prepared for this emergency. A delay of even a few seconds can contribute to increased morbidity and mortality. Therefore, an emergency device should be preassembled, readily applicable and easy to handle. Unintentional closure of the side port of a self-assembled jet device can lead to severe barotrauma in only a few seconds. As a safety feature the closure of all five openings of the OFM and subsequent high gas flow to the patient is only achievable by an intentional digital manoeuver.

In a true clinical emergency one can only speculate whether the airway of the patient opens up at a higher airway pressure. Therefore, it is crucial that any device employed in a CICV situation is able to provide effective flow release and pressure control. This avoids high PACT and the subsequent risk of high PEEP in an obstructed upper airway. Small differences in physical characteristics between emergency jet devices can have huge clinical consequences.

Generally, self-assembled devices have not been tested thoroughly. Although they may resemble dedicated systems in many situations, they can carry intrinsic weaknesses (e.g.

not providing enough flow or pressure) and risks (e.g. creating too much flow or pressure) depending upon the technical environment and the kind of patient they are used in. Of the tested devices, only the OFM ensures sufficient flow and pressure release. Based on our findings, the self-assembled jet devices studied should not be used in clinical practice.

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Chapter 3

Important safety feature of a high-pressure ventilation device

A bench study of two self-assembled jet devices and the Oxygen Flow Modulator in a simulated upper airway obstruction

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Summary

In managing an obstructed upper airway, an emergency transtracheal ventilation device needs to function as a bidirectional airway, allowing both insufflation of oxygen and egress of gas. The aim of the present study was to determine 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. For each device the effective pressures at the catheter's tip during the expiratory phase and the achievable minute volumes were determined in a laboratory set-up. Using the three-way stopcock based jet devices, changing the connection position of the transtracheal catheter from the in-line port to the side port of the three-way stopcock resulted in a decrease of expiratory pressure at the catheter's tip from a dangerous mean (SD) of 71.1 (0.08) cmH_2O to -14.71 (0.05) cmH_2O. Yet this negative expiratory pressure did not facilitate the egress of gas. All devices tested impeded the expiratory outflow and hence decreased the achievable minute volume. This decrease in minute volume was smallest with the Oxygen Flow Modulator.

Introduction

Cricothyroidotomy is one of the last options to restore oxygenation while managing a 'cannot intubate, cannot ventilate' situation and should be performed without delay [1, 2]. Introduction of a small-bore catheter or cannula through the cricothyroid membrane is a simple, quick and relatively safe technique but controversy exists on how best to provide effective oxygenation and ventilation [3–6].

Due to the high flow resistance of a small lumen transtracheal catheter or cannula, a high-pressure oxygen source is needed to ensure adequate oxygen insufflation. Several self-assembled devices have been proposed when an automated or hand-triggered jet injector is not available. In current anaesthesia textbooks [7] and in recent literature [8, 9] a three-way stopcock connected in-line to a transtracheal catheter and non-compliant oxygen tubing is recommended as an emergency ventilation system.

Connected to an oxygen flow meter set at 15 $l \cdot min^{-1}$, this self-assembled device creates an adequate jet injection when the side port of the three-way stopcock is occluded [9], resulting in efficient ventilation in a small pig model [8].

However, in-between jet injections, inadequate pressure and flow release through the open side port of this device results in a continuous flow of oxygen to the patient [10]. In a patient with an obstructed upper airway, merely connecting such a device attached to an oxygen flow of 15 $l \cdot min^{-1}$ can cause a dangerously high intrathoracic pressure [11].

In principle, due to its geometry a three-way stopcock can behave like a Venturi device. Therefore, one may speculate that if the transtracheal catheter is not connected in-line to the three-way stopcock and the oxygen tubing, as is generally suggested [7–9], but instead to its side port, the oxygen flow through the end port of the three-way stopcock will create a negative pressure at the side port and thus at the tip of the catheter.

Our primary hypothesis was that changing the position of the transtracheal catheter in relation to the oxygen flow results in a negative expiratory pressure. This would transform the adapted self-assembled device into a safer option for transtracheal oxygenation with regard to flow and pressure release during the expiratory phase.

Furthermore, the generated negative pressure may support expiration. In a completely obstructed upper airway, devices providing a Venturi-assisted expiration can be expected to achieve a higher minute volume than is known for flow splitter devices, such as the Oxygen

Flow Modulator (OFM; Cook Medical, Bloomington, IN, USA), a commercially available emergency tool for transtracheal oxygenation [12]. We tested these two hypotheses in vitro in a mechanical lung model and compared two self-made devices made from standard three-way stopcocks to the OFM.

Material and methods

Part 1

In the first part of the study the effective 'Pressure At the Catheter's Tip' (PACT) during the expiratory phase was measured at different oxygen flows. Device A consisted of a 2-mm ID standard three-way stopcock (Discofix® C, B. Braun Melsungen AG, Melsungen, Germany) connected in-line to a 75 mm long, 2 mm ID transtracheal airway catheter (Cook Medical) and a noncompliant oxygen tubing (Fig. 1) as previously described [7–9]. In device B the transtracheal airway catheter was not connected in-line to the three-way

stopcock as in device A, but to its side port (Fig. 2). The third device tested, the Oxygen Flow Modulator consists of a short, non-compliant tubing having five openings located at opposite sites with a diameter of 4 mm each and a distal Luer lock connector (Fig. 3), to which the transtracheal catheter was attached.

All devices were connected with 4-mm oxygen tubing to a calibrated, pressure-compensated oxygen flow meter (Dräger Medical AG & Co. KG, Lübeck, Germany) plugged into a wall outlet delivering oxygen at a maximum pressure of 5 bar (±73 psi).

Figure 1 Device A: a 2-mm ID standard three-way stopcock connected in-line to the 2-mm ID transtracheal catheter. The transtracheal catheter is tightly fitted into the orifice for low range positive pressure measurement of the monitor.

The generated PACTs of devices A and B and the OFM, with the side port / holes open, were measured at oxygen flows of 6, 9, 12 and 15 $l \cdot min^{-1}$, respectively.

Pressure measurements were obtained with the Calibration Analyzer series RT-200 pressure and flow monitor (Timeter Instruments Corporation, St Louis, MO, USA). In order to prevent gas leakage, care was taken to keep a tight fit of the transtracheal catheter in the designated orifice of the Calibration Analyzer (Figs 1–3), assuring correct pressure measurements in a static 'no flow' situation. Before every measurement the flow meter reading was checked. Four measurements were performed at each flow rate.

Part 2

The achievable minute volumes of device B and the OFM in simulated upper airway obstruction were determined using an LS800 lung simulator (Dräger Medical AG & Co. KG) set at different compliances (100, 50, 30 and 10 $ml \cdot cmH_2O^{-1}$) and resistances (2, 8 and 32 $cmH_2O \cdot l^{-1} \cdot s^{-1}$), representing healthy and compromised lungs, with the transtracheal catheter tightly fitted in the proximal tube orifice of the mechanical lung.

The time for insufflation of 1000 ml of oxygen by occluding the in-line port of device B (thereby redirecting the flow of oxygen through its side port) and by complete closure of all five openings of the OFM, and the time needed for backflow of this volume through the transtracheal catheter and the attached devices were measured at oxygen flows of 12 and 15 $l \cdot min^{-1}$. In addition, the inspiration time with the oxygen tubing directly connected to the transtracheal catheter and the expiration time through the transtracheal catheter, without any device connected to it, were also determined.

Four repeat tests were performed and achievable minute volumes and inspiration : expiration ratios (I:E ratio) were calculated.

Statistical analysis

Statistical analysis was performed using version 10.0 of SPSS for Windows software package (SPSS Inc., Chicago, IL, USA). Linear regression analysis was performed with expiration time as the dependent variable and pulmonary settings, oxygen flow rates, and devices as independent variables to determine the correlation of different pulmonary settings, oxygen flow, and expiration time in device B and the OFM. A p value of < 0.05 was considered to be statistically significant.

Figure 2 Device B: a 2-mm ID standard three-way stopcock connected to the 2-mm ID transtracheal catheter via the side port. Note that the transtracheal catheter is put into the orifice for low range negative pressure measurement, thus the value indicates a negative pressure.

Figure 3 The Oxygen Flow Modulator connected to the 2-mm ID transtracheal catheter with all five openings released during measurements in the first part of the experiments. In the shadow the two openings at the reverse side of the device can be seen.

Results

Part 1

An oxygen flow of 15 l·min^{-1} applied to device A with the side port of the three-way stopcock open resulted in a mean (SD) pressure of 71.1 (0.8) cmH_2O at the tip of the transtracheal catheter. A reduced oxygen flow of 9 l·min^{-1} still generated a PACT of 25.8 (0.08) cmH_2O (Fig. 4), identical to measurements previously reported [11].

Attachment of device B to a continuous flow of oxygen resulted in a negative PACT. This pressure was inversely proportional to the oxygen flow rate. At an oxygen flow of 15 l·min^{-1} the PACT was -14.71 (0.05) cmH_2O and this fell to -1.75 (0.03) cmH_2O at a flow rate of 6 l·min^{-1}.

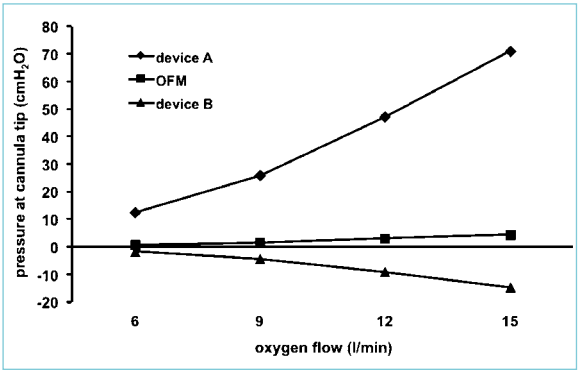

Figure 4 Pressures measured at the tip of the 2-mm ID transtracheal catheter with different oxygen flows in device A (consisting of a 2-mm ID standard three-way stopcock connected in-line to the transtracheal catheter), device B (the transtracheal catheter connected to the side port of the 2-mm ID standard three-way stopcock) and the Oxygen Flow Modulator with all five holes open.

COMPLIANCE (ml·cmH_2O^{-1})			100		50		30		30		30		10	
RESISTANCE (cmH_2O·L^{-1}·S^{-1})			2		2		2		8		32		32	
12 l·min^{-1} oxygen	no device	IT (s)	4.95	(0.06)	5.13	(0.06)	5.40	(0.1)	5.38	(0.06)	5.35	(0.04)	6.64	(0.12)
		ET (s)	13.39	(0.03)	9.90	(0.1)	7.75	(0.09)	7.92	(0.12)	8.02	(0.06)	5.61	(0.23)
	device B	IT (s)	4.99	(0.05)	5.15	(0.06)	5.43	(0.12)	5.37	(0.07)	5.34	(0.05)	6.56	(0.10)
		ET (s)	23.91	(0.11)	19.06	(0.04)	15.22	(0.07)	15.47	(0.08)	15.42	(0.04)	10.12	(0.03)
	OFM	IT (s)	4.91	(0.05)	5.11	(0.05)	5.37	(0.04)	5.40	(0.04)	5.36	(0.01)	6.72	(0.08)
		ET (s)	19.78	(0.09)	14.00	(0.1)	10.60	(0.06)	10.67	(0.06)	10.70	(0.05)	6.94	(0.04)
15 l·min^{-1} oxygen	no device	IT (s)	3.94	(0.06)	4.07	(0.08)	4.25	(0.07)	4.26	(0.03)	4.25	(0.07)	5.24	(0.13)
		ET (s)	13.39	(0.03)	9.90	(0.1)	7.75	(0.09)	7.92	(0.12)	8.02	(0.06)	5.61	(0.23)
	device B	IT (s)	3.97	(0.07)	4.05	(0.11)	4.24	(0.09)	4.26	(0.04)	4.19	(0.04)	5.13	(0.07)
		ET (s)	22.78	(0.12)	18.75	(0.12)	15.71	(0.15)	15.71	(0.17)	15.65	(0.20)	10.63	(0.10)
	OFM	IT (s)	3.91	(0.01)	4.09	(0.03)	4.27	(0.03)	4.26	(0.01)	4.30	(0.01)	5.36	(0.03)
		ET (s)	21.83	(0.11)	14.33	(0.11)	10.85	(0.06)	10.81	(0.06)	11.09	(0.07)	7.05	(0.09)

Table 1 Inspiration times (IT) of 1000 ml oxygen and egress (ET, expiration time) of the same volume through the 2 mm ID transtracheal catheter from the lung simulator in simulated upper airway obstruction without any device connected to the transtracheal catheter or with device B or the Oxygen Flow Modulator (OFM) attached at oxygen flows of 12 or 15 l·min^{-1}, respectively. Values are mean (SD).

Connected to the OFM with all five holes open an oxygen flow of 15 l·min^{-1} resulted in a PACT of 4.4 (0.02) cmH_2O, which is identical to earlier findings [11].

Part 2

At the highest compliance (100 ml·cmH_2O^{-1}) and the lowest resistance (2 cmH_2O·l^{-1}·s^{-1}) tested, the egress of 1000 ml of oxygen through the transtracheal catheter without any device connected to it took 13.39 (0.03)s (Table 1). The calculated minute volume at an insufflation flow rate of 15 l·min^{-1} was thus 3.46 l·min^{-1}. Decreasing compliance increased the calculated minute volume to a maximum of 5.59 l·min^{-1} (Table 2).

Connecting device B to the transtracheal catheter resulted in slower expiration and therefore in a decrease of the calculated minute volume depending on the compliances, resistances, and flow rates set. At a compliance of 10 ml·cmH_2O^{-1} and a resistance of 32 cmH_2O·l^{-1}·s^{-1} the maximally achievable minute volume with device B was 3.81 l·min^{-1}.

Attachment of the OFM to the transtracheal catheter also hindered the egress of gas and increased the expiration

COMPLIANCE (ML·CMH_2O^{-1})				100	50	30	30	30	10
RESISTANCE (CMH_2O·L^{-1}·S^{-1})				2	2	2	8	32	32
12 l·min-1 oxygen	no device	MV	(l·min^{-1})	3.27	3.99	4.55	4.52	4.49	4.93
		I/E-ratio		1/2.68	1/1.92	1/1.43	1/1.48	1/1.50	1/0.85
	device B	MV	(l·min^{-1})	2.08	2.48	2.91	2.88	2.89	3.60
		MV-difference	(l·min^{-1})	-1.19	-1.51	-1.65	-1.64	-1.60	-1.33
		I/E-ratio		1/4.79	1/3.70	1/2.80	1/2.88	1/2.89	1/1.54
	OFM	MV	(l·min^{-1})	2.43	3.14	3.76	3.73	3.74	4.39
		MV-difference	(l·min^{-1})	-0.85	-0.86	-0.81	-0.77	-0.75	-0.47
		I/E-ratio		1/4.03	1/2.74	1/1.97	1/1.98	1/2.00	1/1.03
15 l·min-1 oxygen	no device	MV	(l·min^{-1})	3.46	4.30	5.00	4.93	4.92	5.59
		I/E-ratio		1/3.37	1/2.44	1/1.83	1/1.86	1/1.91	1/1.09
	device B	MV	(l·min^{-1})	2.24	2.63	3.01	3.01	3.02	3.81
		MV-difference	(l·min^{-1})	-1.21	-1.67	-2.00	-1.92	-1.89	-1.78
		I/E-ratio		1/5.73	1/4.63	1/3.71	1/3.69	1/3.73	1/2.07
	OFM	MV	(l·min^{-1})	2.33	3.24	3.97	3.98	3.90	4.84
		MV-difference	(l·min^{-1})	-1.14	-1.05	-1.02	-0.95	-0.97	-0.64
		I/E-ratio		1/5.58	1/3.53	1/2.54	1/2.54	1/2.58	1/1.31

Table 2 Calculated achievable minute volumes (MV) and inspiration:expiration ratios (I:E ratios) based on the time needed for insufflation of 1000 ml oxygen and egress of the same volume through the 2-mm ID transtracheal catheter without any device connected to it or with device B or the Oxygen Flow Modulator (OFM) attached at oxygen flows of 12 or 15 l·min^{-1}, respectively.

time. However, linear regression modelling showed this increase to be significantly lower compared with device B ($p < 0.001$). Subsequently, the achievable minute volume with the OFM was higher and a maximal minute volume of 4.84 $l \cdot min^{-1}$ was calculated (Table 2).

Discussion

In case of an obstructed airway the emergency ventilation technique should ideally act as a bidirectional airway, so that both the delivery of oxygen to the lungs and the egress of respiratory gas can take place via the same lumen. A bidirectional airway requires the backpressure of any ventilation system to be sufficiently low to ensure the egress of gas is not compromised.

As a small lumen catheter or cannula has a high flow resistance, a high driving pressure is needed to achieve adequate gas flow [9, 13, 14]. Our data show that device A and the OFM (so-called flow splitters) will never ensure complete flow and pressure release in between jet injections. Inevitably, this results in a continuous oxygen flow to the patient. Only flow splitters that ensure a low expiratory pressure at the catheter tip (e.g. the OFM) will allow slow exhalation through the transtracheal catheter or cannula [10, 11]. In the first part of the study, high pressures at the tip of the transtracheal catheter during the expiratory phase were measured when using device A. This makes device A an unsuitable and even potentially dangerous device in an obstructed upper airway [15, 16]. We therefore did not test device A further in the second part of our study.

