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Combitube[®] for Emergency Cesarean Section under General Anesthesia. Case Reports.

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ABSTRACT

Objective: Airway-related problems represent the most frequent cause of death among women who die from a complication of general anesthesia for cesarean section (GACS). The Combitube has been introduced as a reliable alternative in patients with difficult airways. We report two cases of emergency cesarean section under general anesthesia in which an ETC 37 F SA (Small Adult) was used for airway management as primary device.

Case reports: In a 17-yr-old, obese pregnant woman an acute severe fetal bradycardia did not allow time for spinal blockade. Therefore, general anesthesia was induced, maternal airway management was performed using a facemask airway and applying the Sellick maneuver. After childbirth, an ETC 37 F SA was blindly inserted into the esophagus while maintaining cricoid pressure. Ventilation and

oxygenation were adequate. In a 27-yr-old deaf-mute pregnant woman, fetal heart rate suddenly became pathologic suggesting AFD. She was taken to the OR for c-section and a spinal blockade was performed. Soon after beginning of surgery, the patient demonstrated clear signs of pain. Therefore, general anesthesia was induced, ventilation was performed via an ETC 37 F inserted in the esophagus under laryngoscopic guidance. No postoperative pharyngeal symptoms and no respiratory complications were detected in both cases.

Conclusion: The main communication of this report is that ETC allowed adequate ventilation and airway protection for emergency GACS in this group of patients. In addition, the ETC was quickly inserted both blindly and with laryngoscopic guidance.

Key Words: Combitube, cesarean section, emergency, general anesthesia, difficult airway

INTRODUCTION

Airway-related problems represent the most frequent cause of death among women who die from a complication of general anesthesia for cesarean section (GACS). Although rate of maternal death from complications of GACS remains low, it has increased despite an apparent decrease in the use of GACS and despite the widespread use of pulse oximetry and end-tidal capnography (1,2). In addition, hypoxic cardiac arrest following failed intubation has superseded deaths attributable to aspiration (3). This suggests that the problems remain adequate ventilation and airway management itself. In our country, there are no official recordings of maternal mortality attributable to airway problems during GACS, but legal litigations against anesthesiologists have increased in the last years.

In recent years, some developments provided new tools for safer procedures. Among these, the Esophageal-Tracheal Combitube (4,5) (ETC, Tyco-Kendall, Mansfield, MA) has raised as a reliable alternative for management of failed intubation/ventilation cases. The ASA algorithm recommends its use for difficult airway management (6).

The ETC is a double lumen airway that can be inserted in the trachea or the esophagus, allowing ventilation in both cases. It is mainly used in out-of-hospital rescue but there is increasing experience in the anesthesiologic setting, in which the ETC has demon-

strated some interesting features (7,8). These include among others, reliable airway protection against regurgitation and aspiration of gastric contents, high successful insertion/ventilation rates and allowance of blind or laryngoscopic insertion. In the obstetric setting, only one report of experience has been published (9).

We report two cases of emergency cesarean section under general anesthesia in which an ETC 37 F SA (Small Adult) was used for airway management as primary device. These cases were not adjusted to a protocol but they were the result of personal experience with the device. All patients had normal airways as previously evaluated an equipment for endotracheal intubation was ready in case of failure of airway management with ETC.

CASE REPORTS

Patient 1. A 17-yr-old, 82-kg, gravida 1 para 0, obese patient (weight/height index=34) presented at term with spontaneous labor. During the early step of labor and without neuraxial blockade, fetal heart rate suddenly became pathologic suggesting AFD. Conventional measures did not work and the patient was quickly taken to the OR for surgical delivery. Because of severe fetal bradycardia, there was no time for spinal blockade and general anesthesia was induced with 200 mg thiopental and 100 mg succinylcholine IV. The critical fetal situation only allowed maternal airway management using a facemask airway

and applying the Sellick maneuver. After childbirth, an ETC 37 F SA was blindly inserted into the esophagus while maintaining cricoid pressure. Ventilation was adequate (SpO₂ >98%, ETCO₂ 33-35 mm Hg). Anesthesia was maintained with sevoflurane in O₂ 100% adding 150-µg fentanyl and 20 mg vecuronium. Newborn Apgar score (1-10) was 9 at 1st and 5th minute, with cordal pH of 7.28. Once surgery finished, ETC was uneventfully withdrawn. No postoperative pharyngeal symptoms and no signs suggesting aspiration of gastric contents were detected.

