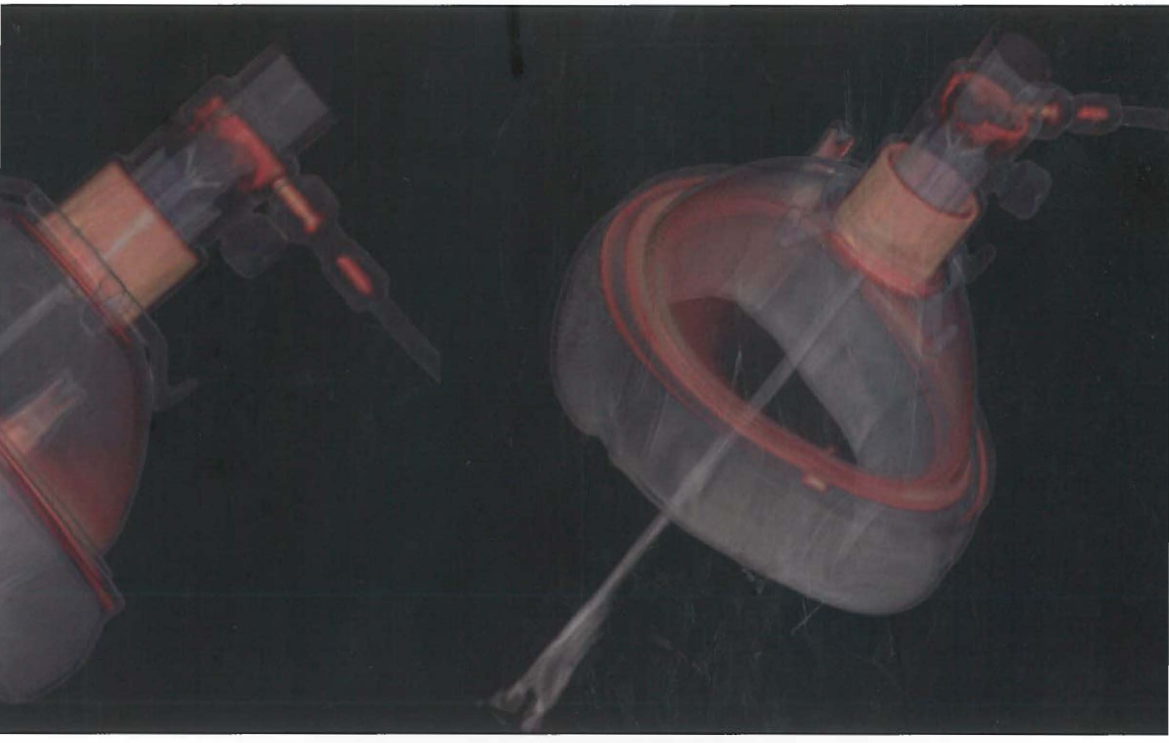
Multiple applications of the Boussignac continuous positive airway pressure system

Dieperink, Willem

MULTIPLE APPLICATIONS OF THE BOUSSIGNAC CONTINUOUS POSITIVE AIRWAY PRESSURE SYSTEM



WILLEM DIEPERINK

MULTIPLE APPLICATIONS OF THE BOUSSIGNAC CONTINUOUS POSITIVE AIRWAY PRESSURE SYSTEM

Stellingen

behorende bij het proefschrift:

Multiple applications of the Boussignac Continuous Positive Airway Pressure system

1. Boussignac CPAP is een eenvoudige, veilige en relatief goedkope vorm van mask-CPAP.

2. Op een hartbewaking waar zorgverleners geen ervaring hebben met beademing kan Boussignac CPAP met beperkte scholing en instructie worden geïmplementeerd.