Changing the connecting position of the transtracheal catheter on the three-way stopcock from the in-line port to the side port (device B) resulted, by the Venturi effect, in a slightly negative pressure at the catheter's tip. This improves the safety of the self-assembled device B compared to device A.

In contrast to devices that fully block the egress of gas through the catheter during the expiratory phase, such as device A or jet ventilators (e.g. Sander's injector or Manujet), both device B and the OFM can act as a bidirectional airway. As the driving pressure during the expiration is mainly determined by the elasticity of the chest wall, the lung, and the intra-abdominal pressure, only slow egress of gas can be expected via small-bore catheters. The time necessary for the egress of 1000 ml of oxygen via a catheter with an internal diameter of 2 mm was > 13 s in case of high compliance, whereas a low compliance assisted expiration considerably.

The concept of expiratory ventilation assistance by suction has already been proven to be effective, also in an obstructed upper airway [17, 18]. However, despite the negative pressure at the tip of device B in a static setting, passive backflow through the transtracheal catheter without any ventilation system connected to it was still quicker, meaning that device B impedes the egress of gas in a dynamic situation instead of supporting expiration.

The apparent explanation is a relatively high inner flow resistance of device B, an effect that is stronger than the expiratory support by negative pressure. All devices tested impeded the expiratory outflow and hence the achievable minute volume. Repetitively connecting and disconnecting oxygen tubing and transtracheal catheter resulted in the highest calculated minute volume in every simulated situation. However, in clinical emergencies this is impractical. With regard to the risk of dislodging the transtracheal catheter, a continuously connected ventilation system is preferable, even though the egress of gas via the catheter is com-

promised. The decrease in minute volume was smallest with the OFM. At a compliance of 50 ml·cmH_2O^{-1} a minute volume of 3.24 l·min^{-1} could be achieved with the OFM. Although hypercapnia seems inevitable in this situation, even limited minute ventilation will increase the oxygen content of the lungs and may (slowly) re-establish adequate oxygenation of the patient.

As demonstrated in this study small differences in physical characteristics between emergency jet devices can have huge clinical consequences. Self-assembled devices have mostly not been thoroughly tested (in relation to their physical properties) and although they may resemble working systems in many situations, potential risks may not be immediately apparent. With a simple modification of current proposals [7–9], three-way stopcock based jet devices for emergency jet ventilation can be made safer.

However, regardless of the negative pressure that can be created at the side port by an in-line flow of oxygen through a three-way stopcock, the efficiency of such self-made devices is disappointing compared with the OFM.

Conflicts of interest and acknowledgements

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Chapter 4

The introduction of the concept of Expiratory Ventilation Assistance

Achieving an adequate minute volume through a 2 mm transtracheal catheter in a simulated upper airway obstruction using a modified industrial ejector

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Summary

Needle cricothyrotomy and subsequent transtracheal jet ventilation (TTJV) is one of the last options to restore oxygenation while managing an airway emergency. However, in cases of complete upper airway obstruction, conventional TTJV is ineffective and dangerous. We transformed a small, industrial ejector into a simple, manual ventilator providing expiratory ventilation assistance (EVA).

An ejector pump was modified to allow both insufflation of oxygen and jet- assisted expiration through an attached 75 mm long transtracheal catheter (TTC) with an inner diameter (ID) of 2 mm by alternately occluding and releasing the gas outlet of the ejector pump. In a lung simulator, the modified ejector pump was tested at different compliances and resistances. Inspiration and expiration times were measured and achievable minute volumes (MVs) were calculated to determine the effect of EVA.

The modified ejector pump shortened the expiration time and an MV up to 6.6 $l \cdot min^{-1}$ could be achieved through a 2 mm ID TTC in a simulated obstructed airway.

The principle of ejector-based EVA seems promising and deserves further evaluation.

Introduction

Needle cricothyrotomy is often suggested as a last option to restore oxygenation while managing an airway emergency. The disadvantage of a small lumen cannula, however, is its high resistance to gas flow [1] and hence the need for a high driving pressure to achieve adequate flow. Several types of high-pressure jet ventilators, able to generate an adequate inspiratory flow through a small lumen cannula, are available: for example, the manual Sanders injector or an automated high-frequency jet ventilator. In these ventilation devices, a one-way mechanical valve is incorporated, so only injection of oxygen through the cannula is assured and a patent upper airway is mandatory for the egress of gas. When the upper airway is obstructed, conventional high-pressure jet ventilation results in gas trapping as insufflated oxygen is unable to escape during the expiratory phase, leading to increased end-expiratory intrathoracic pressures, failure to further generate tidal volumes [2], lung damage by over-distension, and haemodynamic instability [3, 4]

In the case of complete upper airway obstruction, an ideal emergency ventilation system would act as a bidirectional airway, so both the injection of oxygen and the egress of gas can take place through the same lumen [5]. The sole driving force for the egress of gas is the respiratory system's compliance, which results from the elasticity of the lungs and the chest wall. Therefore, passive outflow through a small lumen catheter is limited [6].

Dunlap and Oregon [7] in 1978 suggested applying subatmospheric pressures to augment expiration. Several suction devices to support expiration have been introduced since then, but none has found its way into clinical practice, probably because of the complicated technical set-up [8, 9].

Bernoulli's [10] principle states that for an inviscid flow of a non-compressible (or, with restrictions, a compressible) fluid, an increase in velocity at a constriction in a tube leads to an increase in dynamic pressure (and thus kinetic energy) and a corresponding decrease in static pressure (and potential energy), obeying the first law of thermodynamics (conservation of energy). An industrial ejector is a multi-purpose device able to create subatmospheric pressure based on Bernoulli's principle. Comparable with a Venturi nozzle, the driving gas flowing through an ejector entrains gas (e.g. ambient air) through a side port [11]. Application of this principle might facilitate expiration through a small lumen catheter.

We adapted a small industrial ejector into a simple, manual ventilation device providing expiratory ventilation assistance (EVA). The aim of this study was to test the capability of this modified ejector to aid in achieving adequate minute ventilation through a 2 mm ID transtracheal catheter (TTC) in an artificial lung with a completely obstructed upper airway.

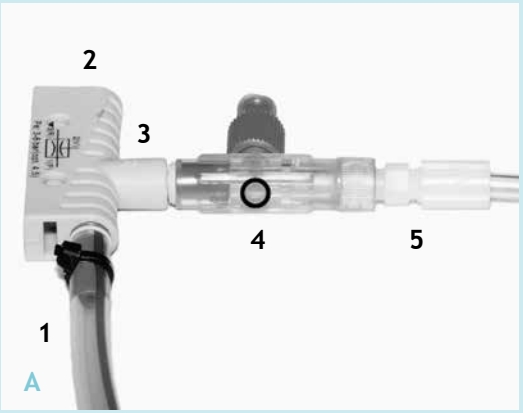
Methods

An industrial ejector (SBP 07, J. Schmalz GmbH, Glatten, Germany) with a 0.7 mm ID jet orifice (Fig. 1), weighing 7.5 g, was modified to allow both insufflation of oxygen and assisted expiration (Fig. 2A and B). The silencer was removed in order to be able to redirect the flow by occluding the outlet of the ejector. To control the flow to the lung simulator, a T-piece with an extra 4 mm side hole was attached as a bypass and functioned as an on-off switch. In a pre-test bench study, it was shown that with the side hole open, sufficient flow and pressure release occurs and the device thereby is functionally switched off, with no relevant flows and pres-

sures acting in the direction of the artificial lung. However, if the side hole is closed, the ejector becomes 'active'. By then simply occluding and releasing the gas outlet of the ejector, either an oxygen flow can be directed to the lung simulator or a subatmospheric pressure can be created (by the Bernoulli principle) to assist expiration. The modified ejector was connected to a pressure-compensated oxygen flow meter (Dräger Medical AG & Co. KG, Lübeck, Germany) by 4 mm ID standard silicone tubing.

In an LS800 lung simulator (Dräger Medical AG & Co. KG), the MV of the modified ejector through a 2 mm ID, 75 mm long TTC (Cook Medical, Bloomington, IN, USA) in a simulated obstructed upper airway was determined at dif-

Figure 1 An industrial ejector with a 0.7 mm ID jet orifice (SBP 07, J. Schmalz GmbH; length 45 mm without the silencer, weight 7.5 g) was modified into an EVA device.



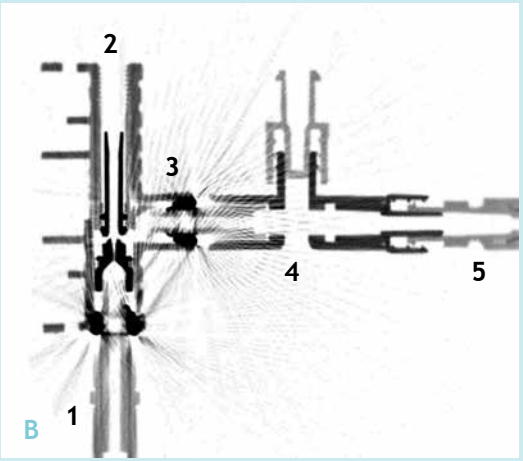


Figure 2 A The EVA device: the silicone oxygen tubing (1) is connected to the ejector's inlet. The silencer has been removed from the outlet (2) to allow closure by a finger for redirecting the flow to the side port (3). A T-piece (4) with an extra 4 mm side hole (shown by the black circle) is attached to the side port as a by-pass and functions as an on–off switch to control gas flow through the connecting tubing (5). The side port of the T-piece covered by a cap is intended for capnometry (not a part of this study). B Computed tomographic (CT) scan of the EVA device showing also the interior of the industrial ejector. The numbers indicate identical parts as in (A). The scatter in the CT scan is caused by the metal sealings at the inlet and the side port of the ejector.

ferent compliances (100, 50, 30, and 10 ml·cmH_2O^{-1}) and resistances (2, 8, and 32 cmH_2O·l^{-1}·s^{-1}), representing healthy and compromised lungs. The catheter was tightly fitted in the proximal tube orifice of the lung simulator, ensuring that the entire gas flow into and out of the artificial lung was directed through the catheter. The time required for insufflation of 1000 ml of oxygen and the time needed for passive backflow of this volume through the catheter and for assisted expiration were measured at oxygen flows of 12 and 15 l·min^{-1}. Timings were recorded by a second operator using a digital stopwatch while observing the bellows' readings.

At a compliance of 100, 50, and 30 ml·cmH_2O^{-1}, only one bellow of the lung simulator was insufflated. Time measurement was started at a bellow volume of 500 ml and, during insufflation on the way to 2000 ml, stopped at 1500 ml. Owing to high-pressure build-up, both bellows of the lung simulator had to be used at a compliance of 10 ml·cmH_2O^{-1} to guarantee correct compliance. Using both bellows, 500 ml was taken as zero and 1000 ml as the endpoint for time measurement. The flow meter was calibrated before the experiments using the Calibration Analyzer series RT-200 pressure and flow monitor (Timeter Instruments Corporation, St Louis, MO, USA). The flow meter reading was checked before each measurement, each test was repeated four times, and minute volumes (MVs) and inspiration/expiration (I/E) ratios were then calculated.

COMPLIANCE (ML·CMH_2O^{-1})	100		50		30		30		30		10	
RESISTANCE (CMH_2O·L^{-1}·S^{-1})	2		2		2		8		32		32	
Flow 12 l·min^{-1}												
Insufflation time (s)	4.9	(0.04)	5.1	(0.07)	5.4	(0.04)	5.4	(0.03)	5.4	(0.09)	6.7	(0.06)
Passive backflow (s)	13.4	(0.03)	9.9	(0.1)	7.8	(0.09)	7.9	(0.12)	8.0	(0.06)	5.6	(0.23)
Assisted expiration (s)	5.6	(0.04)	5.6	(0.07)	5.8	(0.03)	5.7	(0.02)	5.7	(0.03)	6.3	(0.05)
Flow 15 l·min^{-1}												
Insufflation time (s)	4.0	(0.08)	4.1	(0.06)	4.3	(0.09)	4.3	(0.06)	4.2	(0.04)	5.4	(0.11)
Passive backflow (s)	13.4	(0.03)	9.9	(0.1)	7.8	(0.09)	7.9	(0.12)	8.0	(0.06)	5.6	(0.23)
Assisted expiration (s)	5.1	(0.08)	5.1	(0.02)	5.3	(0.03)	5.2	(0.05)	5.3	(0.05)	5.9	(0.08)

Table 1 Mean (SD) times needed for insufflation of 1000 ml oxygen at different compliances and resistances at a flow rate of 12 or 15 l·min^{-1} and for the same volume of oxygen to egress through a 2 mm ID TTC passively (passive backflow) or with EVA (assisted expiration).

Results

Data are presented as mean (SD). At a compliance of 100 ml·cmH_2O^{-1} and a resistance of 2 cmH_2O·l^{-1}·s^{-1}, the mean (SD) time needed for passive egress of 1000 ml oxygen through the TTC was 13.4 (0.03) s (Table 1). A decrease in lung compliance resulted in a faster passive backflow of gas through the TTC and the expiration time decreased to 7.8 (0.09) s at a compliance of 30 ml·cmH_2O^{-1}. An increase in resistance had almost no effect at this compliance. At a compliance of 50 ml·cmH_2O^{-1} and a resistance of 2 cmH_2O·l^{-1}·s^{-1} (representing the lungs of a healthy adult), the passive backflow of 1000 ml through the TTC took 9.9 (0.10) s. With assisted expiration using the modified ejector, this time was shortened to 5.6 (0.07) s at an oxygen flow of 12 l·min^{-1} and to 5.1 (0.02) s at 15 l·min^{-1}. This resulted in an increase in the calculated MV for this pulmonary setting from 4.0 to 5.6 l·min^{-1} at 12 l·min^{-1} oxygen flow and from 4.3 to 6.5 l·min^{-1} at 15 l·min^{-1} respectively (Table 2).

However, at a compliance of 10 ml·cmH_2O^{-1} and a resistance of 32 cmH_2O·l^{-1}·s^{-1}, the modified ejector prolonged the expiration time with 0.7 s at an oxygen flow of 12 l·min^{-1} and 0.3 s at 15 l·min^{-1} compared with passive expiration.

COMPLIANCE (ML·CMH_2O^{-1})	100	50	30	30	30	10
RESISTANCE (CMH_2O·L^{-1}·S^{-1})	2	2	2	8	32	32
Flow 12 l·min^{-1}						
MV (l·min^{-1}, passive backflow)	3.28	4.01	4.55	4.51	4.49	4.87
I/E-ratio (passive backflow)	1/2.72	1/1.95	1/1.43	1/1.47	1/1.50	1/0.84
MV (l·min^{-1}, assisted expiration)	5.73	5.60	5.37	5.42	5.43	4.60
I/E-ratio (assisted expiration)	1/1.13	1/1.11	1/1.06	1/1.05	1/1.06	1/0.94
Flow 15 l·min^{-1}						
MV (l·min^{-1}, passive backflow)	3.46	4.27	4.98	4.92	4.90	5.47
I/E-ratio (passive backflow)	1/3.37	1/2.39	1/1.81	1/1.85	1/1.89	1/1.04
MV (l·min^{-1}, assisted expiration)	6.64	6.46	6.24	6.34	6.33	5.32
I/E-ratio (assisted expiration)	1/1.27	1/1.24	1/1.24	1/1.22	1/1.24	1/1.10

Table 2 Mean calculated MV and I/E ratios achievable through a 2 mm ID TTC in a simulated obstructed upper airway by passive backflow and assisted expiration using the modified ejector connected to an oxygen flow of 12 or 15 l·min^{-1}.

Discussion

Cricothyroidotomy is one of the last options to restore oxygenation while managing a 'cannot intubate, cannot ventilate' (CICV) situation and should be performed without delay [12, 13]. Introduction of a small-bore catheter or cannula through the cricothyroid membrane is for most anaesthetists the first-choice infraglottic emergency technique [14] as it is simple, quick [15] and widely available. For ventilation through a small lumen catheter, a high-pressure ventilator is mandatory. In experienced hands, this ventilation technique has a low morbidity as long as the egress of gas is secured [16]. However, in a CICV situation, one can never be sure whether an obstructed upper airway will open up or will stay blocked after initiation of high-pressure jet ventilation. Several cases of barotrauma and circulatory collapse due to obstruction of the upper airway during jet ventilation have been reported [17-19] although the majority of barotraumas probably result from partial airway obstruction with overvigorous transtracheal jet ventilation combined with inadequate expiratory pause. The ideal ventilation system in this setting would act as a bidirectional airway, so both the delivery of oxygen to and the egress of gas from the lungs are controlled.

When an airway catheter is restricted below a critical diameter, exhalation time becomes rapidly prolonged [6]. In our study, the time needed for passive backflow of 1000 ml oxygen through the 2 mm ID TTC was 13.4 s at a compliance of 100 ml·cmH_2O^{-1}. One option to accelerate expiration when the upper airway is obstructed is to establish a separate egress pathway by the insertion of an additional transtracheal cannula (preferably large bore).