Patient 2. A 27-yr-old, 67.1-kg, deaf-mute gravida 1 para 1 patient presented at term with spontaneous labor. During labor and without neuraxial blockade, fetal heart rate suddenly became pathologic suggesting AFD. She was taken to the OR for c-section and a spinal blockade was performed. Soon after beginning of surgery, the patient demonstrated clear signs of pain. Therefore, general anesthesia was induced with thiopental, without muscle relaxants. An ETC 37 F was inserted in the esophagus under laryngoscopic guidance. Sevoflurane and fentanyl were used for maintenance of anesthesia and the patient was allowed breathing spontaneously. Pulse oximetry and ETCO₂ were adequate (SpO₂ >98%, ETCO₂ 42-45 mm Hg). Newborn Apgar score was 9-9 with cordal pH of 7.39. No postoperative pharyngeal symptoms and no respiratory complications were detected.

DISCUSSION

The main communication of this report is that ETC allowed adequate ventilation and airway protection for emergency GACS in this group of patients. In addition, the ETC was quickly inserted both blindly and with laryngoscopic guidance.

During pregnancy, many well known anatomic and physiologic changes take place that influence either directly or indirectly on the patient's airway, increasing the risk of difficult intubation, aspiration of gastric contents and hypoxia (10). Furthermore, some clinical entities like pre-eclampsia and the hemolysis-elevated liver enzymes and low platelets (HELLP) syndrome may change facial and hence laryngeal edema dramatically over a short period of time. Thus, periodical evaluation of airway conditions during labor is advisable (11). Some other diseases associated with difficult intubation include obesity, diabetes mellitus, rheumatoid arthritis, and acromegaly.

Among the clinical signs that could predict a difficult intubation few help in predicting a possible difficulty and their global positive predictive value remains low in the pregnant patient (12). This is because anatomic changes affect more the glottic and tracheal tissues, which in turn might change a good laryngoscopic view into a difficult one due to severe glottic edema. In addition, as emergency situations do not allow much time to think or look for the equipment or adequate position of the patient, operators should have

an algorithm in mind and equipment immediately available to properly manage these patients.

As the tracheal tube (TT) remains the gold standard for airway management, therefore ETC should be considered as a back up device in obstetrics.

This experience with ETC has changed our approach of managing the obstetric airway, which could be summarized as follows. First, securing oxygenation of the patient is of paramount importance. Second, if first attempt of tracheal intubation fails, the ETC might be inserted directly into the esophagus without removing the laryngoscope. These patients should not be subjected to repeated attempts of tracheal intubation because increasing difficulties might be found after each attempt. On another hand, pre-eclamptic patients presenting with severe tissue edema or severe obese patients in which difficulty is suspected, the ETC might be tried first because it would provide a greater chance than the TT to secure the airway. Usually, there is no time to adequately position these patients for tracheal intubation. In case of failure of ventilation with the ETC, a laryngeal mask airway should be tried maintaining cricoid pressure after insertion and during ventilation.

Although in one of the reported cases muscle relaxants were not used, we think that an adequate depth of anesthesia and the use of "fast" muscle relaxants such as succinylcholine or rocuronium bromide are essential to avoid reflexes that might lead to vom-

iting. In addition, airway must be also secured during the anesthetic emergence, so we preclude maintaining the distal cuff inflated until airway protective reflexes are recovered. The risk of gastric contents aspiration in obstetrics should not be underestimated due to its low incidence (15), because such a complication in a previously healthy patient is always significant.

The only disadvantage of the ETC is the inability to suction the trachea. Esophageal rupture derived from active vomiting (16) is improbable to occur because with the ETC in esophageal position, the esophagus is opened to air through the ETC lumen. Therefore, gastric content will pass through the ETC lumen avoiding an increase in intraesophageal pressure leading to rupture. A similar phenomenon occurs in emergency cases of esophageal intubation with a TT when the patient vomits.

The entire cesarean section may be completed with ETC. Replacement of the ETC with a TT may be required for prolonged postoperative ventilation. The best choice for these cases is using a fiberscope. The fiberscope is introduced nasally because it is easier than the oral approach with an ETC in situ. It does not require of additional maneuvers than partially deflating the pharyngeal balloon while the inflated distal cuff keeps the esophagus sealed. Gaitini et al (17) reported that partial deflation of the pharyngeal balloon would also allow maintaining ventilation during the procedure. The fiberscope is advanced into the trachea and

the TT is threaded over the fiberoptic.