3. De toepassing van Boussignac CPAP is medisch en kosten effectief in de behandeling van acuut cardiogeen longoedeem.

4. Boussignac mask-CPAP kan eerder beschouwd worden als een "super" ventimask dan als beademing.

5. Acuut cardiogeen longoedeem meest dankbare indicatie voor Boussignac Mask-CPAP.

6. Boussignac CPAP kan buiten een IC-setting worden toegepast.

7. In tegenstelling tot de zorgverleners hebben patiënten geen klachten over het comfort van het Boussignac systeem.

8. Er is voldoende argumenten om CPAP behandeling op te nemen in richtlijnen met betrekking tot de vroegtijdige behandeling van acuut cardiogeen longoedeem.

9. De toediening van helium zuurstofmengsels (heliox) in combinatie met CPAP stuit op veel problemen indien hiervoor traditionele beademingsmachines worden gebruikt. Met Boussignac CPAP systeem worden deze problemen omzeild.

10. Bij acute hoge luchtweg obstructies kan Boussignac CPAP in combinatie met heliox een overbrugging naar een definitieve oplossing betekenen.

11. Niet de vaardigheden tonen wie we zijn maar onze keuzes.

12. Wat tijd niet oplost is geen probleem.(*Gevelsteen Lijnbaanstraat Groningen*)

Willem Diepe ink

Cover: Computed tomography (CT) scan of the Boussignac CPAP system connected to a face mask in which contrast fluid is injected instead of oxygen to highlight the 4 micro-channels.

CT scan Wim Tukker

ISBN 978-90-367-4163-8

Cover design Willem Dieperink
Illustrations Ernst Nijsten
Printed by Gildeprint drukkerijen BV, Enschede

RIJKSUNIVERSITEIT GRONINGEN

MULTIPLE APPLICATIONS OF THE BOUSSIGNAC CONTINUOUS POSITIVE AIRWAY PRESSURE SYSTEM

PROEFSCHRIFT

Ter verkrijging van het doctoraat in de Medische
Wetenschappen aan de Rijksuniversiteit Groningen
op gezag van de
Rector Magnificus, dr. F. Zwarts,
In het openbaar te verdedigen op
woensdag 20 februari 2008
om 16:15 uur

door

Willem Dieperink
geboren op 20 september 1955
te Zutphen

Promotores

Prof. dr. L.P.H.J. Aarts

Prof. dr. F. Zijlstra

Copromotores

Dr. M.W.N. Nijsten

Mw. dr. T. Jaarsma

Beoordelingscommissie

Prof. dr. A.R.J. Girbes

Prof. dr. D.J. van Veldhuisen

Prof. dr. D.F. Zandstra

Paranimfen

Dr. D.J. Kleijer

Drs. G.C. Niemeijer

Oan Hinke

ABBREVIATIONS

ACPE	acute cardiogenic pulmonary edema
APACHE ll	acute physiologic and chronic health evaluation
BCPAP	Boussignac continuous positive airway pressure
CCU	coronary care unit
CLD	chronic lung disease
CPAP	continuous positive airway pressure
FDA	food and drug administration
FiO_2	fraction of inspired oxygen
FRC	functional residual capacity
Heliox	helium–oxygen mixture
ICU	intensive care unit
IQR	interquartile ranges
NIV	non-invasive ventilation
PaO_2	partial pressure of arterial oxygen
PCI	percutaneous intervention
PEEP	positive end-expiratory pressure
PICU	paediatric intensive care unit
SAPS	simplified acute physiological score
SD	standard deviation
SpO_2	peripheral arterial oxygen saturation
STEMI	ST-elevation myocardial infarction
TBM	tracheobronchomalacia
TT	tracheostomy tube