However, this is not always feasible. Alternatively, the egress of gas through a single, small-lumen catheter can be facilitated by applying suction. Several techniques to apply subatmospheric pressure have been proposed in the past. Dunlap and Oregon demonstrated the efficacy of a thumb-operated three-way valve (actually a simple T-piece) attached to a connector for piped oxygen [7]. Oxygen was insufflated at a rate of 800 ml·s^{-1} and respiratory gas could be withdrawn from the trachea at about 185 ml·s^{-1} (11.1 l·min^{-1}). Unfortunately, the oxygen consumption for suctioning was very high (almost 50 l·min^{-1}) and the oxygen flow was difficult to control: in both dogs and post-mortem humans s.c. emphysema was described. The computer-controlled pressurized injection/suction ventilation device equipped with separate, highly pressurized injection and suction tubings described by Schapera and colleagues [8] efficiently maintained pulmonary gas exchange in 25–35 kg dogs through a 2.5 mm ID, 45 cm long ventilating stylet for more than 15 min during a period of total occlusion of the airway except for the passage offered by the catheter. Adequate tidal volumes were also achieved by the 'total laryngeal bypass device', which had an inner cannula to provide high pressure oxygen insufflation and an outer cannula through which suction was applied throughout both inspiratory and expiratory phase [9].

However, none of the above-mentioned techniques and devices found its way into clinical practice, probably because of specific drawbacks and requirements (high oxygen demand, complex set-up, and/or bulky equipment).

Our modified ejector ventilator is portable and ready to use after simply connecting it to a pressure compensated flow meter set at an oxygen flow of 12–15 l·min^{-1}. In a simulated upper airway obstruction, an MV of up to 6.6 l·min^{-1} can be achieved through a 2 mm ID TTC over a broad range of different pulmonary conditions.

Furthermore, gas flow to and from the TTC can easily be controlled by the integrated on-off switch.

We appreciate the limitations of applying results from this simplified in vitro model into clinical practice. The effects of EVA on gas exchange, circulation, and lung tissue have not been studied. Additional in vivo experiments should elucidate this.

Small, industrial ejectors are designed to pick up and hold parts until these are, for example, dropped into feeders of automated assembly lines. These ejectors cannot be expected to work perfectly as a ventilator. As the data demonstrate, the modified ejector/ventilator works most effectively at high compliances. At lower compliances, expiratory assistance becomes less effective, and at a compliance of 10 $ml \cdot cmH_2O^{-1}$, the ejector does not support expiration, but even slightly prolongs the expiration time. Possible explanations are the build-up of high pressure (up to 100 mbar) in the artificial lung during the inspiratory phase in this extreme setting and a disturbed way of gas egress from the ejector caused by turbulent mixing of the jet flow with the gas pressed back into the ejector by low compliance during the expiratory phase. However, redesigning the ejector might solve this problem.

The principle of expiratory assistance during jet ventilation is not new, although different expressions have been used to describe the concept. The tested modified ejector is, however, the first device that is simple and portable, will work with an oxygen cylinder at flows of 12 to 15 $l \cdot min^{-1}$ and is capable of achieving an adequate MV through a 2 mm ID TTC even in the case of an obstructed upper airway. Nevertheless, improvement of the design seems to be required and further in vivo evaluation of the efficiency and safety of EVA is needed.

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Chapter 5

Optimizing Expiratory Ventilation Assistance

Ventilation through a small-bore catheter: optimizing expiratory ventilation assistance.

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Summary

Emergency ventilation through a small-bore transtracheal catheter can be life-saving in a 'cannot intubate, cannot ventilate' situation. Ejectors, capable of creating suction by the Bernoulli principle, have been proposed to facilitate expiration through small-bore catheters. In this bench study, we compared a novel, purpose-built ventilation ejector (DE 5) with a previously proposed, modified industrial ejector (SBP 07).

The generated insufflation pressures, suction pressures in static and dynamic situations, and also suction capacities and entrainment ratios of the SBP 07 and the DE 5 were determined. The DE 5 was also tested in a lung simulator with a simulated complete upper airway obstruction. Inspiratory and expiratory times through a transtracheal catheter were measured at various flow rates and achievable minute volumes were calculated.

In a static situation, the SBP 07 showed a more negative pressure build-up compared with the DE 5. However, in a dynamic situation, the DE 5 generated a more negative pressure, resulting in a higher suction capacity. Employment of the DE 5 at a flow rate of 18 $l \cdot min^{-1}$ allowed a minute volume through the transtracheal catheter of up to 8.27 $l \cdot min^{-1}$ at a compliance of 100 $ml \cdot cmH_2O^{-1}$. The efficiency of the DE 5 depended on the flow rate of the driving gas and the compliance of the lung simulator.

In laboratory tests, the DE 5 is an optimized ventilation ejector suitable for applying expiratory ventilation assistance. Further research may confirm the clinical applicability as a portable emergency ventilator for use with small-bore catheters.

Needle cricothyroidotomy with subsequent transtracheal jet ventilation is one of the last options to restore oxygenation in a 'cannot intubate, cannot ventilate' (CICV) situation [1]. One of the problems associated with jet ventilation is the difficulty in controlling expiration. Outflow of gas has to take place passively through the upper airway. In a CICV situation, one can never be sure whether an obstructed upper airway will open up or will stay blocked after initiation of high-pressure jet ventilation. Obstruction of the outflow tract, insufficient expiratory time, or both can result in air trapping with subsequent barotrauma and haemodynamic instability [2–4]. Oedema, laryngospasm, and the presence of surgical instruments have all been reported to compromise the outflow of gas [3, 5, 6].

Time needed for passive backflow of gas depends on the resistance of the outflow tract (determined by its diameter and length) and on the driving force (determined by the compliance of the respiratory system which results from the elasticity of the lungs and the chest wall). If the diameter of the natural or artificial airway is restricted below a critical point (4 mm usually being considered as the cut-off point), exhalation time is prolonged exponentially [7]. Air trapping becomes a real danger if the expiratory time in relation to the diameter and length of the outflow tract is too short [8, 9]. Changing the I:E ratio only provides a partial solution to the problem.

A bidirectional ventilatory system that requires only a small-bore airway catheter for both the delivery of oxygen to the lungs and the outflow of gas could completely solve the above-mentioned problems associated with jet ventilation. Application of jet flow generated suction has been proposed to facilitate expiration through large-bore [10] and small-bore paediatric tracheal tubes [11]. Although directly addressing the concern about using jet ventilation in the presence of airway obstruction, other ventilation concepts for adult patients applying suction to small-bore catheters have not found their way into clinical practice [12–14].

Recently, we described a modified industrial ejector (SBP 07) using expiratory ventilation assistance (EVA) based on the Bernoulli principle [15]. Although a minute volume of up to 6 $l \cdot min^{-1}$ could be achieved through a 75 mm long, 2 mm ID transtracheal catheter, this industrial ejector is not specified for ventilation but has been designed to create a maximum negative pressure to pick up and hold parts during industrial manufacturing processes. Therefore, we developed and tested in several bench studies a novel ejector-based ventilation device (DE 5) designed to provide an optimized entrainment effect for EVA [16].

The aims of this study were to compare the generated pressures, suction capacities, and entrainment ratios of the modified SBP 07 and the DE 5 and to determine the achievable minute volumes through a small-bore catheter in a simulated obstructed upper airway.

Methods

The modified SBP 07 (Figs 1A and 2A) has been described previously [15]. The modification of the original industrial device involved both removal of the silencer and connection of a modified T-piece as a flow control unit. The DE 5 consists of a specifically designed ejector with a 0.7 mm jet needle and an identical T-piece (Figs 1B and 2B). The driving gas, coming from a calibrated, pressure-compensated oxygen flow meter, is highly accelerated by being forced through the jet needle and creates a negative pressure downstream of this needle. This effect is based on the Bernoulli principle and results in entrainment of gas through the side port

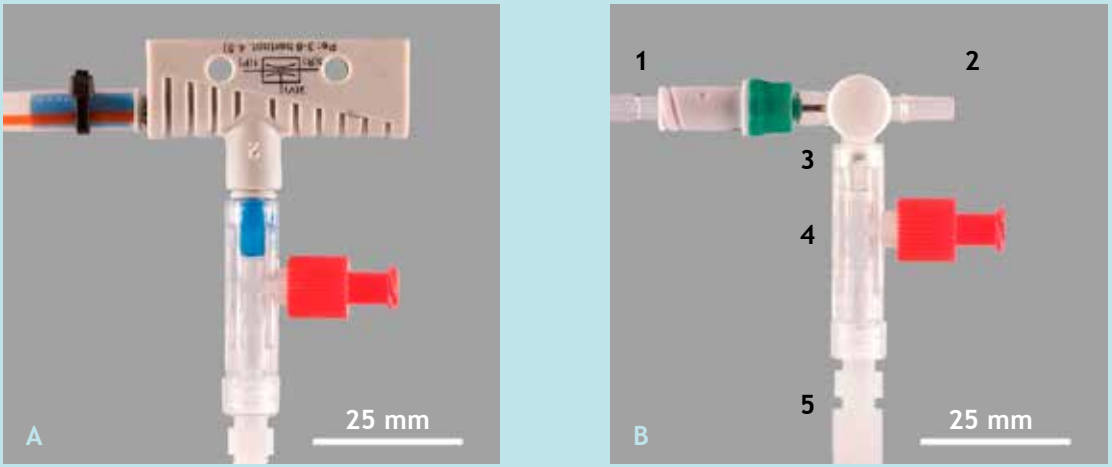

Figure 1 A The modified industrial SBP 07 as previously described [15]. Silicone oxygen tubing from a pressure-compensated flow meter is attached to the ejector's inlet. The silencer has been removed from the outlet to allow closure by a finger for redirecting the flow to the side port. A T-piece with an extra 4 mm side hole at the lateral surface (not visible in this picture) is attached to the side port as a bypass. This side hole functions as an on/off switch to control gas flow through the connecting tubing to the transtracheal catheter.
B The ventilationejector DE 5: silicone oxygen tubing from a pressure-compensated flow meter is connected to the ejector's inlet (1). Gas flow is directed through a 0.7 mm ID jet needle to the outlet (2). Closure of the outlet (jet/EVA switch) by the finger allows redirection of the flow to the side port (3). The T-piece with the extra 4 mm side hole (4) and the connecting tubing (5) are identical to those of the SBP 07.

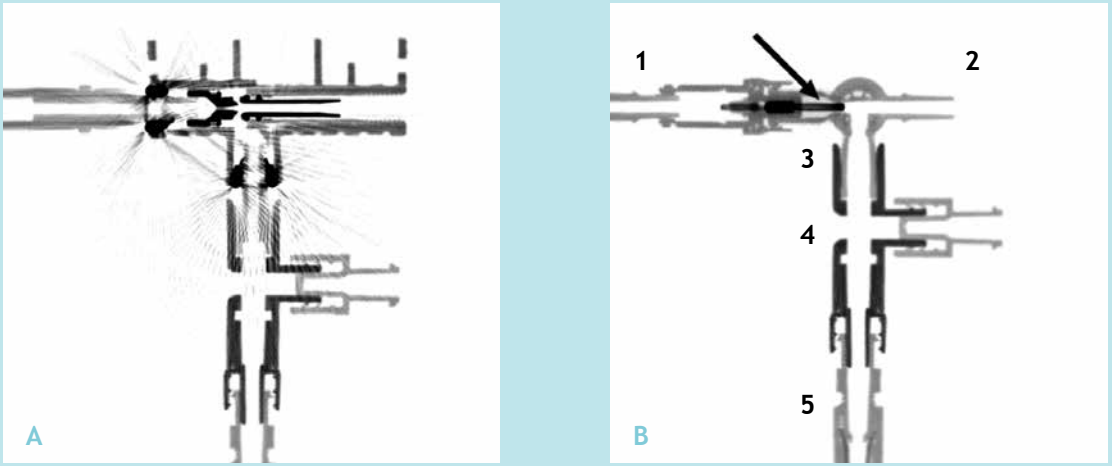

Figure 2 A CT scan of the modified SBP 07. The orientation is the same as in Figure 1A. The scatter is produced by metal parts of the SBP 07.
B CT scan of the DE 5. The orientation is the same and the numbers refer to identical structures as in Figure 1B. The outflow pipe with the jet/EVA switch (2) and the on/off switch (4) can clearly be identified. The arrow indicates the 0.7 mm ID jet needle.

(3 in Figs 1B and 2B). By simply occluding the outlet (jet/EVA switch; 2 in Figs 1B and 2B) of the ejector, the oxygen flow can be redirected to the transtracheal catheter (connected to 5 in Figs 1B and 2B).

To control the expiratory and inspiratory flows, a T-piece (part number 84048, Qosina, Edgewood, NY, USA) with an extra 4 mm side hole (on/off switch; 4 in Figs 1B and 2B) is attached to the side port of the ejector and functions as the flow control unit of the ventilation device.

In a pre-test bench study, it was shown that with the on/ off switch open, sufficient flow and pressure release is established and both the SBP 07 and the DE 5 thereby are functionally switched off, with no relevant flows and pressures acting downstream of the flow control unit. However, if the on/off switch is closed, the ejectors become active. By then alternately occluding and releasing the jet/EVA switch, either the oxygen flow is directed to the transtracheal catheter or a subatmospheric pressure is created to assist expiration (Fig. 3A and B).

Part 1: insufflation and suction pressures

In the first part of our study, the generated pressures of the modified SBP 07 and the DE 5 were studied. Both ejectors were connected to a calibrated, pressure-compensated flow meter (Dräger Medical AG & Co. KG, Lübeck, Germany) and attached to a transtracheal catheter (75 mm length, 2 mm ID; Cook Medical, Bloomington, IN, USA) by a 15 cm long, 3 mm ID connecting tubing including a distal T-piece (see Fig. S1 in the Supplementary material at British Journal of online).

At oxygen flows of 6, 9, 12, 15, and 18 $l \cdot min^{-1}$, the insufflation and suction pressures were measured at the distal T-piece, while simulating a static (no gas entrainment with the catheter tip closed) and a dynamic situation (continuous

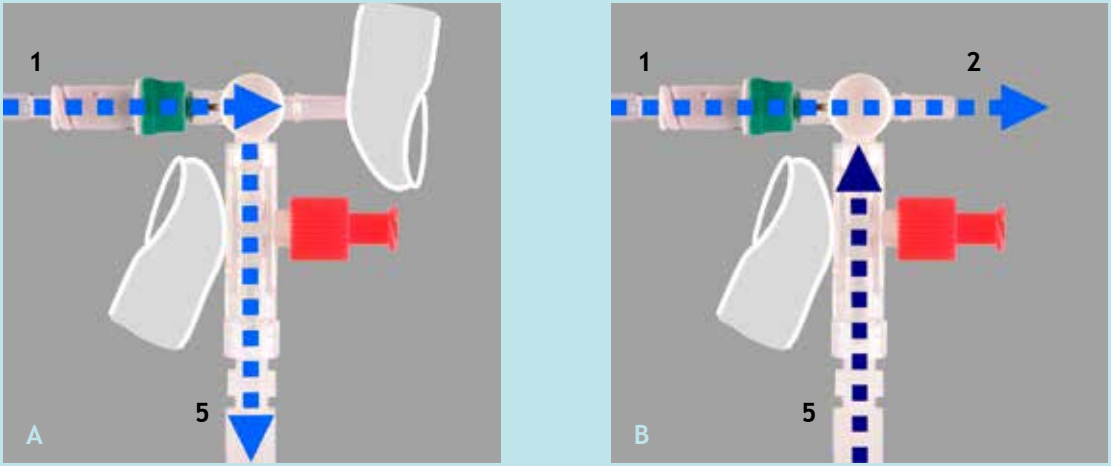

Figure 3 The DE 5 in two functional modes. A Jet insufflation: the on/off switch and the jet/EVA switch are closed by finger. Oxygen flows from the ejector's inlet (1) to the connecting tubing (5). B EVA: only the on/off switch is closed by finger. Oxygen flows from the ejector's inlet (1) to the outlet (2) entraining gas from the connecting tubing (5).

	FLOW ($L \cdot MIN^{-1}$)	PINSP (CMH_2O)	PSTAT (CMH_2O)	PDYN (CMH_2O)	SC ($L \cdot MIN^{-1}$)	ER
SBP 07	6	19.4 (0.24)	-53.8 (1.14)	- 9.8 (0.14)	4.1	0.68
	9	43.6 (0.38)	-196.1 (1.23)	-31.3 (0.21)	7.8	0.87
	12	75.4 (0.41)	-377.3 (0)	-51.0 (0.29)	10.1	0.84
	15	113.0 (0.32)	-540.4 (0)	-63.1 (0.14)	11.4	0.76
	18	148.8 (0.71)	-660.3 (5.1)	-70.4 (0.24)	12.5	0.69
DE 5	6	19.8 (0.39)	-70.6 (0.92)	-22.9 (0.43)	6.8	1.13
	9	43.7 (0.1)	-161.9 (0.54)	-49.0 (0.38)	10.2	1.13
	12	75.5 (0.41)	-263.5 (0.75)	-76.4 (0.34)	12.6	1.05
	15	110.9 (0.5)	-346.7 (0)	-94.7 (0.23)	14.3	0.95
	18	147.2 (2.06)	-400.2 (5.1)	-108.5 (0.19)	15.9	0.88

Table 1 Results of Part 1: insufflation and suction pressures and Part 2: suction capacities and entrainment ratios. Pinsp, Pstat, and Pdyn indicate pressures during inspiration and during expiration in a static situation (no gas entrainment with the catheter tip closed) and a dynamic situation (continuous gas entrainment with the catheter tip open to the atmosphere), respectively, using flow rates of 6–18 $l \cdot min^{-1}$. Data given as mean (SD). Suction capacity (SC) and entrainment ratio (ER¼entrained flow/driving flow) are calculated values.

gas entrainment with the catheter tip open to the atmosphere). Four repetitive pressure measurements were done using the Calibration Analyzer series RT-200 (Timeter Instrument Corporation, St Louis, MO, USA). Before each measurement, the flow meter reading was checked.