In conclusion, the ETC 37 F SA was easily inserted and provided adequate ventilation and airway protection to this group of emergency obstetric patients. Other case reports might increase the experience with ETC use in these patients to elicit more precise recommendations.

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Analysis of 500 uses of the Combitube[®]: Safety, efficacy, and maximum ventilatory pressures during routine surgery

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ABSTRACT

Objective: Evaluation of safety, efficacy, and maximum ventilatory pressures during routine surgery.

Material and Methods: 500 patients experiencing general anesthesia were enrolled into the study. Type of surgery, duration of surgery, ease of insertion, and potential complications were recorded. In addition, maximum ventilatory pressures and leaks were evaluated in this study.

Results: The Combitube worked well in all but 2 patients. Duration of surgery varied between 30 and 360 min. The Combitube happened to be placed into the esophagus in 97% of the patients. More than 95% of the blind Combitube insertions were successful at the first attempt

with an average intubation time of less than 15 seconds. Efficacy of oxygenation and ventilation of the Combitube, as evaluated by pulse oximetry and end-tidal carbon dioxide, showed an oxygen saturation of more than 95% in all cases and an end-tidal carbon dioxide between 35 and 45 mm Hg. Leak, as expressed as a fraction of the inspired volume, did not increase more than 5% up to a ventilation pressure of 50 cm H₂O.

Conclusion: The Combitube appears to be a safe and easy device which may be used whenever endotracheal intubation is not immediately possible. In addition, this study demonstrates its usefulness during routine surgery.

Key Words: Combitube, elective, safety, efficacy, maximum ventilatory pressures, routine surgery

Worldwide, conventional endotracheal intubation is the accepted gold standard for securing the airways and for proper ventilation. Due to the respective circumstances, endotracheal

intubation is not always immediately possible or advisable. Several methods and devices, among them the laryngeal mask airway (LMA), fiberoptic intubation, transilluminated stylet etc. have

been introduced as alternatives to inappropriate or failed conventional laryngoscopic endotracheal intubation. Another alternate airway is the Combitube®. The Combitube® (Tyco-Kendall Healthcare, Mansfield, MA) has been developed for emergency, difficult and routine airway management and has been tested during routine surgery (1-5), cardiopulmonary resuscitation (6-11), as well as at the intensive care unit (12). In addition, several case reports describe its efficacy as an emergency airway in critical situations (13-17). The aim of the following analysis was to determine the value of the Combitube for general anesthesia as well as its safety and efficacy during routine surgery. Furthermore, the maximum ventilation pressure guaranteeing a tight seal was evaluated by comparing.

METHODS

The study was performed during a 9 month study period at the General Hospital of Vienna. The patients enrolled into the study underwent general, gynecology, urology, and orthopedic surgery. The study was approved by the local Institutional Review Board. Since Combitube insertion is current practice, informed consent of the patients was waived.

The Combitube (www.combitube.org and www.combitube.net) is a double - lumen airway. One lumen resembles an endotracheal airway with an open upper and distal end, the second lumen resembles an esophageal

obturator airway with an open upper and a blocked distal end and perforations at the pharyngeal level. A large oropharyngeal provides sealing of mouth and nose after insertion, while the distal cuff serves to seal either the trachea or the esophagus. The Combitube is used as follows: After administration of 1.5 µg/kg fentanyl, anesthesia was induced with 2 mg/kg propofol, followed by 0.1 mg/kg vecuronium. The onset of relaxation was tested using a nerve stimulator (MiniStim MS II; Professional Instruments, Houston, TX). Insertion of the Combitube was performed after disappearance of the fourth twitch of the train-of-four. Electric activity of the heart, non-invasive blood pressure, oxygen saturation, and expired carbon dioxide levels were monitored continuously (CMS-Monitor, Hewlett-Packard Products Group, Böblingen, Germany).