Contents

Chapter 1:	General introduction and outline of the thesis	9
Part I:	**Boussignac continuous positive airway pressure for the treatment of acute cardiogenic pulmonary edema** (chapter 2-5)	
Chapter 2:	Implementation of continuous positive airway pressure on the coronary care unit: experiences and attitudes *Submitted*	21
Chapter 3:	A 64-year old man who sustained many episodes of acute cardiogenic pulmonary edema successfully treated with Boussignac continuous positive airway pressure: a case report *International Journal of Cardiology 2006*	35
Chapter 4:	Boussignac continuous positive airway pressure for the management of acute cardiogenic pulmonary edema: prospective study with a retrospective control group *BMC Cardiovascular disorders. In print.*	41
Chapter 5:	Treatment of acute cardiogenic pulmonary edema in the ambulance with Boussignac continuous positive airway pressure *Submitted*	55

Part II: **Novel applications for the Boussignac continuous positive airway pressure system** (chapter 6-8)

Chapter 6: Walking with continuous positive airway pressure 69
European Respiratory Journal 2006

Chapter 7: Boussignac CPAP for weaning with tracheostomy tubes 79
Respiration 2007

Chapter 8: Combination of heliox and CPAP without a ventilator: bench test and clinical observations 91
European Journal of Anaesthesiology 2007

Chapter 9: Summary and conclusions 97

Chapter 10: Samenvatting en conclusies 103

Dankwoord 109

Chapter 1

General introduction and outline of the thesis

GENERAL INTRODUCTION

Serious dyspnea is an alarming symptom and probably one of the most frightening symptoms for patients. Anxiety is often of such an order that already early in history there are descriptions of methods which provide some relieve during serious dyspnea.

An obvious method to treat severe dyspnea is to support breathing. The first method of breathing support dates back to the creation of mankind. The Bible writes *"And the Lord God formed man of the dust of the ground, and breathed into his nostrils the breath of life, and man become a living soul"* (Genesis 2:7). Also in the Bible - in the Old testament - there is a mention of the Prophet Elisha applying pressure support from his mouth to the mouth of a child who was dying (Kings 4:34-35). Ever since many methods of breathing support have been described and from the middle of the 19th century technology had sufficiently advanced so that a large number of devices were invented which could take over breathing [1]. Apparatus to support the chest as a driving force behind breathing were developed. Complex and impressive machines were used to generate negative pressures around the body or thoracic cavity – these devices became known as negative pressure ventilators or so called 'iron lungs' [2]. Two successful designs became popular; in one, the body of the patient was enclosed in an iron box or cylinder and the patient's head protruded out of the end. The second design was a box or shell that precisely fitted over the thoracic area only (chest cuirass). The iron lung was very important during the outbreak of polio epidemics in the 1950s [3].

During the late 1950s and the early 1960s the endotracheal intubation technique became more and more important whereas at the same time there were major technological advances in the development of positive pressure ventilators. As a consequence the body-enclosing iron lungs became obsolete.

Nowadays positive pressure ventilation with an artificial airway is the standard mode of mechanical ventilation in most patients with respiratory insufficiency. Nevertheless interest in so called non-invasive ventilation (NIV) has increased since the 1970s as a result of the recognition of the complications and discomfort related to invasive ventilation [4].

A basic component of many forms of respiratory support – either invasive or non-invasive - is to maintain a positive airway pressure throughout inspiration and expiration. During mechanical ventilation this pressure is usually termed as positive end-expiratory pressure (PEEP), while during spontaneous breathing it is known as continuous positive airway pressure (CPAP). There may be discussion whether CPAP constitutes mechanical ventilation or support. We consider that CPAP represents support because the patient must initiate all breaths and no additional pressure above the CPAP pressure is provided during those breaths. CPAP is commonly used for treatment of several forms of respiratory failure.

Mask-CPAP

CPAP may be used invasively through an endotracheal tube or tracheal canula or non-invasively with a face mask or nasal prongs. Non-invasive CPAP via a facemask is better known as mask-CPAP.