Part 2: suction capacities and entrainment ratios

The suction capacities and entrainment ratios (= entrained flow/driving flow) of both devices through the 75 mm long, 2 mm ID transtracheal catheter were determined at oxygen flows of 6, 9, 12, 15, and 18 $l \cdot min^{-1}$ by insufflation and desufflation of a common 35 litre plastic garbage bag (product number 136146, Albert Heijn, Zaandam, The Netherlands) as a closed ventilation model with an infinite compliance. Four repetitive trials were performed by insufflating the plastic bag for 1 min and measuring the time it took to completely empty the bag by suction.

Part 3: inspiratory and expiratory times and minute volumes

In the third part of the study, the efficacy of the DE 5 at different pulmonary compliances and resistances was tested in an LS800 lung simulator (Dräger Medical AG & Co. KG) with a simulated complete upper airway obstruction. The 75 mm long, 2 mm ID transtracheal catheter was tightly fitted in the proximal tube orifice of the lung simulator ensuring that the entire gas flow into and out of the bellows was guided through the catheter.

To determine minute volumes, the times required for insufflation of 1000 ml of oxygen and the times needed for passive backflow of this volume through the catheter and for assisted expiration using the DE 5 were measured as previously described [15]. Four repetitive tests were performed at different compliances (100, 50, 30, and 10 $ml \cdot cmH_2O^{-1}$), resistances (2 and 32 $cmH_2O \cdot l^{-1} \cdot s^{-1}$), and different oxygen flows (6, 9, 12, 15, and 18 $l \cdot min^{-1}$).

COMPLIANCE ($ML \cdot CMH_2O^{-1}$)	100		50		30		30		10	
RESISTANCE ($CMH_2O \cdot L^{-1} \cdot S^{-1}$)	2		2		2		32		32	
Inspiratory time (s)										
6 $l \cdot min^{-1}$	10.2	(0.03)	10.6	(0.09)	11.2	(0.04)	11.2	(0.08)	14.1	(0.12)
9 $l \cdot min^{-1}$	6.7	(0.05)	6.9	(0.04)	7.3	(0.03)	7.3	(0.03)	9.1	(0.30)
12 $l \cdot min^{-1}$	5.0	(0.05)	5.1	(0.07)	5.4	(0.02)	5.3	(0.09)	6.7	(0.08)
15 $l \cdot min^{-1}$	4.0	(0.06)	4.2	(0.03)	4.4	(0.11)	4.4	(0.05)	5.4	(0.04)
18 $l \cdot min^{-1}$	3.4	(0.03)	3.6	(0.02)	3.8	(0.04)	3.7	(0.04)	4.6	(0.04)
Expiratory time passive (s)	13.4	(0.03)	9.9	(0.10)	7.8	(0.09)	8.0	(0.06)	5.6	(0.23)
Expiratory time EVA (s)										
6 $l \cdot min^{-1}$	8.0	(0.10)	7.7	(0.06)	7.23	(0.06)	7.3	(0.06)	6.7	(0.07)
9 $l \cdot min^{-1}$	5.6	(0.06)	5.6	(0.05)	5.5	(0.10)	5.6	(0.07)	5.6	(0.04)
12 $l \cdot min^{-1}$	4.5	(0.09)	4.5	(0.06)	4.5	(0.02)	4.5	(0.05)	4.9	(0.20)
15 $l \cdot min^{-1}$	4.0	(0.07)	4.1	(0.03)	4.1	(0.01)	4.1	(0.04)	4.4	(0.17)
18 $l \cdot min^{-1}$	3.9	(0.06)	4.0	(0.02)	4.1	(0.03)	4.1	(0.02)	4.5	(0.06)

Table 2 Results of Part 3: inspiratory and expiratory times. Times needed for insufflation of 1 litre oxygen at different compliances and resistances using flow rates of 6–18 $l \cdot min^{-1}$ and for the same volume to egress through the 75 mm long, 2 mm ID transtracheal catheter passively (expiratory time passive) or with expiratory ventilation assistance (expiratory time EVA). Data are given as mean (SD).

Statistical analysis

For descriptive statistics, MS-Excel 2002 SP3 was used. Results are presented as mean (SD). Suction capacities, entrainment ratios, and achievable minute volumes were calculated.

Results

Part 1: insufflation and suction pressures

The modified SBP 07 and the DE 5 generated similar insufflation pressures proportional to the flow rate of the driving gas (Table 1). Subatmospheric pressures in both the static and the dynamic settings were proportional to the flow rate of the driving gas. In all static situations, except at a flow rate of 6 $l \cdot min^{-1}$, the subatmospheric pressure generated by the DE 5 was less negative compared with that generated by the SBP 07 at the same flow rate. However, in all dynamic situations, the DE 5 maintained a more negative pressure.

Part 2: suction capacities and entrainment ratios

The suction capacity of the DE 5 was higher compared with that of the SBP 07 and ranged from 6.8 to 15.9 $l \cdot min^{-1}$ depending on the flow rate of the driving gas (Table 1). Consequently, also the entrainment ratio of the DE 5 was higher than that of the SBP 07 at all flow rates.

Part 3: inspiratory and expiratory times and minute volumes

Applying EVA using the DE 5 at a flow rate of 6 $l \cdot min^{-1}$ resulted, at a compliance of 100 $ml \cdot cmH_2O^{-1}$ and a resistance of

COMPLIANCE (ML·CMH$_2$O^{-1})	100	50	30	30	10
RESISTANCE (CMH$_2$O·L^{-1}·S^{-1})	2	2	2	32	32
6 l·min-1					
MV passive (l·min^{-1})	2.55	2.92	3.17	3.13	3.04
MV EVA (l·min^{-1})	3.30	3.27	3.26	3.25	2.87
Δ MV (l·min^{-1})	0.75	0.35	0.09	0.12	-0.17
9 l·min-1					
MV passive (l·min^{-1})	2.99	3.57	3.98	3.93	4.09
MV EVA (l·min^{-1})	4.89	4.80	4.69	4.66	4.08
Δ MV (l·min^{-1})	1.89	1.23	0.71	0.74	0.00
12 l·min-1					
MV passive (l·min^{-1})	3.27	4.00	4.56	4.49	4.88
MV EVA (l·min^{-1})	6.35	6.26	6.06	6.07	5.17
Δ MV (l·min^{-1})	3.07	2.27	1.49	1.58	0.29
15 l·min-1					
MV passive (l·min^{-1})	3.45	4.27	4.95	4.83	5.45
MV EVA (l·min^{-1})	7.48	7.30	7.09	7.05	6.10
Δ MV (l·min^{-1})	4.04	3.03	2.15	2.22	0.65
18 l·min-1					
MV passive (l·min^{-1})	3.58	4.46	5.21	5.12	5.87
MV EVA (l·min^{-1})	8.27	7.97	7.68	7.68	6.55
Δ MV (l·min^{-1})	4.69	3.50	2.47	2.57	0.68

Table 3 Results of Part 3: minute volumes. Achievable minute volumes at different compliances and resistances using flow rates of 6–18 l·min^{-1} through the 75 mm long, 2 mm ID transtracheal catheter with passive expiration (MV passive) and expiratory ventilation assistance (MV EVA), DMV=MV EVA - MV passive

2 cmH$_2$O·l^{-1}·s^{-1}, in a decrease in the expiratory time from 13.4 (0.03) to 8.0 (0.10) s (Table 2). Raising the flow rate of oxygen resulted in a further decrease in expiratory times and consequently in an increase in the calculated MV, achievable through the transtracheal catheter for this pulmonary setting, from 3.58 to 8.27 l·min^{-1} (Table 3). The maximum effect of the DE 5 on the expiratory time was reached at 15 l·min^{-1} (Table 2). The increase in the achievable minute volume at a flow rate of 18 l·min^{-1} compared with that at a flow rate of 15 l·min^{-1} only resulted from a shorter inspiratory time due to the higher flow rate of the driving gas. A decrease in compliance reduced the effect of EVA (Table 3). At a compliance of 10 ml·cmH$_2$O^{-1}, the expiratory time with EVA using the DE 5 at a flow rate of 6 l·min^{-1} was 1.1 s longer compared with passive backflow (Table 2), resulting in a decrease in calculated minute volume of 170 ml·min^{-1}

(Table 3). The increase in the achievable minute volume at a flow rate of 18 $l \cdot min^{-1}$ compared with that at a flow rate of 15 $l \cdot min^{-1}$ only resulted from a shorter inspiratory time due to the higher flow rate of the driving gas.

A decrease in compliance reduced the effect of EVA (Table 3). At a compliance of 10 $ml \cdot cmH_2O^{-1}$, the expiratory time with EVA using the DE 5 at a flow rate of 6 $l \cdot min^{-1}$ was 1.1 s longer compared with passive backflow (Table 2), resulting in a decrease in calculated minute volume of 170 $ml \cdot min^{-1}$ (Table 3). At higher flow rates, the minute volume achieved by EVA at this low compliance was similar (at 9 $l \cdot min^{-1}$) or slightly higher compared with passive backflow.

Further data relating to the experimental set up and results using cannulas of different sizes and non-compliant tubing (2 mm ID) are found in the supplementary material.

Discussion

Employment of Bernoulli's principle can facilitate expiration through a small-bore transtracheal catheter. The results of the present study show that the novel ventilation ejector (DE 5) is more suitable for ventilation purposes than the modified industrial ejector (SBP 07). The DE 5 substantially shortened the required expiratory time and achieved a minute volume of up to 8.27 $l \cdot min^{-1}$ through a 75 mm long, 2 mm ID transtracheal catheter.

At a pulmonary setting representing a healthy adult (compliance 50 $ml \cdot cmH_2O^{-1}$, resistance of 2 $cmH_2O \cdot l^{-1} \cdot s^{-1}$), passive backflow of 1000 ml oxygen through the transtracheal catheter takes 9.9 (0.10) s [15]. Thus, at an oxygen flow of 15 $l \cdot min^{-1}$ repetitively connecting and disconnecting the oxygen tubing and the transtracheal catheter could result in a theoretical minute volume of 4.27 $l \cdot min^{-1}$. However, in an emergency situation, a continuously connected bidirectional ventilation system is highly preferable, because of the risk of dislodging the transtracheal catheter by manipulations. The Oxygen Flow Modulator (OFM; Cook Medical) is a bidirectional emergency tool for transtracheal oxygenation. In an in vitro study, it achieved a calculated minute volume of 3.24 $l \cdot min^{-1}$ in case of a completely obstructed upper airway [17]. Although this minute volume would be sufficient to re-establish oxygenation, hypercapnia seems to be inevitable.

To speed up expiration through a small-bore catheter, the driving force can be increased, for example, by applying compression to the thorax, abdomen, or both. The resistance of the outflow tract may also be diminished by inserting an additional transtracheal catheter to facilitate expiration [6, 18, 19]. To minimize trauma to the airway and to get more control over the expiration, it has also been suggested to augment the outflow of gas through a single small-bore catheter by the application of suction [12, 14).

The mechanism of both tested devices (modified SBP 07 and DE 5) is based on the ejector's principle. An ejector is a multipurpose device able to create a subatmospheric pressure by the Bernoulli principle and to entrain air from a side port. The amount of entrainment and consequently the degree of expiratory assistance depend on the velocity of the driving gas and the resistance of the ejector. Although an ejector's resistance to flow is primarily defined by its inner geometry, the velocity of the driving gas jet passing through the ejector modulates the effective resistance while the ejector is active. If, at a given flow, the velocity of the driving gas is decreased (e.g. by turbulent mixing with entrained gas), an ejector will become less efficient.

The SBP 07 was modified and the DE 5 was specifically designed to serve as emergency ventilation ejectors,

allowing both insufflation of oxygen and EVA. Although the modified SBP 07 has previously been reported to achieve a minute volume of more than 6 l·min^{-1} through a 75 mm long, 2 mm ID transtracheal catheter [15], this industrial ejector has been designed to create a maximum negative pressure to pick up and hold parts during manufacturing processes in industrial assembly lines and is not specified for ventilation.

The results of this study show that the SBP 07 is indeed capable of generating a high negative pressure in a static situation, that is, no gas is entrained. However, in a dynamic situation, when gas is continuously entrained through the transtracheal catheter, the generated pressure was considerably less negative. Compared with the SBP 07, the DE 5 built up a less negative pressure in a static situation, but maintained a higher negative pressure in a dynamic situation, leading to an improved suction capacity and a higher entrainment ratio. The differences in test results prove that the design of the DE 5 turns it into being better suited for ventilation purposes than the SBP 07.

As shown in Figure 2A and B, the outflow tract and the side port of the SBP 07 and the DE 5 are designed differently. The outflow tube of the SBP 07, having a constant diameter over three-quarters of its length, has an optimal shape for creating a maximum negative pressure build-up in a static situation. In contrast, the slightly conical shape of the outflow pipe of the DE 5 has a length and an internal diameter that were designed to maximize entrainment from the side port while minimizing inner turbulence and thus optimizing the egress of entrained gas.

We are aware of the fact that application of results from this in vitro study into clinical practice has its limitations. Completely blocking the upper airway is an extreme simplification of clinical reality. The diameter of the upper airway is dynamically variable, and in clinical practice, it will open up at a certain intratracheal (intrathoracic) pressure in most cases. Although this situation resembles a relatively rare event, we decided to simulate a completely blocked upper airway as the best experimental setting for the evaluation of the DE 5. Thus, the current study did not address the usefulness of the DE 5 in various degrees of upper airway obstruction and did not determine the influence of patency of the upper airway on the effect of EVA. Furthermore, the effects of EVA on gas exchange, lung tissue, and circulation have not yet been fully studied. Ongoing in vivo experiments will have to address these clinical questions.

In summary, our novel EVA applying ventilation ejector DE 5 is capable of achieving an adequate minute volume through a small-bore transtracheal catheter. If further research confirms the safety and applicability of EVA in vivo, the DE 5 might be used as a portable emergency ventilator for small-bore catheters in the future.

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Conflict of interest

D.E. is the inventor of the Oxygen Flow Modulator and receives royalty payments from Cook Medical. Furthermore, D.E. has applied for a patent on the DE 5.

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Chapter 6

The effect of expiratory ventilation assistance on re-oxygenation and ventilation

Emergency ventilation through a small-bore transtracheal cannula in severe hypoxic pigs using expiratory ventilation assistance (EVA)
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Summary

Background. Suction-generated expiratory ventilation assistance (EVA) has been proposed to facilitate bidirectional ventilation through a small-lumen transtracheal cannula. The aim of this study was to investigate the efficiency of EVA on restoring oxygenation and ventilation in an acute hypoxic pig model.

Methods. After approval by the local Animal Welfare Committee six pigs (61-76 kg) were anaesthetized and ventilated (IPPV) via a cuffed endotracheal tube (ET). Monitoring lines were placed and a 75 mm long, 2 mm ID TC was inserted. After baseline recordings the ventilator was disconnected. After two minutes of apnoea re-oxygenation with EVA was initiated through the TC and continued for 15 minutes with the ET occluded. In the second part of the study the experiment was repeated with the ET either partially obstructed or left open. Airway pressures and hemodynamic data were recorded and blood samples were collected. Descriptive statistical analysis was performed.

Results. With a completely or partially obstructed upper airway EVA restored oxygenation in all animals within 20 seconds. PCO_2 remained stable over 15 minutes in case of a completely obstructed airway. As airway patency increased re-oxygenation was delayed. In the completely open airway 2 out of 6 animals had a pO_2 below 85 mmHg even after 15 minutes and mean pCO_2 was 90 mmHg after 15 minutes of EVA

Conclusions. In severe hypoxic pigs EVA restored oxygenation quickly in case of a completely as well as a partially obstructed upper airway. Re-oxygenation and ventilation by EVA was less effective in case of an open upper airway.

In a 'cannot intubate, cannot oxygenate' (CICO) situation a percutaneous cricothyroidotomy should be performed rapidly to restore oxygenation and avoid brain damage or death [1, 2]. This life-saving procedure can be performed with either a small-bore (inner diameter (ID) ≤ 2 mm) or a (cuffed) wide-bore cannula (ID of 4 mm or larger) [3]. Survey studies have demonstrated that a majority of anaesthetists prefer a small-bore cannula technique when performing an emergency cricothyroidotomy [4, 5], as insertion might be easier and less traumatic. However, providing effective re-oxygenation and ventilation through such a narrow cannula may be difficult [6, 7] and not without risks. As resistance to gas flow is inversely related to the internal diameter (ID) a high-pressure oxygen source is mandatory to create an adequate flow through a small-bore cannula [8]. Additionally, passive expiratory outflow through a small-bore airway cannula is limited [9] and egress of gas must take place through the upper airway. Obstruction of the upper airway (e.g. due to edema, laryngospasm or tumour) and / or insufficient expiratory time can result in airtrapping. Several reports of barotrauma and circulatory collapse resulting from high-pressure ventilation can be found in the literature [10-13].

Various techniques have been proposed to facilitate the egress of gas through a small-bore cannula: applying thoracic and abdominal compression, inserting an additional cannula [14, 15] or applying suction to the airway cannula during the expiratory phase [16, 17]. Previously, we described a, manually operated ventilation ejector (DE 5) which uses high velocity gas flow to create expiratory ventilation assistance (EVA) and thus controls both the inspiratory and expiratory phase. (figure 1A+B) [18].