The patient's head is kept in a neutral position. Then, jaw and tongue are lifted with one hand, and the Combitube is introduced in a curved downward movement until the printed ring-marks are lying between teeth or alveolar ridges. In some patients a rocking motion alleviates insertion. Now, the oropharyngeal balloon is inflated with 85 ml with the Combitube SA 37 F (patient's height: 4 to 6 feet) and 100 ml with the Combitube 41 F (patient's height: taller than 6 feet). With inflation, the Combitube is simultaneously fixed without need for a tape. Then, the distal cuff is inflated with 10 to 15 ml of air. In most cases,

the Combitube happens to be placed into the esophagus after blind insertion. Therefore, test ventilation is recommended via the longer blue connector No. 1. Air is forced via the perforations into the hypopharynx and from there over the open epiglottis into the trachea. If auscultation over the lungs is positive and epigastric insufflation negative, ventilation may be continued. If auscultation is negative, the Combitube has been inserted into the trachea: without changing the position of the Combitube, ventilation is changed to the shorter clear connector No. 2. Air now enters directly the trachea. In rare occasions, air cannot be blown neither via the esophageal nor the tracheal lumen due to the oropharyngeal balloon blocking the laryngeal aperture: Then, the Combitube has to be withdrawn for about three centimeters and ventilation to be tried again via the esophageal lumen.

Inclusion criteria were patients undergoing elective or non-elective surgery older than 19 years. Exclusion criteria were esophageal diseases, ingestion of caustic agents, obstruction of the upper airways, patients smaller than four feet, incomplete anesthesia.

Standardized protocols were used for computerized analysis. Protocols include patients characteristics such as age, sex, and ASA grade, as well as type of surgery, and duration of surgery. In addition, Combitube size (37 F or 41 F), ease of insertion with the Combitube (with a range from easy = 1 to impossible = 5), number of intubation attempts, time for insertion,

esophageal or tracheal position, possible complications (soft tissue trauma, bleeding, dental trauma, aspiration), and type of anesthesia were recorded. In twenty consecutive patients with the Combitube in esophageal position, maximum ventilation pressures were evaluated by increasing the respirator generated pressures at six different respirator settings (25, 30, 35, 40, 45, 50 cm H₂O). Flow transducers were placed in the inspiratory and expiratory limbs of the breathing circuit and the output integrated to determine inspiratory and expiratory volumes. Gastroesophageal insufflation and gas leak were qualitatively assessed by placing a stethoscope over the stomach and neck respectively during ventilation. For each ventilation pressure, presence of gas leak in the pharynx, presence of gastroesophageal insufflation, airway pressure, inspiratory and expiratory volumes were recorded.

A $p < 0.05$ was considered significant.

RESULTS

During the 9 month study period, 500 patients were enrolled in the study. Patients' age is shown in Table 1, type of surgery, and duration of surgery in Table 2, and Table 3, respectively. The mean age was 45.6 yr (19.5), there have been 264 male and 236 female patients ($p = n.s.$). ASA grades of the patients were grade I 66.3 %; grade II 33.7 %. Spontaneous ventilation was maintained in 12 % of the patients, while 88 % patients were controlled mechani-

cally ventilated. In 487 patients, the Combitube happened to be placed into the esophagus (97 %), in 13 patients into the trachea (3 %). All but 2 patients (0.4 % of the study population) could be adequately oxygenated and ventilated. The failures were due to difficult ventilation. These two patients were then intubated with a conventional endotracheal airway. More than 95 % of the blind Combitube insertions were successful at the first attempt with an average intubation time of less than 15 seconds. Efficacy of oxygenation and ventilation of the Combitube, as evaluated by pulse oximetry and end-tidal carbon dioxide, showed an oxygen saturation of more than 95 % in all cases and an end-tidal carbon dioxide between 35 and 45 mm Hg. In 51 patients (10 %) superficial laceration occurred without further sequelae. No severe traumas could be observed during the study period as evaluated by immediate postoperative laryngoscopic inspection.

The average height was 168 cm \pm 21, in 94 % of the patients the Combitube 37 F SA was used. Average ease of insertion with the Combitube was rated 1.1, number of intubation attempts, time for insertion was 10 to 25 seconds.

Leak, as expressed as a fraction of the inspired volume, did not increase more than 5 % up to a ventilation pressure of 50 cm H₂O, except in 2 patients an audible gas leak was present at a ventilation pressure of 40 cm H₂O, which disappeared after overinflation of the oropharyngeal balloon

with an additional 20 to 45 ml of air. Gastroesophageal insufflation could not be observed in the study group.

An anecdotal observation includes two singers of the Viennese opera house, who were afraid of damage of the vocal cord function during conventional endotracheal intubation. A 31 yr old female and a 39 yr old male singer underwent elective surgery lasting for 80 and 60 minutes, respectively. Both patients recovered after surgery without any vocal cord dysfunction.