Figure 1.1 Poulton and Oxon's "pulmonary plus pressure machine" assembled from a vacuum cleaner

Non-invasive application of positive pressure was already used in the 1912 by Sterling Bunnell to preserve lung expansion during thoracic surgery [5]. In 1936 Poulton and Oxon describe the treatment of pulmonary edema in 22 patients by using a "pulmonary plus pressure machine" assembled from a Hoover or Electrolux vacuum cleaner [6]. (Figure 1.1) In 1937 Alvan Barach reported the use of mask-CPAP – then called continuous positive pressure breathing - in the treatment of respiratory obstruction as well as pulmonary edema [7,8]. The subsequent development of the endotracheal tube during and directly after the Second World War with the widespread introduction of mechanical ventilators ensured that the application of mask-CPAP remained virtually unused.
The revival of CPAP came in 1971 when Gregory et al. use it via an endotracheal tube in spontaneously breathing neonates with hyaline membrane disease. It was also Gregory who coined the term continuous positive airway pressure (CPAP) [9]. In 1976 Greenbaum et al. used mask-CPAP in an attempt to prevent endotracheal intubation in patients with acute respiratory distress syndrome [4].
In general CPAP is effective in improving oxygenation and reducing the work of breathing in patients with a reduction in functional residual capacity (FRC) in the lung cause by alveolar collapse (atelectasis) or alveolar edema (pulmonary edema). In atelectasis CPAP restores lung volume and makes that alveolar recruitment will be achieved which as result a reduction in the work of breathing and an improvement of the partial pressure of arterial oxygen (PaO_2) [10,11]. In acute cardiogenic pulmonary edema CPAP also reduces venous return, decreasing ventricular filling pressures and improving cardiac performance [12,13].
Nowadays the most frequent use of CPAP is to treat obstructive sleep apnea, where airway pressure acts as a pneumatic splint to prevent pharyngeal collapse during sleep [14,15]. Likewise CPAP may expand and splint the upper airways and prevent or reduce airway obstruction during manual mask ventilation before routine endotracheal intubation [16].

Mask-CPAP has been proved to be a safe and effective treatment in several forms of acute respiratory failure. Some important applications are:

- The prevention and treatment of atelectasis [17].

- Obstructive sleep apnoea [14,15].
- Pulmonary edema [18-22].

Currently, there are only a few indications for applying invasive CPAP. For example:

- Weaning (endotracheal tube and/or trachea canula) [23].
- Tracheobronchomalacia [24].

Because of the renewed interest in non-invasive CPAP new devices were developed.
An example of a simple but effective CPAP device applicable invasive as well as non-invasive is the Boussignac system.

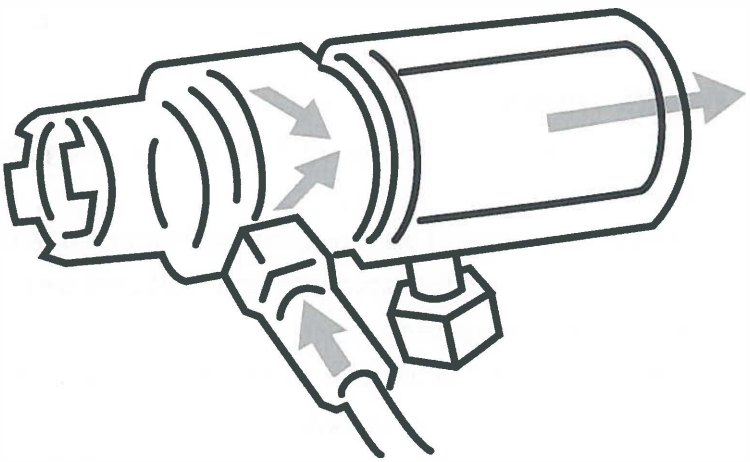


Figure 1.2 Boussignac continuous positive airway pressure system

Boussignac CPAP

The Boussignac CPAP (BCPAP) system is named after its inventor Georges Boussignac. The BCPAP system is an FDA-approved simple, safe, cheap and lightweight (10 g) disposable plastic cylinder with an inner diameter of 1.2 cm (0.5"). A jet flow of air and or oxygen that accelerates to nearly the speed of sound through a series of four micro-channels in this plastic tube creates a flow-

dependent pressure [25-27]. The BCPAP system contains no sensors or mechanical valves and was developed to deliver CPAP for facemasks but can be easily applied to tracheostomy tubes as well as endotracheal tubes. (Figure 1.2) A second, distal port on the BCPAP system allows the application of additional oxygen, the measurement of pressures or the application of humidification.