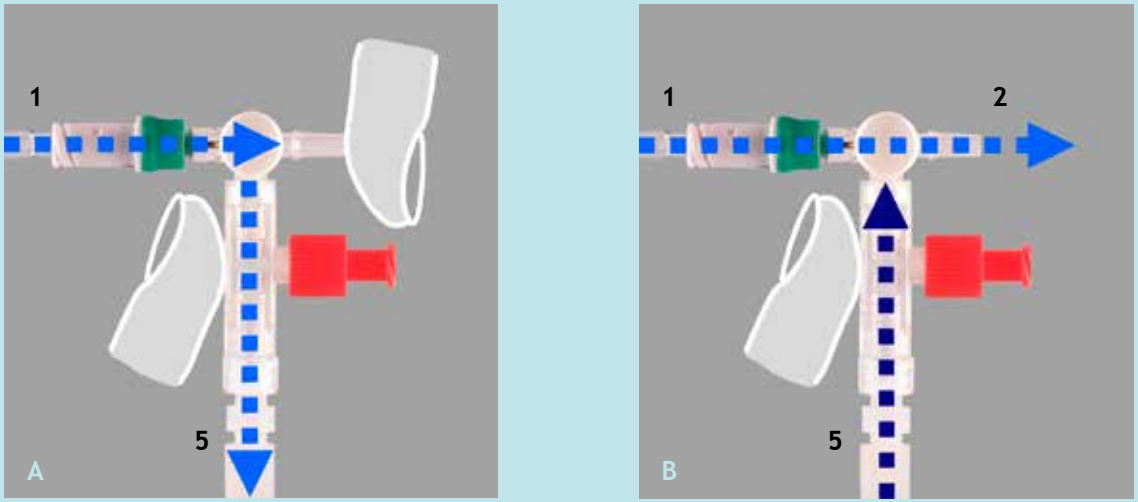

Figure 1 The two functional modes of the DE 5
A Device activated, insufflation: Oxygen flows from the inlet (1) to the connecting tubing (3). The outlet (2) is occluded by finger.
B Device activated, expiratory ventilation assistance (EVA): Oxygen flows from the inlet (1) to the outlet (2) entraining gas from the connecting tubing (3) by the Bernoulli effect.

This emergency ventilation device achieved a calculated minute volume up to 8.3 $l \cdot min^{-1}$ through a 2 mm ID transtracheal cannula in an artificial lung model with complete outflow obstruction [19]. Although EVA in vitro appears promising, in vivo evaluation is mandatory. The primary aim of the present study was to determine the efficiency of EVA regarding re-oxygenation in an acute hypoxic pig model with an obstructed upper airway. Additionally, we studied the influence of upper airway patency on re-oxygenation and ventilation by EVA.

Methods

Experimental Set-Up

The study was approved by the Animal Welfare Committee of the University of Maastricht (DEC number 2009-070). After overnight fasting with free access to water, six pigs (61-76 kg) were premedicated with intramuscular tiletamine / zolazepam (6 $mg \cdot kg^{-1}$) and atropine (0.05 $mg \cdot kg^{-1}$). Anaesthesia was induced with propofol 4-8 $mg \cdot kg^{-1}$ and sufentanil 1 $\mu g \cdot kg^{-1}$ via an intravenous catheter inserted in a vein in the animals' ear. The trachea was intubated with a 9.0 mm ID cuffed endotracheal tube. The pigs were mechanically ventilated (intermittent positive pressure ventilation (IPPV)) with a tidal volume of 10 $ml \cdot kg^{-1}$. The respiratory rate was adjusted to establish an $etPaCO_2$ around 40 mmHg. FiO_2 was set at 0.40. Anaesthesia was maintained by continuous infusions of sufentanil (8 $\mu g \cdot kg^{-1} \cdot h^{-1}$), propofol (9 $mg \cdot kg^{-1} \cdot h^{-1}$) and pancuronium (0.3 $mg \cdot kg^{-1} \cdot h^{-1}$). A 9 Fr sheath (ref AH-09801, Arrow, Reading, PA, USA) was inserted in the right jugular vein and a pulmonary artery catheter (ref 746HF8, Edwards Lifesciences Corporation, Irvine, CA, USA) was positioned. Both femoral arteries were cannulated with an 18 G arterial catheter (ref FA-04018, Arrow, Reading, PA, USA) for continuous arterial pressure monitoring and arterial blood sampling. The trachea was surgically exposed with a mid-line incision and a 75 mm long, 2 mm ID transtracheal cannula (TC; Emergency Transtracheal Airway Catheter, Cook Medical, Bloomington, IN, USA) was inserted into the trachea between the 3rd and 4th cartilage ring under bronchoscopic guidance. Intratracheal pressure was measured continuously using a modified epidural catheter inserted via the tracheal tube and positioned 2 cm above the carina with bronchoscopic guidance. All pressure catheters were connected via pressure transducers to a multichannel recorder and a digital data acquisition system (IDEEQ-system, University Maastricht, Maastricht, The Netherlands) and were recorded continuously throughout the experiment.

Part 1

Following stable baseline recordings including arterial blood gases for at least 30 minutes the ventilator was disconnected, leaving the tracheal tube open to room air. After 2 minutes of apnoea the tracheal tube was occluded and re-oxygenation was initiated through the TC. EVA was applied using the DE 5, connected to a pressure-compensated oxygen flow meter set at 15 $l \cdot min^{-1}$. Employing an 30 min^{-1} rate, an initial inspiration/expiration-ratio (I/E-ratio) of 1 to 1 was adjusted to keep the end-expiratory intratracheal pressure between 0 and 10 cmH_2O. Arterial blood samples were collected at baseline (prior to the apnoea period of 2 minutes), at the start of EVA (0) and after 10, 20, 30, 60, 180, 300, 600, and 900 seconds (s). After 15 minutes EVA was stopped and the pigs were mechanically ventilated through the ET. After completion of the experiment a bronchoscopic evaluation of the airway was performed.

Part 2

In the second part of the study the experiment was repeated with varying degrees of tracheal tube obstruction simulating different levels of upper airway patency. After stable baseline recordings for 30 minutes the mechanical ventilator was again disconnected and after 2 minutes of apnoea EVA was initiated in random order with the ET either left open to room air or partially obstructed using a capping device with either a 3 mm orifice or a 50 mm long, 2 mm ID catheter. EVA was applied using the DE 5 at a rate of 30·min^{-1} with an I/E-ratio of 1 to 1. Arterial blood samples were collected at baseline (prior to apnoea for 2 minutes), at the start of EVA (0) and after 10, 20, 30, 60, 180, 300, 600, and 900 s. The animals were mechanically ventilated and all monitored pressures and blood gas values were allowed to return to normal between experimental runs. Additionally, between each run a bronchoscopic evaluation of the trachea was performed. Upon completion of the experiments the pigs were euthanized with pentobarbital (150 mg·kg^{-1}) and in 4 pigs a sternotomy was performed for macroscopic examination of the lungs.

Statistical Analysis

Descriptive statistical analysis was performed and the data are presented as median [range].

Results

At baseline the minute volume during IPPV to achieve normocapnia was 9.9 [9.1-12.0] l·min^{-1}. The mean compliance at baseline was 30.5 [28.1-33.8] ml·cmH_2O^{-1}.

Part 1: completely obstructed upper airway

After 2 minutes of apnea the arterial PaO_2 fell to a median of 25 mmHg [20-31] and the oxygen saturation was 45% [33-60] (table 1). Within 20 seconds after the initiation of EVA, hypoxemia was corrected (SaO_2 > 95%) in all animals. During the apnea period $PaCO_2$ rose to a median of 54 mm Hg [46-56] and did not change significantly during EVA ventilation.

	-120 S	0	10 S	20 S	60 S	180 S	900 S
PaO_2 (mmHg)	171 [156-200]	25 [20-31]	84 [47-208]	254 [178-310]	404 [381-416]	539 [494-562]	537 [490-565]
SaO_2 (%)	100	45 [33-60]	96 [82-100]	100	100	100	100
$PaCO_2$ (mmHg)	39 [37-40]	54 [46-56]	55 [48-60]	55 [50-62]	56 [49-59]	55 [51-60]	57 [56-75]

Table 1 PaO_2 and $PaCO_2$ at complete upper airway obstruction prior (-120 s) and after two minutes of apnoea (0) and subsequent EVA over 15 minutes (part 1 of the study). Data presented as mean [range].

Part 2: increased upper airway patency

With the ET partially obstructed EVA restored oxygenation within 20 seconds (SaO_2 > 95%). However, when the airway was left completely open, 2 out of 6 animals had a pO_2 below 85 mmHg after 15 minutes. The efficacy of EVA decreased as the ET was less obstructed resulting in protracted re-oxygenation and severe hypercarbia in the open airway (fig. 2A-C).

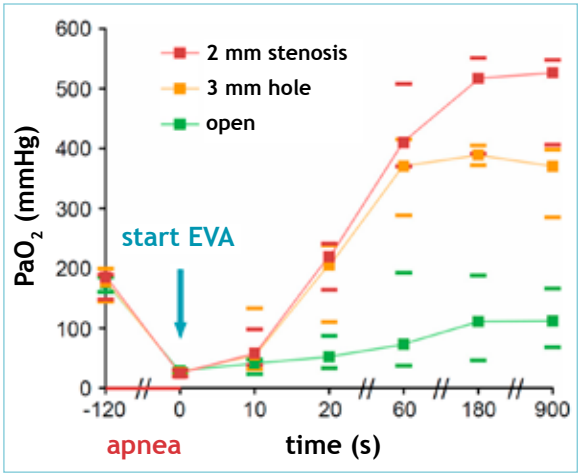

Figure 2A Course of PaO_2 at different upper airway patency prior (-120 s) and after two minutes of apnoea (0) and subsequent EVA over 15 minutes (part 2 of the study). The ET was either fully open or obstructed with a 3 mm hole or a 50 mm long, 2 mm stenosis. Data presented as mean and range.

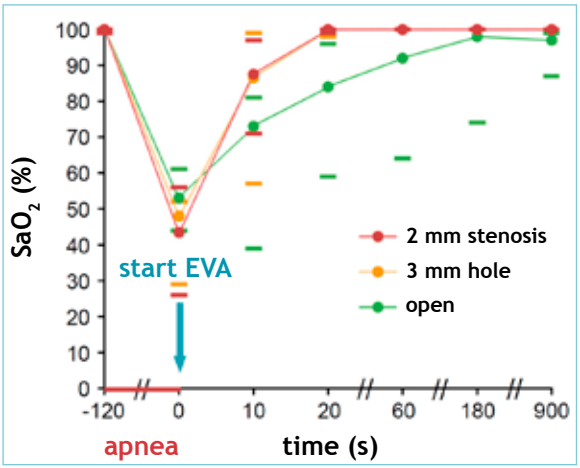

Figure 2B Course of SaO_2 at different upper airway patency prior (-120 s) and after two minutes of apnoea (0) and subsequent EVA over 15 minutes (part 2 of the study). The ET was either fully open or obstructed with a 3 mm hole or a 50 mm long, 2 mm stenosis. Data presented as mean and range.

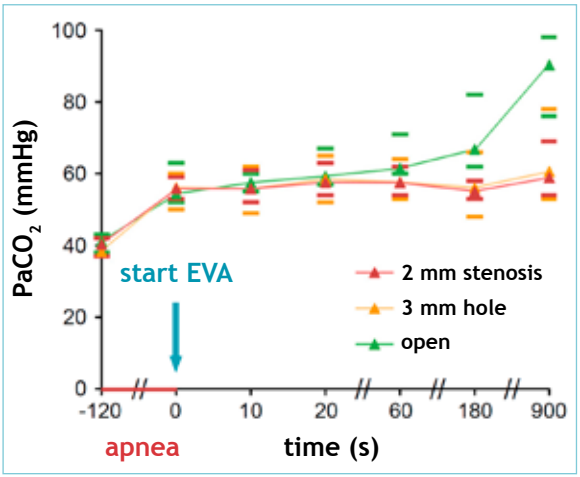

Figure 2C Course of $PaCO_2$ at different upper airway patency prior (-120 s) and after two minutes of apnoea (0) and subsequent EVA over 15 minutes (part 2 of the study). The ET was either fully open or obstructed with a 3 mm hole or a 50 mm long, 2 mm stenosis. Data presented as mean and range.

Macroscopic Examination

Hyperaemia of the posterior tracheal wall at the level of the TC insertion was seen in all patients by trachea-bronchoscopy. There were no lacerations of the mucosa, macroscopically evident oedema or bronchial haemorrhagic secretions. Post-mortem examination revealed no pneumothorax or subcutaneous emphysema.

Discussion

A CICO scenario will likely result in brain damage or death if not corrected in a timely manner. If oxygenation cannot be maintained by conventional means, an invasive airway must be established without delay. The insertion of a small-bore catheter through the cricothyroid membrane can be performed quickly [20]. EVA, applied by the DE5, restored oxygenation through a small-bore TC in severely hypoxic pigs with a completely as well as partially obstructed upper airway within 20 seconds.

The exact amount and / or flow of oxygen necessary to rapidly re-oxygenate an adult patient is unknown. Flack et al. calculated in a mathematical model that an increase in tidal volume results in faster re-oxygenation [21]. The Difficult Airway Society guidelines recommend using a high-pressure device capable of delivering a high minute volume to re-oxygenate a patient in a CICO situation following small-bore cricothyroidotomy [22]. In a previous in vitro study the DE5 achieved a calculated minute volume of 7.1 $l \cdot min^{-1}$ through a TC in a lung model with a compliance of 30 $ml \cdot cmH_2O^{-1}$ (similar to the compliance of the pigs) and driven by an oxygen flow of 15 $l \cdot min^{-1}$ [19]. In an adult this minute volume would not only be enough for swift re-oxygenation, but it would also provide adequate ventilation. Although in our study hypercarbia could be limited over a period of 15 minutes in the animals with an obstructed upper airway, $PaCO_2$ did not returned to baseline levels during ventilation with EVA. A plausible explanation is that during IPPV the pigs required a minute volume of 9.9 $l \cdot min^{-1}$ for normoventilation (Table 1). This is far above the maximum minute volume achievable with the DE 5.

In the case of a completely obstructed upper airway and the application of EVA there is a risk of air trapping by over-vigorous TC insufflation and the potential for development of prohibitive subatmospheric pressure by prolonged gas evacuation. In the present study the EVA I/E ratio was varied to keep intratracheal pressures between 0 and 10 cmH_2O. In clinical resuscitation, such intratracheal pressures are unlikely to be monitored. Attention to chest wall excursion and relaxation in the inspiratory and expiratory phases respectively, may be the only monitor. However, modest subatmospheric end-expiratory pressure may be desirable and improve venous return, and be beneficial for both cardiac and cerebral perfusion [23].

EVA was found to be less efficient in a completely open ET. To achieve sufficient ventilation in an open airway a high driving pressure is mandatory [24]. The driving pressure necessary for “classic” jet ventilation in an adult patient ranges between 1.5 and 3.0 bar. As the inspiratory pressure of the DE5 measured in front of the TC is just about 110 mbar at 15 $l \cdot min^{-1}$ [19], it needs to be emphasized that EVA is not just a “modified” type of jet ventilation. Flow-controlled EVA for ventilation through small-bore cannulas or catheters can be considered a new hybrid ventilation mode filling in the gap between “classic” jet ventilation through a small-bore catheter using high-pressures in an open airway and conventional low-pressure ventilation (e.g. IPPV) through a large-bore tube in a closed airway.

One of the limitations of our study design is that the insertion of the TC was under stable conditions after surgical exposure of the trachea. This study does not address the difficulty of successfully performing a cricothyroidotomy in a CICO situation, which is clearly a problem as became obvious in the fourth national audit project in the UK [25]. Furthermore, EVA was used only for 15 minutes. This resembles the period of time required to re-oxygenate and stabilize a patient in a CICO situation after getting access to the airway by needle cricothyroidotomy. However, effects of prolonged ventilation with EVA, for instance damage to the mucosa of the respiratory tract because of the ventilation with cold and dry air, have not been studied. The degree of airway patency was modelled using a fixed diameter, which is a simplification of clinical reality. In clinical practice the diameter of the upper airway is dynamically variable and is likely influenced by the intratracheal pressures. This study, however, did not determine the influence of EVA on patency of the upper airway.

In summary, EVA restored oxygenation quickly in severely hypoxic animals with a partially or completely obstructed upper airway. The efficacy of EVA decreased in an open airway.

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Conflict of interest

Ankie Hamaekers is an unpaid consultant for 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.

Dietmar Enk is the inventor of DE5 and receives royalty payments from Dolphys Medical, Eindhoven, The Netherlands.

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Chapter 7

Implementation of EVA in a commercially available product

Ventrain: an emergency ventilation ejector
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Summary

A small, flow-regulated, manually operated ventilator designed for ventilation through a narrow-bore transtracheal catheter (TTC) has become available (Ventrain, Dolphys Medical BV, Eindhoven, The Netherlands). It is driven by a predetermined flow of oxygen from a high-pressure source and facilitates expiration by suction. The aim of this bench study was to test the efficacy of this new ventilator.

The driving pressure, generated insufflation, and suction pressures and also the suction capacity of the Ventrain were measured at different oxygen flows. The minute volume achieved in an artificial lung through a TTC with an inner diameter (ID) of 2 mm was determined at different settings.