DISCUSSION

All but two patients were satisfactorily ventilated with the Combitube as assessed by expiratory volumes and pulse oximetry. Results show that even with high ventilatory pressures no significant air leak occurs. In addition, there was no audible leak neither in the cervical region nor in the epigastrium. The Combitube appeared to be an efficient and safe device, no severe injuries could be observed.

Its advantages include: Noninvasive as compared to cricothyrotomy; ready to use; blind insertion possible, however, a laryngoscope may be used if desired; no neck flexion necessary; minimized risk of aspiration; simultaneous fixation after inflation of the oropharyngeal balloon; use of controlled mechanical ventilation possible at higher ventilation pressures; well suited for obese patients; helpful under difficult circumstances with respect to space and illumination; valuable device in pa-

Table 1. Age Range

Age in years	Number of patients	Percent
19 - 65	389	77.8
66 - 80	62	12.4
> 81	49	
Total	500	

Table 2. Type of surgery

Type of surgery	Number of patients	Percent
General surgery	297	59.4
Gynecology	123	24.6
Urology	37	7.4
Orthopedic	43	8.6
Total	500	

Table 3. Duration of surgery

Duration (min)	Number of patients	Percent
30 - 60	201	40.2
61 - 120	157	31.4
121 - 240	69	13.8
241 - 360	53	10.6
301 - 360	20	4.0

tients with continued vomiting; and works in either tracheal or esophageal position.

The Combitube has gained worldwide interest and has been recommended in the difficult airway algorithm of the "Practice Guidelines for Management of the Difficult Airway" of the American Society of Anesthesiologists (18). It is also included in the "Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care" of the American Heart Association (19), and in the "Guidelines for the Advanced Management of the Airway and Ventilation during Resuscitation" of the Airway and Ventilation Management Working Group of the European Resuscitation Council (20).

Opposite to the classic LMA, the Combitube allows for ventilation pressures far beyond 16 cm H₂O and guarantees prevention of aspiration after inflation of both balloons.

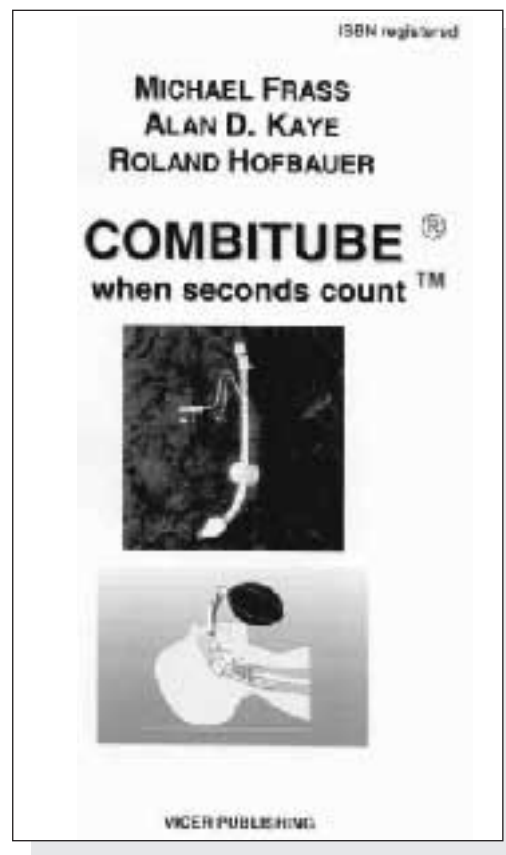
The Combitube appears to be a safe and easy device which may be used whenever endotracheal intubation is not immediately possible in an emergency situation. In addition, this study demonstrates its usefulness during routine surgery.

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Preliminary results of abdominal negative pressure ventilation (ANPV) in intubated patients: an alternative device on external ventilation?

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ABSTRACT

Objective: Negative pressure ventilation can be used as a substitute for positive pressure ventilation to circumvent possible disadvantages, for controlled and / or assisted ventilation, as well as for weaning of ventilated patients from a conventional positive pressure respirator. While the iron lung is the most known device for negative pressure ventilation, its use is limited since the whole patient's body except the head is surrounded by the device. Aim of our investigation was to determine whether ANPV is able to oxygenate and ventilate patients sufficiently. Effectivity was determined by repeated withdrawals of blood gas samples and by pulse oximetry.

Patient and Methods: Fifteen patients requiring prolonged moderate controlled mechanical ventilation were enrolled into this pilot-study for a study period of 240 min. Abdominal negative pressure ventilation (ANPV) consists of a self-supporting shape surrounding the whole circumference of the body only in the region between the xiphoid process and the symphysis. As described below, sufficient ventilation can be achieved in

anesthetized patients. The small workload of the device allows easy nursing and establishing central-venous lines or ECG-electrodes. In addition, the small weight might result in higher mobility and additional higher comfort for awake patients.

Results: As results of blood gas analyzes and pulse oxymetry remained within physiological range during the whole investigation, the study period of 240 min could be completed in all patients. All patients remained hemodynamically stable during ANPV. In the following we describe

Conclusion: Advantages of ANPV over previous constructions seem to be the low weight and a at least partial flexibility, allowing higher comfort for the patients. In contrast to other similar devices, central venous lines may be established at any time. In hospital, ANPV might allow the application of ECG-electrodes on the chest and easy nursing. ANPV results in sufficient arterial blood gases in mandatory ventilation at least in anesthetized patients. Although ANPV has not been tested in supportive ventilation, this device might be an enrichment of the ventilation modes.

Key Words: negative pressure ventilation, abdominal negative pressure ventilation, positive pressure ventilation, supportive ventilation.

The history of negative pressure ventilation (NPV) seems to be an old idea, although most of the reports must be commented with the words of Giordano Bruno (1548-1600): "Se non e vero, e molto ben' trovato". For example, in 1832 a nearly drowned Scottish seaman was said to have been resuscitated with a bellows-operated box with a seal around the neck or the shoulders, producing breathing movements in this patient (1).

Nevertheless, a series of scientists worked on the problem of artificial ventilation, as e.g. even Alexander Graham Bell (1847-1922), usually mentioned in conjunction with the invention of telephone. 1876 was the year of birth of the first workable iron lung, built by Woillez in Paris. Braun in Vienna (1889), and Chillingworth and Hopkins in USA (1919) developed body enclosing machines for ventilation (1).

The work that finally led to success was done by Drinker and Shaw. In 1928 Philip Drinker put a curarized cat in a plethysmographie, its head protruding enclosed by a rubber collar seal at the neck, and found it easily to ventilate with a hand-held syringe connected to the interior of the box (2). The development of this device proceeded with the addition of a variable-speed motor-driven cycling valve and the incorporation of access panels for nursing care of the patient. Within a few months the stage was set for clinical use. The so called iron lung continued in widespread use through the mid-1950s (3, 4). During the 1951-

1953 polio epidemics, the principle of external negative-pressure ventilation gave way to internal positive-pressure ventilation because of shortage of iron lungs (1).

Nowadays, positive-pressure ventilation (PPV) is the most frequently used method of ventilation. This method allows easy nursing or transport of the patient, since access to almost all parts of the body is possible. However, this method does not simulate physiologic conditions, since it leads to a non-physiologic excess of positive pressure either during the whole or at least a part of the respiratory period, especially in the presence of positive end-expiratory pressure (PEEP). This increase in intrathoracic pressure is well known to cause negative inotropic effects on the heart, thereby leading to adverse circulatory and hormonal responses (5). On the other hand, the disadvantage of the iron lung is the impeded access to the patient's body. Nursing is difficult and establishing arterial and venous lines is limited. A recent report describes the successful use of NPV as hemodynamic therapy in three children with a low output secondary to restrictive right ventricular physiology following repair of tetralogy of Fallot. NPV produced a significant hemodynamic improvement, with increases in cardiac output of greater than 100 % in two of the children (6).

Modifications of the iron lung surround only parts of the thorax making nursing easier. These devices provide adequate ventilation by creating neg-

ative pressure around the thorax (3, 6). For this purpose, a chamber surrounding the thorax with a hollow space around these parts is used. This chamber is sealed against the patient's body, allowing the creation of a sufficient negative pressure. Other patents describe a shell-like device. The mechanism of negative pressure ventilation lies in a rapid decrease of the air volume under the shell creating negative pressure and thereby increasing the body volume. However, a large amount of this action is thwarted since the patient's body is impressed in the area of the working surface. In addition, most of these devices are constructed only for support of spontaneous breathing, since effectivity is limited (7, 8).

The above mentioned disadvantages may be overcome by a modification presented in this paper, the so called "abdominal negative pressure ventilation" (ANPV) device. With this device, negative pressure is only applied in the abdominal region.

Aim of our investigation was to determine whether ANPV is able to oxygenate and ventilate patients sufficiently. Effectivity was determined by repeated withdrawals of blood gas samples and by pulse oxymetry.