Oxygen flows of 6 - 15 $l \cdot min^{-1}$ resulted in driving pressures of 0.5 - 2.3 bar. Insufflation pressures, measured proximal to the TTC, ranged from 23 to 138 cmH_2O. The maximal subatmospheric pressure build-up was -217 cmH_2O. The suction capacity increased to a maximum of 12.4 $l \cdot min^{-1}$ at an oxygen flow of 15 $l \cdot min^{-1}$. At this flow, the achievable minute volume through the TTC ranged from 5.9 to 7.1 litres depending on the compliance of the artificial lung.

The results of this bench study suggest that the Ventrain is capable of achieving a normal minute volume for an average adult through a 2 mm ID TTC. Further in vivo studies are needed to determine the value of the Ventrain as a portable emergency ventilator in a ‘cannot intubate, cannot ventilate’ situation.

Transtracheal cannulation and subsequent high-pressure source ventilation (often called 'jet ventilation') can be lifesaving in a 'cannot intubate, cannot ventilate' (CICV) situation [1, 2]. Although 'jet ventilation' has a low morbidity in elective cases [3], numerous case reports underline the risk of high-pressure source ventilation in emergency situations [4–6]. Safe application of a high-pressure source ventilator requires an open upper airway to allow the gas to flow out during expiration. Obstruction of the upper airway caused by laryngospasm, oedema or anatomical distortion, combined with over-vigorous jet insufflation can result in air trapping with subsequent barotrauma and haemodynamic instability [7, 8].

Suction-generated augmentation of expiration has been proposed to minimize the risk of air trapping [9] and to increase the achievable minute volume through a narrow-bore airway catheter [10].

Recently, we described a purpose-built ventilation ejector (DE 5) that achieves *in vitro* a minute volume up to 7.5 $l \cdot min^{-1}$ through a 7.5 cm long transtracheal catheter (TTC) with an inner diameter (ID) of 2 mm by using expiratory ventilation assistance (EVA) [11, 12]. In a hypoxic animal model with a completely obstructed airway, this ventilation ejector restored oxygenation through the TTC within 20 s and limited hypercarbia for over 15 minutes [13]. Based on the construction of the DE 5, a portable, flow-regulated, manually operated, and ergonomically shaped ventilation device was developed: Ventrain (Dolphys Medical BV, Eindhoven, The Netherlands; http://www.ventrain.com). Recently, this ventilation ejector has become commercially available. The aim of this study was to evaluate the Ventrain *in vitro*.

Methods

Description of the Ventrain

The Ventrain is a single-use, manually operated, narrow-bore ventilation device capable of oxygen insufflation and EVA. The functional inner component is a specially designed ejector (Fig. 1A and B), which is driven by an oxygen flow coming from a high-pressure source with a controllable flow, e.g. a wall-mounted, pressure-compensated flow meter, or an oxygen cylinder with a flow regulator [14]. Before use, the oxygen tubing attached to the ejector's inlet (1 in Fig. 1A and B) must be connected to the oxygen source, and the short connecting tubing at the side port (2 in Fig. 1A and B) must be attached to the TTC. The oxygen flow coming from the flow meter or flow regulator is accelerated by a 0.7 mm ID jet nozzle (3 in Fig. 1B) and enters the exhaust pipe (4 in Fig. 1B) at high speed. As long as the bypass is open, the device is claimed to be functionally switched off with no clinically relevant flows to and from the patient. Closing the aperture of the bypass activates the Ventrain. The high-speed oxygen flow now creates a subatmospheric pressure and entrains gas from the side port (2 in Fig. 1B), thereby facilitating the egress of gas through the narrow-bore catheter. Closing both the bypass and the aperture of the exhaust pipe (inspiration/expiration switch) redirects the flow to the side port and oxygen is insufflated. By alternately occluding and releasing the aperture of the exhaust pipe, while keeping the bypass closed, either oxygen is insufflated or a subatmospheric pressure is created to assist the egress of gas through the attached narrow-bore catheter: EVA (details of how to operate the Ventrain are shown in Supplementary Fig. S1A and B).

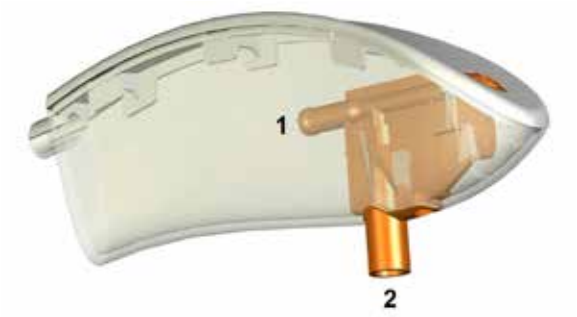

Figure 1A CAD model of the Ventrain. The shell is shown transparently, so the ejector as the functional centrepiece can be seen inside the shell. The oxygen tubing (not shown) is connected to the ejector's inlet (1) and short connecting tubing (not shown) is glued to the side port (2).

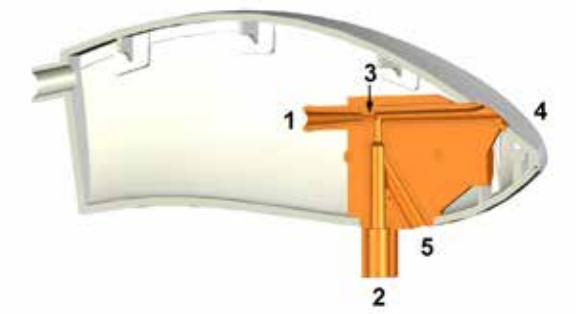

Figure 1B CAD cross-section of the Ventrain. Again, the oxygen and connecting tubing are not shown. The cross-section reveals the inner construction of the ejector: from the inlet (1) to the jet nozzle (3), the diameter decreases. Oxygen passing the jet nozzle is accelerated and enters the slightly conically shaped exhaust pipe (4) at high speed. Thereby, subatmospheric pressure is created at the side port (2) resulting in assisted expiration if the bypass (5) (functioning as an on/off switch) is completely closed. For inspiration, the flow of oxygen can be redirected to the side port by firmly sealing the aperture of the exhaust pipe (functioning as an inspiration/expiration switch).

Experimental set-up

The experiments were performed in two stages. First, the driving pressure and the pressures generated by the Ventrain were determined using the Calibration Analyzer Series RT-200 (Timeter Instrument Corporation, St Louis, MO, USA). A pre-release version of the Ventrain was connected to a calibrated, pressure-compensated flow meter (Dräger Medical AG & Co. KG, Lübeck, Germany) and attached to a 7.5 cm long, 2 mm ID TTC (Cook Medical, Bloomington, IN, USA). The driving pressure was defined as the pressure in the oxygen tubing between the flow meter and the ejector part of the Ventrain. It was measured via the side port of a T-piece placed between the oxygen tubing and the flow meter. To evaluate whether the Ventrain was indeed functionally switched off, pressures at the tip of the TTC were determined with the bypass of the Ventrain open as previously described [15]. The insufflation and suction pressures were measured at the side port of the distal T-piece proximal to the attached catheter. The maximum suction pressure was determined with the tip of the attached catheter blocked. All pressures were measured at oxygen flows of 6, 9, 12, and 15 $l \cdot min^{-1}$.

Furthermore, the suction capacity of the Ventrain was determined for oxygen flows of 6 - 15 $l \cdot min^{-1}$ by insufflating a 35 litre plastic garbage bag (product number 136146, Albert Heijn, Zaandam, The Netherlands), as a closed ventilation model with an infinite compliance, for 1 minute and measuring the time to completely empty the bag through the TTC by suction. In addition, entrainment ratios (= entrained flow/oxygen flow) were calculated.

In the second part of the experiment, the efficacy of the Ventrain was studied at different pulmonary compliances and resistances in an LS800 lung simulator (Dräger Medical

AG & Co. KG, Lübeck, Germany) with a simulated complete upper airway obstruction. The TTC was tightly fitted in the proximal tube orifice of the lung simulator, ensuring that the entire gas flow into and out of the bellows was directed through the catheter. The measurements were performed at compliances of 100, 50, 30, and 10 ml·cmH_2O^{-1} and resistances of 2, 8, and 32 cm$H_2O \cdot l^{-1} \cdot s^{-1}$. The achievable minute volume was determined as previously described [15] by measuring the time required for insufflation of 1000 ml of oxygen and the times needed for passive backflow of this volume through the TTC (with the Ventrain disconnected) and for assisted expiration using the Ventrain connected to oxygen flows of 6, 9, 12, and 15 l·min^{-1}.

Statistical analysis

Each experiment was repeated four times. Means and standard deviations (SDS) were determined and used for further calculations. Suction capacities, entrainment ratios (ER), achievable minute volumes, and inspiration/expiration ratios (I/E ratios) were calculated. For descriptive statistics, MS-Excel 2002 SP3 was used.

Results

Increasing the oxygen flow created higher driving pressures (Table 1). Values of 2300 cmH_2O (2.3 bar) were measured in the oxygen tubing to the ejector at a flow of 15 l·min^{-1}. With the bypass open (Ventrain 'off'), closure of the exhaust pipe resulted in a maximal pressure at the tip of the TTC of 2.3 cmH_2O at a flow of 15 l·min^{-1}, whereas a slight subatmospheric pressure of - 6.5 cmH_2O was found at this flow rate if the aperture of the exhaust pipe was released (Table 1).

The insufflation pressure and the suction pressure of the Ventrain were related to the oxygen flow. At an oxygen flow of 15 l·min^{-1}, the insufflation pressure was 138 cmH_2O.

OXYGEN FLOW (L·MIN^{-1})	6		9		12		15	
Driving pressure (cmH_2O)	459	[7.2]	1017	[8.5]	1665	[4.4]	2297	[8.5]
Ventrain "off" (bypass open):								
PACT, exhaust pipe closed (cmH_2O)	0.5	[0.06]	0.8	[0.05]	1.9	[0.06]	2.3	[0.10]
PACT, exhaust pipe open (cmH_2O)	-1.7	[0.05]	-3.5	[0.05]	-5.2	[0.05]	-6.5	[0.12]
Ventrain "on" (bypass closed):								
Insufflation pressure (cmH_2O)	22.5	[0.58]	50.8	[0.50]	90.5	[1.00]	137.8	[2.06]
Suction pressure (cm H_2O)	-25.5	[0.58]	-51.3	[0.96]	-75.5	[0.58]	-96.8	[1.50]
Maximal suction pressure (cmH_2O)	-57.8	[1.26]	-112.8	[0.50]	-171.0	[2.16]	-217.3	[3.95]
Suction capacity (l·min^{-1})	6.5		9.3		11.0		12.4	
Entrainment ratio	1.08		1.03		0.92		0.83	

Table 1 Physical characteristics of the Ventrain at different oxygen flows; measured data are presented as mean (SD). 'Driving pressure' indicates the pressure measured in the upstream oxygen tubing with oxygen flowing through the Ventrain, while the device is functionally switched off; 'PACT' means pressure at the TTC's tip; 'insufflation pressure' and 'suction pressure' have been measured proximal of the attached TTC during inspiration and expiration, respectively; 'maximal suction pressure' indicates the maximal subatmospheric pressure build-up that can be created by the Ventrain.

COMPLIANCE (ML·MBAR^{-1})	100	50	30	10
RESISTANCE (MBAR·L^{-1}·S^{-1})	2	2	8	32
Insufflation time (s)	4.96 [0.04]	5.14 [0.04]	5.42 [0.04]	6.63 [0.02]
Expiration time (s), passive	14.03 [0.07]	10.20 [0.02]	8.09 [0.10]	5.69 [0.09]
MV (l·min^{-1}), passive	3.16	3.91	4.44	4.87
I/E-ratio, passive	1/2.83	1/1.99	1/1.49	1/0.86
Expiration time (s), Ventrain	5.11 [0.04]	5.14 [0.02]	5.07 [0.03]	5.21 [0.07]
MV (l·min^{-1}), Ventrain	5.96	5.84	5.72	5.07
I/E-ratio, Ventrain	1/1.03	1/1.00	1/0.93	1/0.79

Table 2A Achievable minute volumes through the 2 mm ID TTC at an oxygen flow of 12 l·min^{-1}; measured data presented as mean (SD)

COMPLIANCE (ML·MBAR^{-1})	100	50	30	10
RESISTANCE (MBAR·L^{-1}·S^{-1})	2	2	8	32
Insufflation time (s)	3.91 [0.08]	4.15 [0.02]	4.32 [0.05]	5.38 [0.03]
Expiration time (s), passive	14.03 [0.07]	10.20 [0.02]	8.09 [0.10]	5.69 [0.09]
MV (l·min^{-1}), passive	3.34	4.18	4.84	5.42
I/E-ratio, passive	1/3.59	1/2.46	1/1.87	1/1.06
Expiration time (s), Ventrain	4.58 [0.07]	4.56 [0.05]	4.62 [0.03]	4.85 [0.03]
MV (l·min^{-1}), Ventrain	7.07	6.89	6.71	5.87
I/E-ratio, Ventrain	1/1.17	1/1.10	1/1.07	1/0.90

Table 2B Achievable minute volumes through the 2 mm ID TTC at an oxygen flow of 15 l·min$_{-1}$; measured data presented as mean (SD)

The suction pressure was -97 cmH_2O while continuously aspirating air through the TTC and reached a maximum of -217 cmH_2O when the tip of the TTC was blocked (Table 1). At a flow rate of 15 l·min^{-1}, the Ventrain shortened the expiratory time in all simulated pulmonary settings. This effect was for all flows most pronounced at a compliance of 100 ml·cmH_2O^{-1} (Table 2 and Supplementary Tables S1 and S2). At this compliance, the expiratory time for 1 litre of oxygen decreased from 14.03 s in the case of passive egress through the TTC to 4.58 s with expiratory assistance by the Ventrain at an oxygen flow of 15 l·min^{-1}, resulting in a calculated minute volume of 7.1 l·min^{-1}. A decrease in compliance, however, limited the efficacy of the Ventrain. At a compliance of 10 ml·cmH_2O^{-1}, the (theoretically) achievable minute volume decreased to 5.9 l·min^{-1}.

Discussion

Passive outflow of gas during ventilation through a narrow-bore TTC is limited by the high internal resistance of the catheter [16]. One solution to facilitate the egress of gas is to apply suction during the expiratory phase [10]. The novel emergency ventilation ejector evaluated in this study (Ventrain) achieved a minute volume of up to 7.1 $l \cdot min^{-1}$ through a 2 mm ID catheter, by generating expiratory suction applying the Bernoulli principle.

The Bernoulli principle states that for an inviscid fluid, an increase in flow velocity at a constriction leads to an increase in dynamic pressure (kinetic energy) and causes a corresponding decrease in static pressure (potential energy).

The Ventrain turns the high driving pressure (up to 2.3 bar), measured in the oxygen tubing, into high velocity of the oxygen stream. As can be estimated from the driving pressure and the diameter of the jet nozzle, the 0.7 mm ID jet nozzle of the Ventrain accelerates the oxygen at a flow rate of 15 $l \cdot min^{-1}$ to a flow velocity close to the speed of sound. The subatmospheric pressure of up to - 97 cmH_2O caused by the Bernoulli effect facilitates the egress of gas through the narrow-bore catheter. The degree of expiratory assistance is flow-dependent, with a maximum suction capacity of 12.4 $l \cdot min^{-1}$ at an oxygen flow of 15 $l \cdot min^{-1}$.

The DAS guidelines recommend using a high-pressure device capable of delivering a high minute volume to re-oxygenate a patient in a CICV situation through a narrow-bore cricothyroidotomy [2]. Although the Ventrain is a high-pressure oxygen source device (as defined by its driving pressure), the insufflation pressure measured proximal to the TTC is significantly lower than the pressure usually used for conventional 'jet ventilation'. In contrast to conventional high-pressure source ventilation devices, the Ventrain is flow-regulated and the insufflated oxygen is only slightly compressed. This might decrease the risk of barotrauma as the volume of insufflated oxygen can easily be estimated (e.g. redirecting an oxygen flow of 15 $l \cdot min^{-1}$ for 1 second results in insufflation of 250 ml of oxygen).

To ensure a stable inspiratory flow, a pressure-compensated flow meter or flow regulator capable of handling back-pressure is mandatory. Insufflation and also suction pressures, suction capacity, inspiration and expiration times, and resulting inspiration/expiration ratio depend highly on the flow resistance of the attached catheter. The Ventrain has been specified to be used in combination with a 75 mm long, 2 mm ID TTC allowing manual control of ventilation in healthy adults with an inspiration/expiration ratio of about 1 to 1 at oxygen flows of $12^{-1}5$ $l \cdot min^{-1}$.

Changes in oxygen flow, pulmonary compliance, and flow resistance of the catheter might change the inspiration/expiration ratio. Therefore, it needs to be emphasized that during use of the Ventrain, one should always watch the chest movements of the patient. Failure to do so could lead to hyperinflation or the development of negative intrathoracic pressure.

In the case of hyperinflation or negative intrathoracic pressure, one needs to adjust the duration of the inspiration or expiration, or one might allow (slow) equilibration of the

intrathoracic pressure with the atmosphere by releasing the aperture of the exhaust pipe and the bypass of the Ventrain.

If the Ventrain is connected to an oxygen flow, low levels of subatmospheric pressure (maximally -6.5 cmH_2O at 15 $l \cdot min^{-1}$) are generated with both openings released. This subatmospheric pressure can compensate for the flow resistance of the connecting tubing with the distal T-piece. Thus,

with the exhaust pipe and the bypass open, the Ventrain will be not only switched off, but also functionally disconnected from the catheter.