PATIENTS AND METHODS

ANPV-device

The ANPV-device consists of a chamber surrounding the whole circumference of the patient's body in the region of the abdomen (Fig. 1). This

chamber surrounds the area of the abdomen between the circumferences at the site of the xyphoid process and at the site of the symphysis. The chamber is sealed by the help of a cover against the patient's body. Using an aperture in the chamber, negative pressure is applied periodically. Fig. 2 shows how negative pressure draws the belly into the chamber. Thereby, the diaphragm is drawn downwards into the region of the abdomen. This leads to expansion of the lungs followed by an air insufflation into the lungs. In conclusion belly ventilation - quite common in male subjects - is simulated. Figures 1 to 3 show the construction used for ANPV.

PATIENTS

Fifteen patients requiring prolonged controlled mechanical ventilation were enrolled into this pilot-study (patients characteristics see table 1). All patients had been ventilated with positive pressure for 5 to 29 days. All patients received permanent anesthesia with midazolam (0.25 - 1 mg/kg/h) and sufentanil (0.1 µg/kg/h). Respirator settings (Servo 300, Siemens Elema, Sweden) were as followed: FiO₂ 0.3 to 0.5, tidal volume 10 to 12 mL/kg, respiratory frequency between 10 and 15 breaths per minute, an inspiratory-expiratory (I:E) ratio of 1:2, and a positive end-expiratory pressure (PEEP) of 5 mbar.

STUDY DESIGN

The study was approved by the local Ethical Committee of the University Hospital of Vienna.

Patients received pancuronium-bromide (4 mg i.v.) for relaxation and ANPV was started. Oxygen was administered via a T-piece connected to the endotracheal tube with a constant flow of 12 L/min initially. During ventilation with ANPV, arterial blood gases were evaluated, first every 5 minutes, later on in increasing intervals up to 30 minutes. In all patients, the investigation was stopped after 240 minutes and patients were ventilated with positive pressure again as described above. Blood gases were evaluated again. Patients were additionally monitored by pulse oxymetry (SaO₂).

ANPV was performed with the help of NEV-100 (Lifecare International Inc, Lafayette, CO, USA). Frequency was set between 10 and 15/min; oxygen insufflation via endotracheal intubation was set at 12 L/min at the beginning of ANPV and was adjusted to a desired paO₂ of around 100 mm Hg; negative inspiratory pressure was applied between 25 and 38 mm Hg, negative expiratory pressure between 3 and 5 mm Hg, inspiratory : expiratory ratio was 1:1.

RESULTS

As results of blood gas analyzes and pulse oxymetry remained within physiological range during the whole investigation, the study period of 240

min could be completed in all patients. All patients remained hemodynamically stable during ANPV. In the following we describe patients No. 3 and 12 in more detail:

Patient 3 started with following data during positive pressure ventilation: pH 7.25, paCO₂ 36 mm Hg, paO₂ 156 mm Hg, HCO₃ 15 mmol/L, BE -11 mmol/L, and SaO₂ 98 %. After 20 min ANPV, paO₂ and SaO₂ increased to 208 mm Hg and 99 %, respectively. After 60 min ANPV and 6 L/min oxygen insufflation, blood gases were pH 7.16, paCO₂ 41 mm Hg, paO₂ 108 mm Hg, HCO₃ 14 mmol/L, BE -13 mmol/L, and SaO₂ 95 %, respectively. After 240 min blood gas analysis was as follows: pH 7.27, paCO₂ 39 mm Hg, paO₂ 117 mm Hg, HCO₃ 17 mmol/L, BE -9 mmol/L, and SaO₂ 96 %, respectively.

Patient 12 showed following blood gas parameters during positive pressure ventilation: pH 7.36, paCO₂ 41 mm Hg, paO₂ 79 mm Hg, HCO₃ 23 mmol/L; BE -2 mmol/L; and SaO₂ 94 %. During ANPV and oxygen insufflation with 15 L/min, paO₂ and SaO₂ rapidly increased to 106 mm Hg and 97 %, while paCO₂ decreased to 37 mm Hg, and pH, HCO₃, and BE remained nearly unchanged. During the whole phase of ANPV, blood gas parameters were within the normal range. At the end, blood gases were as follows: pH 7.39, paCO₂ 39 mm Hg, paO₂ 140 mm Hg, HCO₃ 23 mmol/L, BE -1.0 mmol/L; and SaO₂ 98 %, respectively (see table 2).