The maximal subatmospheric pressure created by the Ventrain in this bench study was -217 cmH_2O. In a clinical setting, this pressure can only be reached if the upper airway is completely obstructed and if more gas is suctioned out of the patient than has been insufflated. Negative pressure pulmonary oedema, however, is a potential complication that might develop even after a short period of high subatmospheric intrapulmonary pressure. Therefore, ongoing in vivo trials are needed to determine the clinical effects of any subatmospheric pressure potentially generated by the Ventrain.

However, if used correctly, the Ventrain provides positive pressure ventilation with controlled expiration with a minute volume of up to 7.1 $l \cdot min^{-1}$, an increase in minute volume of 112% at a compliance of 100 $ml \cdot cmH_2O^{-1}$ compared with the minute volume achievable through a narrow-bore catheter with passive expiration. This minute volume would not only be enough for re-oxygenation, but it would also prevent hypercarbia in most adults. The value of the Ventrain compared with ventilation with passive backflow is influenced by pulmonary compliance and upper airway resistance. The Ventrain is proved to be most efficient at a high compliance, whereas a decrease in pulmonary compliance limited the effect of expiratory assistance. However, at a compliance of a healthy adult patient (50 $ml \cdot cmH_2O^{-1}$), the minute volume at an oxygen flow of 15 $l \cdot min^{-1}$ was still 6.9 $l \cdot min^{-1}$. EVA can be regarded as a hybrid technique for narrow-bore ventilation between intermittent positive pressure ventilation with passive expiration, which requires a wide-bore and sealed airway, and conventional 'jet ventilation' through a narrow-bore catheter, which requires an open upper airway. The Ventrain applies EVA efficiently *in vitro*. If ongoing studies confirm the safety and efficacy of this ventilation ejector in vivo, it may become a beneficial tool in modern airway management, for example, as a portable ventilator for transtracheal emergency ventilation.

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Declaration of interest

A.H. is 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. D.E. is the inventor of the Ventrain and receives royalty payments from Dolphys Medical, Eindhoven, The Netherlands. Also the Maastricht University Medical Centre receives royalty payments from Dolphys Medical.

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Chapter 8

General discussion

Maintaining adequate oxygen supply to the tissues and removal of carbon dioxide from the lungs is essential to sustain life. The inability to oxygenate via mask or supraglottic airway device in a patient in which endotracheal intubation attempts have failed, is one of the most severe emergencies in anaesthesia, intensive care medicine and emergency care. Immediate insertion of a percutaneous emergency airway can prevent hypoxic brain damage and death in a 'cannot intubate, cannot oxygenate' (CICO) situation [1, 2]. Inserting a narrow-bore catheter or cannula through the cricothyroid membrane is for the majority of anaesthetists the first-choice [3], as this technique is widely available and suggested to be simple and quick [4]. However, the increased flow resistance of these catheters requires a ventilator with a high driving pressure [5] and a patent upper airway to assure the egress of gas. Obstruction of the upper airway caused by laryngospasm, oedema or anatomical distortion, and overvigorous oxygen insufflation can result in air trapping. Many cases of barotrauma and haemodynamic instability associated with deleterious outcome using this type of ventilation are reported in the literature [6-8]. Therefore, within the scientific community, there is a lot of controversy on how to ventilate safely and efficiently in an emergency situation [9, 10].

The aims of this thesis were to investigate potential drawbacks of the currently available emergency jet ventilation devices and to develop a new ventilation mode controlling and facilitating expiration through a narrow-bore catheter.

Aim 1: Are self-assembled emergency jet-ventilation devices safe?

In elective surgical cases a conventional jet ventilator (e.g. a manual Sanders ejector or an automated high frequency jet ventilator) is used to achieve adequate ventilation through a narrow-bore cannula. These devices are often not immediately available in emergency situations. Therefore, various simple, self-assembled devices made of a three-way stopcock and oxygen tubing, have been proposed for emergency jet ventilation [11-13]. When connected to a high-pressure, flow-regulated oxygen source these devices do transmit sufficient pressure and flow to allow effective low frequency jet ventilation by intermittent occlusion of the side port of the three-way stopcock [12, 14]. However, during emergency jet ventilation it is mandatory that flow from the oxygen source is stopped (as in the conventional jet ventilators) or adequately released through the side port of the emergency jet device during the expiration phase.

As shown in chapter 2, a three-way stopcock based, self-assembled device acts as a 'flow splitter' and, when connected to an oxygen flow, even with the side port completely open, never ensures total flow and pressure release. In a completely obstructed upper airway, the oxygen flow will inevitably create high airway pressure during the expiratory phase that can lead to barotrauma and hemodynamic instability. Thus, the use of a three-way stopcock device to control oxygen flow during emergency jet ventilation, as described in current textbooks and recent literature, has a potentially dangerous effect and should not be recommended. Moreover, when comparing different devices, only the commercially available Oxygen Flow Modulator ensured sufficient flow and pressure release.

Aim 2: Which emergency jet-ventilation device can function as a bidirectional airway?

Transtracheal jet ventilation has a low morbidity as long as the egress of gas is secured [4]. As conventional jet ventilators have a mechanical one-way valve incorporated, no gas will egress through the transtracheal catheter and a patent upper airway is mandatory to assure efficient and safe ventilation. When the upper airway is obstructed, jet ventilation results in air trapping [15] with subsequent lung damage by over-distension and haemodynamic instability [6-8]. In a clinical emergency it is usually unknown whether the airway of the patient is patent or opens at a higher airway pressure. Therefore, it is crucial that every device used in a CICO situation is not only able to provide effective flow release and pressure control, but also allows bidirectional airflow. Only under these circumstances, the injection of oxygen and the egress of gas can take place through the same airway catheter.

The self-assembled jet ventilation devices studied in Chapter 2 did not ensure total flow and pressure release during the expiratory phase. However, changing the connecting position of the transtracheal catheter on the three-way stopcock from the in-line port (as in chapter 2) to the side port (device B in chapter 3) resulted in a slightly negative pressure at the catheter's tip (Chapter 3). This improves the safety of the emergency ventilation device because under these circumstances device B allows bidirectional airflow. So even in a fully obstructed upper airway air can escape. This is in contrast to the conventional jet ventilators that fully block the egress of gas through the catheter and need to be disconnected from the catheter to allow any air to escape in an obstructed airway. The negative expiratory pressure created by device B did however not improve the egress of gas through the narrow-bore catheter compared to passive

outflow. All devices tested impeded the expiratory outflow and hence decreased the achievable minute volume.

Aim 3: Feasibility of expiration through a narrow-bore cannula by suction.

Passive outflow of gas through a narrow-bore transtracheal catheter is limited because of the high internal resistance of the catheter and the low driving force for the egress of gas. The time necessary for the egress of 1000 ml of oxygen via a catheter with an internal diameter of 2 mm is 13.4 seconds. An increase of flow through a small-bore catheter during expiration can only be performed via three mechanisms: First, the driving force can be increased, for example by applying compression to the thorax and abdomen. Second, the resistance of the outflow tract can be diminished, by inserting an additional transtracheal catheter. Third, it has been suggested to augment the outflow of gas by applying external suction [16-18]. In pediatric ventilation this third option has shown to be very useful [19]. However, in emergency ventilation in adults none of the proposed techniques and devices found their way into clinical practice, because they were not effective or too complex to use.

To solve this problem, we developed an alternative ventilation mode and constructed a simple emergency ventilation device. This device was based on an ejector. In principle, an ejector is a multipurpose device able to create a subatmospheric pressure via the Bernoulli principle and to entrain air from a side port [20]. A small, industrial ejector was transformed into a simple, manual ventilator providing oxygen insufflation and expiratory ventilation assistance (EVA) induced by suction. This device was able to shorten the expiration time significantly and achieved a calculated expiratory minute volume up to 6.6 $l \cdot min^{-1}$ through a 2 mm ID transtracheal catheter in a simulated obstructed airway.

Aim 4: Technical features necessary to optimize the entrainment effect for Expiratory Ventilation Assistance (EVA).

Bernoulli's principle implies that for an inviscid flow of a non-compressible (or, with restrictions, a compressible) fluid, an increase in velocity at a constriction in a tube leads to an increase in dynamic pressure (and thus kinetic energy) and a corresponding decrease in static pressure (and potential energy). This is in accordance with the first law of thermodynamics (conservation of energy) [21]. Our results illustrate that the amount of entrainment and consequently the degree of expiratory assistance depend on the velocity of the driving gas and the resistance of the outflow tract of the ejector. Although an ejector's resistance to flow is primarily defined by its inner geometry, the velocity of the driving gas jet passing through the ejector modulates the effective resistance while the ejector is active. If, at a given flow, the velocity of the driving gas is decreased (e.g. by turbulent mixing with entrained gas), an ejector will become less efficient. In most industrial ejectors and also in a previously described ventilation ejector [22] the outflow tract has been designed to create a maximum subatmospheric pressure. The results of our study show that an industrial ejector (SBP07) is indeed capable of generating a high negative pressure in a static situation, that is, if no gas is entrained. However, in a dynamic situation, when gas is continuously entrained through the transtracheal catheter, the generated pressure was considerably less negative. Compared with the industrial ejector, our ventilation ejector (prototype DE5) built up a less negative pressure in a static situation, but maintained a higher negative pressure in a dynamic situation, leading to an improved suction capacity and a higher entrainment ratio. Our ventilation ejector was designed to provide an optimized entrainment effect for EVA

and achieved a minute volume of up to 8.3 litres through a 75 mm long, 2 mm ID transtracheal catheter. So, Expiratory Ventilation Assistance (EVA), when applied by an optimized ventilation ejector, can achieve a minute volume adequate for normoventilation of an adult patient through a 'straw'.

Aim 5: Efficiency of EVA on restoring oxygenation and ventilation.

In six monitored and anaesthetized pigs a narrow-bore transtracheal catheter was placed under controlled circumstances. Following baseline recordings the pigs were exposed to 2 minutes of apnoea and the endotracheal tube was occluded. The oxygen saturation decreased to a median of 45% [range 33-60%]. EVA was applied via the transtracheal catheter using the DE5 prototype. Within 20 seconds after the initiation of EVA, hypoxemia was corrected (SaO_2 > 95%) in all animals. In the second part of the study, the experiment was repeated with a partly obstructed or open endotracheal tube, simulating different levels of upper airway patency. Under conditions of a partly obstructed endotracheal tube, EVA restored oxygenation again within 20 seconds (SaO_2 > 95%). However, when the airway was left completely open, 2 animals still had an oxygen saturation below 90% after 15 minutes. The efficacy of EVA decreased as the endotracheal tube was less obstructed resulting in protracted re-oxygenation and severe hypercarbia when the airway is open. Our results demonstrate that the adapted ventilation mode (EVA) applied by our optimized ventilation ejector can achieve rapid re-oxygenation and efficient ventilation through a narrow-bore catheter in an obstructed airway.

Aim 6: To evaluate the efficacy of Ventrain®: a commercially available emergency ventilator applying EVA

The novel emergency ventilation ejector introduced and evaluated in chapter 7 (commercial name: Ventrain®) turns a high driving pressure (up to 2.3 bar) at the jet nozzle into a high velocity oxygen stream and creates a subatmospheric pressure up to -217 cmH_2O to facilitate the egress of gas. The driving pressure, inspiratory pressure and degree of expiratory assistance of the Ventrain® are flow-dependent. The maximum suction capacity was reached at an oxygen flow of 15 $l \cdot min^{-1}$. Although the Ventrain® is a high-pressure ventilation device, the insufflation pressure proximal to the transtracheal catheter (maximum 138 cmH_2O) is significantly lower than the pressure used for conventional 'jet ventilation'. In the bench study the Ventrain® achieved a minute volume of up to 7 $l \cdot min^{-1}$ through a 2 mm ID transtracheal catheter and seems an efficient ventilation ejector.

Based on our studies we can conclude that all available self-assembled emergency jet ventilation devices, with the exception of the OFM, cannot be used safely in a CICO situation, as there is always a risk of upper airway obstruction. Expiratory Ventilation Assistance (EVA), however, enables normoventilation through a narrow-bore airway catheter, minimizes the risk of air trapping and achieves rapid reoxygenation in pigs with an obstructed airway. The concept of EVA is successfully implemented in a novel commercially available emergency ventilation device: Ventrain®.

Should EVA via Ventrain® be integrated in standard clinical recommendations for management of a 'cannot intubate, cannot oxygenate' situation?

Narrow-bore cannula insertion with jet ventilation is included in the guidelines of the Difficult Airway Society (DAS) and American Society of Anesthesiologists (ASA) as an option for achieving swift re-oxygenation in a CICO situation. However, the fourth UK National Audit Project (NAP4) reports a series of cases where narrow-bore cricothyroidotomies had a very low success rate (37%), whereas surgical percutaneous access was successful in all cases [23]. These results stimulated the debate on the dilemma of whether or not to attempt insertion of a narrow-bore cannula. Several recent publications have questioned the role of narrow-bore cricothyroidotomy and advised placement of a large-bore cannula in an airway emergency [2, 24, 25].

The rate of successful re-oxygenation via a narrow-bore cricothyroidotomy reported in the literature varies between 37 and 66% [23, 26]. This low success rate might be inherent to the technique, but is also suggested to be a consequence of lack of training and inadequate equipment [23]. Various studies and surveys indicate that most anaesthetists are not prepared for performing an emergency percutaneous airway. Moreover, knowledge on the technique and availability of the necessary equipment to ventilate through a narrow-bore catheter is often inadequate [3, 27, 28]. Self-assembled ventilation devices are inefficient and as discussed in this thesis use in an emergency case can even result in serious complications. The application of EVA via the Ventrain® device will provide swift re-oxygenation as it achieves a minute volume of 7 litres through a narrow-bore cricothyroidotomy cannula and minimizes the risk of airtrapping.

Besides appropriate equipment, the skills of a trained professional able to make the decision to perform an emergency percutaneous airway and then performs this procedure successfully before the patient suffers irreversible brain damage or death is needed. Surgical cricothyroidotomy is a reliable technique with a high success rate, but is often performed too late to avoid a poor outcome [29]. The time needed to reach sufficient re-oxygenation is of critical importance. Thus, delayed decision-making in CICO is a common reason for bad outcome [23, 30]. Reluctance to perform a cricothyroidotomy (ie, human factors reasons) is most likely the primary cause for delay [31]. Anaesthetists are naturally reluctant to perform an emergency percutaneous airway [32]. However, in general, they feel more comfortable inserting a narrow-bore cannula (needle cricothyroidotomy) when compared to a large-bore cannula and have low confidence in performing a surgical airway themselves [3].

With the introduction of EVA and Ventrain® we need to change the focus of the debate on small-bore versus large-bore cricothyroidotomy. Both cricothyroidotomy techniques now allow efficient and safe ventilation, but there may be differences in the speed of insertion, the success rate and the incidence of complications of cannula placement. Furthermore, the level of experience needed, the familiarity of the operator with the technique and the time needed to teach and retain the skills may differ between small and large-bore cricothyroidotomy.

Unfortunately, there is not sufficient evidence so far to answer the above questions. Future research should compare small-bore versus large-bore cannula placement by anaesthetists and should focus on the ease of use of Ventrain® in an emergency situation and the retention of skills of performing a surgical cricothyroidotomy and of applying

EVA. As a CICO situation is a rare complication, it seems questionable whether a clinical study on this subject is feasible. Thus alternative studies including scenario simulation research need to be performed.

However, successful cricothyroidotomy and swift re-oxygenation in an airway emergency perhaps relies more on the operator's general clinical experience, practice and skills than on the devices themselves [33]. Whatever emergency technique is chosen, it is essential that the equipment is readily available, the anaesthetic team is familiar with its use and is trained regularly. Coming back on the question at the beginning of this paragraph: should EVA via Ventrain® be an integral part of standard clinical recommendations for management of a 'cannot intubate, cannot oxygenate' situation? Should this technique be available on the OR and be trained by the anaesthetic team? The strength of current evidence does not justify recommending one cricothyroidotomy technique over the other. However, for emergency ventilation through a narrow—bore cricothyroidotomy catheter, EVA is the safest ventilation mode available. For anaesthetists, insertion of a narrow-bore airway catheter and subsequent use of EVA by Ventrain® is a sensible first choice to achieve swift re-oxygenation under CICO conditions.

EVA as a new ventilation mode

It needs to be emphasized that EVA is not just a "modified" type of jet ventilation. Flow-controlled EVA for ventilation through small-bore cannulas can be considered a hybrid technique in between intermittent positive pressure ventilation with passive expiration, which requires a wide-bore tube and sealed airway, and jet ventilation through a narrow-bore catheter, which requires high injection pressures and an open upper airway. Although at its introduction the indication for EVA was deliberately and cautiously limited to emergency ventilation, the ability of controlling the expiration and achieving a sufficient respiratory minute volume of 7 litres through a narrow-bore catheter in a blocked airway allows for a new array of clinical applications and offers a source for many interesting research questions.