DISCUSSION

Artificial ventilation is one of the main problems in critically ill patients. As described above, history of mandatory ventilation started with negative pressure ventilation. Later on, positive pressure ventilation was developed, resulting in easy handling, transport, and nursing of the patients. Unfortunately, long time mandatory ventilation with positive pressure may result in severe side effects such as decreased cardiac index (CI), impeded venous return to the heart, reduced secretion of atrial natriuretic peptide (ANP), and an increase in vasopressin (i.e. antidiuretic hormone) secretion, thereby reducing kidney function (5, 9-11). An increase of intracellular volume parallels these findings (5, 9). In addition, an excess of positive pressure may lead to a mechanical damage of alveolar endothelium and therefore to an increased incidence of the adult respiratory distress syndrome (ARDS; 12). External negative pressure ventilation appears to be a suitable choice during rigid bronchoscopy (13).

Side effects of negative pressure ventilation include upper airway obstruction or lower esophageal sphincter dysfunction (14, 15). Nevertheless, this kind of ventilation rather imitates physiological hemodynamics and hormonal regulations (16). Previous descriptions of NPV include a variety of different indications, such as weaning from the respirator, ventilation of patients with respiratory insufficiency due to neuromuscular diseases or noc-

turnal hypoxia. In addition, immunocompromised patients or patients with high transverse lesion of the cord with paraplegia are said to benefit from those devices, since nosocomial infections are very rare with negative pressure ventilation in contrast to conventional respirators. A recent report demonstrates that intermittent respiratory muscle rest induced by NPV can relax inspiratory muscles in most patients with stable severe COPD, but fails to improve RM function and exercise capacity (17).

Nevertheless, as described above, NPV in the common way (iron lung) includes several disadvantages as impeded nursing or immobility of the patient. In contrast, ANPV might allow both, controlled ventilation in patients receiving sedation and muscle relaxation as described above, or supported ventilation in out patients. Therefore, the advantages of ANPV might be helpful in several additional indications when compared with NPV, e.g. in awake patients, since ANPV might allow sitting, walking around, and as long as intubation is not needed, eating and drinking. The belly-weight's negative effects on the ventilation of obese patients caused by upwards displacement of the diaphragm might be positively influenced, too.

Advantages over previous constructions seem to be the low weight and a at least partial flexibility, allowing higher comfort for the patients. In contrast to other similar devices, central venous lines may be established at any time. In hospital, ANPV might allow the ap-

plication of ECG-electrodes on the chest and easy nursing, and perhaps patients requesting an intensive care unit could be managed at an intermediate care unit or a general ward.

As shown above, ANPV results in sufficient arterial blood gases in mandatory ventilation at least in anesthetized patients. Although ANPV has not been tested in supportive ventilation, this device might be an enrichment of the ventilation modes, since it seems to be the only one including sufficient ventilation and practicable nursing, and, in addition, might even allow comfortable respiratory therapy in out-of-hospital patients. Therefore, further investigations in conscious patients are urgently warranted.

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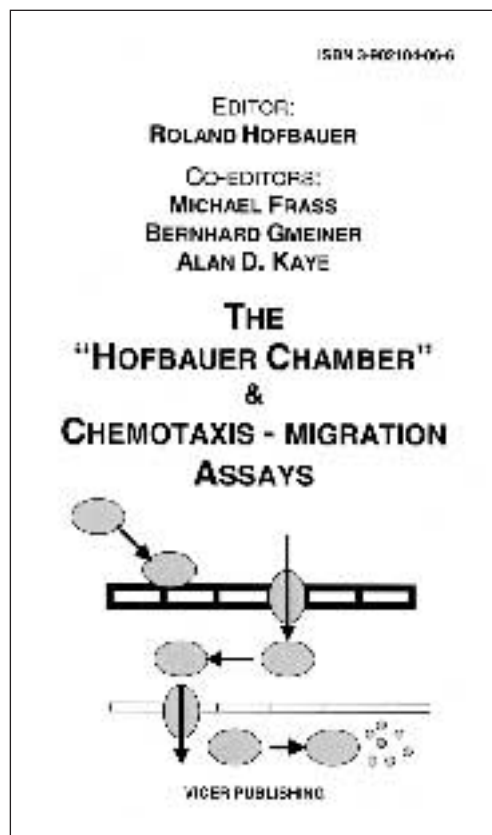
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