Two application features of EVA can be distinguished:

1 **The possibility of fully ventilating through a narrow-bore catheter while blocking the rest of the airway.**
EVA can be used for ventilation through narrow-bore catheters. In this thesis the results in combination with a transtracheal catheter are reported. However, one can also apply EVA with other airway catheters. This might offer new treatment options for patients with an airway stenosis, could improve the surgical view during a procedure in the airway, and might lower the laryngeal morbidity associated with endotracheal intubation. One could even place narrow-bore cuffed catheters in the main bronchi to ventilate both lungs separately. This could mean an important advantage in thoracic surgery, but also in critically ill patients with an acquired respiratory disease, cystic fibrosis, infectious diseases or pathology of one lung.
Currently, Ventrain® is the only commercially available ventilation device able to apply EVA. It is manually operated, can only insufflate 100% non-humidified oxygen and has no pressure reading. Therefore, long-term use is still problematic and thus the above-mentioned clinical applications are not well feasible yet. An electronic ventilator with EVA incorporated is mandatory to study these clinical and experimental applications.
There are, however, several clinical situations in which EVA via Ventrain® has additional value compared to

existing ventilation modes. Its use might already be considered in clinical practice for ventilation through:

- a jet ventilation catheter in case of failure of jet ventilation due to airtrapping in an obstructed airway,
- a tube exchanger for reoxygenation while managing a difficult airway,
- the working channel of a flexible intubation scope in case of desaturation while performing endoscopy and intubation, and
- transtracheal cannulas in elective laryngeal surgery in patients with a large space occupying lesion with a high risk of jet ventilation failure (see Epilogue).

2 **Controlling expiration**

Using EVA it is possible to control the expiration. EVA can increase the expiratory flow, shortens the expiration time and can create negative end expiratory pressure if desired. Furthermore, the EVA ventilation mode produces distinct flow and pressure curves and has different ventilation properties compared to conventional ventilation modes. These features may have a beneficial effect on venous return, pulmonary circulation and cardiac output and may create different shear stress patterns. EVA could provide a novel strategy of lung-protective ventilation.

It is fascinating to hypothesize about the potential applications of the EVA principle and as Prof. William Rosenblatt, Yale University stated:

"The limitation of EVA is probably your own imagination"

Conclusion

Expiratory Ventilation Assistance (EVA) is introduced as a new ventilation mode for ventilation through narrow-bore catheters in an obstructed airway. The concept of EVA is successfully implemented in a novel commercially available emergency ventilation device: Ventrain®. Ventrain® is a valuable tool for ventilation through a narrow-bore catheter in an airway emergency. The full potential of EVA within modern airway management, including elective routine use, has yet to be explored.

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Epilogue

The use of expiratory ventilation assistance in clinical practice

Ventrain® for ventilation of the lungs
Pieter Borg, Ankie Hamaekers MD, Martin Lacko MD PhD, Jochen Jansen MD PhD and Dietmar Enk MD PhD

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Case Report

Editor—Ventrain (Dolphys Medical, Eindhoven, The Netherlands) has been registered as an emergency ventilation device (Fig. 1) [1]. We report its use in an ENT patient.

A 60-yr-old man with an exophytic glottis tumour and significant inspiratory stridor presented for diagnostic laryngo-tracheo-bronchoscopy and possibly tracheostomy. Several options were considered for management of the airway.

First, high-frequency jet ventilation (HFJV) is the routine ventilation technique in our hospital for diagnostic laryngoscopies. Usually, a narrow-bore jet ventilation catheter is introduced via the nose into the trachea with the help of a Magill forceps, guided by routine direct laryngoscopy. The second option was routine (flexible) laryngoscopy and (awake) tracheal intubation with a wide-bore (≥4 mm ID) tube over a flexible bronchoscope, gum elastic bougie, or Aintree intubation catheter. However, both the options carry the risks of bleeding and swelling of the tumour, making an emergency

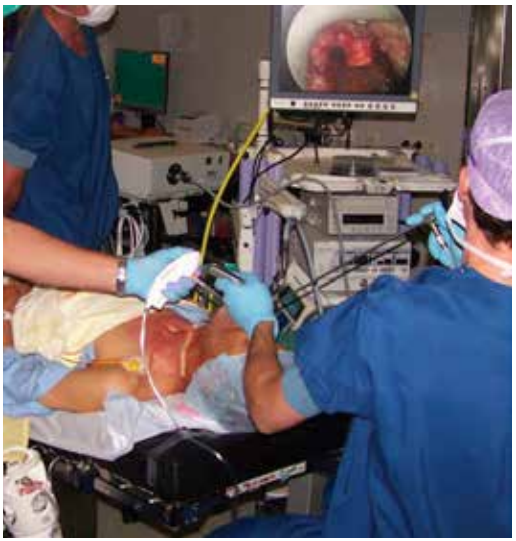

Figure 1 Ventrain being used for an elective laryngoscopy.

tracheostomy more likely in a situation with pre-existing serious stridor. The third option would be an elective awake wide-bore tracheostomy, having a higher success rate than an emergency procedure, but this may be unnecessary and is not preferable from the oncological point of view.

Fourthly, introducing a narrow-bore cannula through the cricothyroid membrane into the trachea to apply HFJV is also a common procedure in our hospital. It creates a temporary, minimally invasive access to the airway below the level of the obstruction. However, any jet ventilator is a unidirectional device only providing inspiration, so expiration by the natural upper airway is mandatory. A large tumour might hinder expiration, leading to air trapping, with the risks of barotrauma and the inability to ventilate efficiently. In contrast, the Ventrain is capable of controlling both inspiration and expiration through a narrow-bore catheter and might thus reduce the risk of air trapping. We agreed on using this option as it is minimally invasive and safe compared with the other techniques and furthermore leaves all therapeutic options intact.

It was explained to the patient that a cannula would be introduced in the neck in order to ventilate the lungs throughout the procedure. The patient consented and was quiet and cooperative all the time. After local infiltration and injection of 3 ml 4% lidocaine into the trachea, a 2 mm ID, 75 mm long emergency transtracheal airway catheter (ETAC; Cook Medical, Bloomington, IN, USA) was introduced via the cricothyroid membrane and its intratracheal position was confirmed by aspiration of air and by capnography. The Ventrain was then connected to the ETAC and to a 2 litres oxygen cylinder with a built-in pressure compensated flow regulator set to 15 $l \cdot min^{-1}$. General anaesthesia was provided by our standard procedure: initially, propofol and remifentanil boluses and subsequently continuous pump-driven infusion combined with boluses of cisatracurium, gauged by train-of-four monitoring. Ventilation with the Ventrain (2 seconds each for inspiration and expiration, thus a frequency of 15 min^{-1}) produced moderate, but clearly visible, thoracic excursions with the chest always returning to its original shape. Temporarily closing nose and mouth led to greater excursions, but not to air trapping. Laryngoscopy by the ENT surgeon revealed left-sided vocal paralysis besides the large glottic tumour, explaining the inspiratory stridor at least in part. Laryngoscopy and biopsies lasted 15 minutes. SpO_2 was 100% throughout. After the surgical procedure, the syringe drivers were stopped, the neuromuscular blocking agent was reversed, and ven-

tilation was reduced by lowering the driving oxygen flow to 5 $l \cdot min^{-1}$, to raise the PCO_2. Capnography was connected to the Ventrain and spontaneous ventilation started at an end-tidal PCO_2 of 6.3 kPa. The patient woke up quietly. The Ventrain was disconnected and the ETAC was left in position and was only removed 6 hours later on the post-anaesthesia care unit, when it was clear there was no increase in inspiratory stridor by swelling or bleeding. The whole procedure was uneventful. The diagnostic information gathered led to the decision to start radiotherapy.

In conclusion, we report the successful and uneventful elective use of the Ventrain with 20 minutes of adequate ventilation and oxygenation in a patient with a partial obstruction of the laryngeal inlet.

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Appendices

Summary

The inability to maintain oxygenation in a patient by non-invasive airway maneuvers is one of the most pressing emergencies in anaesthesia and emergency care. To prevent hypoxic brain damage and death, emergency percutaneous airway access must be performed immediately. In the **prologue** a case of a 'cannot intubate, cannot oxygenate' (CICO) situation is described. In this case a narrow-bore catheter was successfully inserted in the airway and oxygen could be insufflated into the lungs. However, a new problem arose as it was impossible to provide an adequate outflow of the gas, which resulted in air trapping and haemodynamic instability.

The various techniques, strategies and equipment available for emergency oxygenation are described in **chapter 1**. Unfortunately all available techniques have their limitations and the ideal rescue technique for a CICO situation seems not yet to exist. Although a narrow-bore cricothyroidotomy catheter is easy to insert and anaesthetists generally feel comfortable placing it, reoxygenation and ventilation through a narrow-bore catheter poses new challenges. In order to overcome the resistance of a narrow cannula, a high-pressure oxygen source is necessary for achieve adequate flow through the narrow cannula.
Because an automated or hand-triggered jet injector may not be immediately available, various self-assembled devices consisting of a three-way stopcock and oxygen tubing have been proposed for emergency jet ventilation through a narrow-bore airway catheter. Combined with a high oxygen flow, these devices are generally supposed to provide adequate pressure and flow for emergency reoxygenation. However, as shown in the bench study described in **chapter 2**, a three-way stopcock based, self-assembled device acts as a 'flow splitter' and, when connected to an oxygen flow, even with the side port completely open, never ensures total flow and pressure release. In a completely obstructed upper airway, the oxygen flow will inevitably create high airway pressure during the expiratory phase that can lead to barotrauma and hemodynamic instability. Thus, the use of a three-way stopcock device to control oxygen flow during emergency jet ventilation, as described in current textbooks and recent literature, is potentially dangerous and should not be recommended.

When using an automated or hand-triggered jet injector it is mandatory to maintain a patent upper airway for the egress of gas. Obstruction of the outflow tract or insufficient expiratory time results in air trapping with subsequent barotrauma and haemodynamic instability as described in the prologue. In a CICO situation partial obstruction of the upper airway, resulting from oedema, laryngospasm or distorted anatomy occurs frequently and it is uncertain whether the upper airway will open at a higher airway pressure. Therefore, it is crucial that a device used in a CICO situation is not only

able to provide effective flow release and pressure control, but also allows bidirectional airflow. The self-assembled jet ventilation devices studied in Chapter 2 did not ensure total flow and pressure release during the expiratory phase. However, changing the connecting position of the transtracheal catheter on the three-way stopcock from the in-line port (as in chapter 2) to the side port (device B in **chapter 3**) resulted in a slightly negative pressure at the catheter's tip. This improved the safety of the emergency ventilation device as it allowed bidirectional airflow. So even in a fully obstructed upper airway gas could escape.

Passive outflow of gas through a small-bore catheter is limited because of the high internal resistance of the catheter and the low driving force for the egress of gas. The time needed for passive backflow of 1000 ml oxygen through a catheter with an internal diameter (ID) of 2 mm is 13.4 seconds. To facilitate the outflow external suction can be applied during the expiratory phase. In pediatric ventilation this has shown to be very useful. However, in emergency ventilation in adults none of the proposed techniques and devices found their way into clinical practice, because they were not effective or too complex to use. In **chapter 4** a small, modified industrial ejector is introduced for applying Expiratory Ventilation Assistance (EVA). An ejector is a multi-purpose device able to create subatmospheric pressure based on Bernoulli's principle. Comparable with a Venturi nozzle, the driving gas flowing through an ejector entrains gas (e.g. ambient air) through a side port. The modified ejector was able to shorten the expiration time significantly and achieved a calculated expiratory minute volume through a 2 mm ID transtracheal catheter in a simulated obstructed airway up to 6.6 $l \cdot min^{-1}$.

An industrial ejector is designed to create a maximum negative pressure to pick up and hold parts during manufacturing processes in industrial assembly lines. It cannot be expected to work perfectly as a ventilator. In **chapter 5** the technical features and abilities of the modified industrial ejector and an optimized ejector-based ventilation device (DE5) are described. The results illustrate that the amount of entrainment and consequently the degree of expiratory assistance depend on the velocity of the driving gas and the resistance of the outflow tract of the ejector. The optimized DE5 achieved a calculated minute volume up to 7.5 l·min-1 through a 2 mm ID transtracheal cannula in an artificial lung model with complete outflow obstruction

In severely hypoxic pigs with a completely obstructed airway EVA, applied by the DE5, restored oxygenation through a small-bore transtracheal catheter within 20 seconds and kept PCO_2 stable (**chapter 6**). EVA was found to be less efficient in a setting simulating a completely open airway. As airway patency increased re-oxygenation was delayed and severe hypercapnia developed.

Based on the optimized prototype for EVA (DE5, chapter 5), a portable, flow-regulated, manually operated, and ergonomically shaped ventilation device was developed: Ventrain® (Dolphys Medical BV, Eindhoven, The Netherlands).

The results of the bench study as described in **chapter 7** show that the degree of expiratory assistance is flow-dependent, with a maximum suction capacity of 12.4 $l \cdot min^{-1}$ at an oxygen flow of 15 $l \cdot min^{-1}$. At this flow rate Ventrain® can achieve through a 2 mm ID transtracheal catheter a minute volume of 7.1 litres. This minute volume would not only be enough for swift re-oxygenation, but it would also prevent hypercarbia in most adults. In a CICO situation use of EVA by Ventrain® would be the most efficient and safest technique currently available to reoxygenate the patient through a narrow-bore transtracheal catheter.

Expiratory Ventilation Assistance (EVA) is introduced as a new ventilation mode for ventilation through narrow-bore catheters in an obstructed airway. The full potential of EVA within modern airway management, including elective routine use, has yet to be explored. The general discussion (**chapter 8**) focuses on the possible role of EVA by Ventrain® in emergency ventilation and on potential future applications of EVA as a new ventilation mode for airway surgery, single lung ventilation and lung-protective ventilation strategies.

Valorisation addendum

The focus of this thesis was on the management of a 'cannot intubate, cannot oxygenate' (CICO) scenario. This is a clinical situation wherein attempted tracheal intubation has failed and oxygenation cannot be maintained by non-invasive means. If not corrected rapidly hypoxia will inevitably lead to brain damage and death. The incidence of CICO in general anaesthetic practice is low. The 4th National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society (NAP4) reported a calculated incidence of emergency percutaneous airway of 1 in 50,000 general anaesthetics. However, the incidence is strongly influenced by clinical setting and case-mix, and an incidence as high as 11% has been reported in the pre-hospital setting.

The clinical impact of the work described in this thesis is three-fold. Firstly, one of our studies revealed a potential hazard of currently recommended practice. Various simple, self-assembled devices made of a three-way stopcock and oxygen tubing have been proposed in standard anesthesia textbook for emergency jet ventilation. The assembling of these devices was also taught on several national and international airway and emergency courses (including ATLS). We tested the proposed devices and noticed that they carried an intrinsic risk as the they didn't control the oxygen flow to the patient. We concluded that the self-assembled devices based on a three-way stopcock, as described in the textbooks, should not be used in a CICO situation. The results of our study let to a change in the learning objectives of many airway course, are included in updated airway algorithms and are already referred to in some anesthesia textbooks.

The second part of this thesis focused on the introduction of a new ventilation mode called expiratory ventilation assistance (EVA). Flow-controlled EVA is used for ventilation through small-bore cannulas and can be considered a hybrid technique in between intermittent positive pressure ventilation with passive expiration, which requires a wide-bore tube and sealed airway, and jet ventilation through a narrow-bore catheter, which requires high injection pressures and an open upper airway. The ability of controlling the expiration and achieving a sufficient respiratory minute volume of 7 litres through a narrow-bore catheter in a blocked airway allows for a new array of clinical applications. The full potential of EVA within modern airway management, including elective routine use for airway surgery, single lung ventilation and lung-protective ventilation, has yet to be explored.

Thirdly, probably the most evident impact on current clinical practice of this thesis is the development of an emergency ventilation device using EVA. Based on the optimized prototype for EVA (DE5, chapter 5), a portable, flow-regulated, manually operated, and ergonomically shaped ventilation device was developed by Dolphys Medical. The Ventrain® (Dolphys Medical BV, Eindhoven, The Netherlands) is available in Europe, Australia and the United States. Several

case reports of adults and children that have been rescued by emergency oxygenation using the Ventrain® illustrate the importance of the work described in this thesis.

In addition to the risk reduction for the patient and of course the commercial benefits this thesis has an important implication for all physicians responsible for securing the airway and maintaining oxygenation. For us it is a relief to know that when you get into serious difficulties insertion of only a 2 mm airway catheter will be sufficient to get control over the situation again.

Curriculum vitae

Ankie Hamaekers was born in Geleen, The Netherlands on August 8th 1975. In 1993 she graduated at Stella Maris College in Meerssen and enrolled into the study of Medicine at Maastricht University. Before obtaining her master degree she did a research elective of 11 months at the research group of professor Marc Hanson at the University College London. In 2000 she finished medical school and graduated with honors. She worked for a period of almost one year as a physician at the department of cardiothoracic surgery before beginning her residence training in anaesthesia at the Maastricht University Hospital. After finishing her training in 2006 she became a staff member at the same department.

Her interest in airway management was evoked by a dramatic case of an emergency tracheostomy during her residency. Under the guidance of Pieter Borg she entered into the "world of airway management" and developed her clinical and teaching skills. She joined the project "Ventilation through a straw" initiated by Thomas Goetz and Dietmar Enk and together with Pieter Borg they conducted the research that led to this thesis.

In the last five years Ankie was course director, instructor and guest faculty for numerous national and international airway management courses and served on a few medical advisory and executive boards. Furthermore, she wrote several book chapters regarding different topics in airway management.

Although her research has focused on a specific technical part of airway management, she has always been interested in the non-technical aspects of anaesthesia. Whether it was teaching CRM to clinicians, talking about the second victim effect or discussing patient-centered care, these topics gave her energy and drive. Her future focus will, therefore, be more on the "soft" aspects of anaesthesia and empowering the heart in anaesthestic and medical care.

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Abstracts

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Awarded top 2 best oral presentation

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