The fact that the BCPAP system generates CPAP in situ, were other ventilators or CPAP apparatus generate CPAP in the machine, provides several advantages. The system allows lightweight construction as ventilators or machines with mains connection and heavy tubing are not needed. It is very easy to use the system in combination which other gases such as helium-oxygen mixtures.

The aim of this thesis is to describe multiple applications of the BCPAP system in clinical practice.

OUTLINE OF THE THESIS

Part I (chapter 2-5) concern the use of BCPAP to treat acute cardiogenic pulmonary edema.

Chapter 2 describes of the process of education and implementation of BCPAP on the coronary care unit (CCU) and the experiences and challenges we encountered during this process with staff and patients.

Chapter 3 describes the repeated application of BCPAP in an extraordinary but illustrative case of a patient with many episodes of cardiogenic edema. Chapter 4 describes the results of a prospective study on the utility of BCPAP for acute cardiogenic pulmonary edema in the CCU.

In chapter 5 we report the implementation of the BCPAP system for the treatment of acute pulmonary edema on the ambulances in the region of Groningen.

In Part II (chapter 6-8) we explore the use of the BCPAP system in more exceptional settings.

Chapter 6 is a case report of a child who was fully mobilized with a BCPAP system which was applied to her tracheostomy tube.

In chapter 7 we discuss a retrospective study on the application of the BCPAP device on tracheostomy tubes during weaning in 50 patients treated on the intensive care unit.

Chapter 8 focuses on the particular properties of the BCPAP device when used with helium-oxygen mixtures. We describe bench tests and clinical observations on the combination of the BCPAP system with helium-oxygen mixtures.

REFERENCES

1. Dalziel J. On sleep and apparatus for promoting artificial respiration. *Br Assoc Adv Sci* 1838; 2:127-134.
2. Drinker P, Shaw LA, An apparatus for the prolonged administration of artificial respiration. 1. A design for adults and children. *J Clin Invest* 1929; 7: 229-247.
3. Lassen HCA. A preliminary report on the 1952 epidemic of poliomyelitis in Copenhagen with special reference to the treatment of acute respiratory insufficiency. *Lancet* 1953; i:37-41.
4. Greenbaum DM, Millen JE, Eross B, Snyder JV, Grenvik A, Safar P. Continuous positive airway pressure without tracheal intubation in spontaneously breathing patients. *Chest* 1976; 69:615-620.
5. Bunnel S. The use of nitrous oxide and oxygen to maintain anesthesia and positive pressure for thoracic surgery. *JAMA* 1912; 58:835-838.
6. Poulton EP, Oxon DM, Left-sided heart failure with pulmonary oedema its treatment with the "pulmonary plus pressure machine". *Lancet* 1936; 228:981-983.
7. Barach AL, Martin J, Eckman M. Positive pressure respiration and its application. *Ann Intern Med* 1938; 12:754-795.
8. Barach AL, Martin J, Eckman M, Positive pressure respiration and its application for the treatment of acute pulmonary edema and respiratory obstruction. *Proc Am Soc Clin Invest* 1937; 16:664-680.
9. Gregory GA, Kitterman JA, Phibbs RH, Tooley WH, Hamilton WK. Treatment of ideopathic respiratory- distress syndrome with continuous positive airway pressure. *N Eng J Med* 1971; 284:1333-1340.
10. Mehta S, Hill NS. Noninvasive ventilation. *Am J Respir Crit Care Med* 2001; 16:540-577.
11. Stock MC, Downs JB, Corkran ML, Pulmonary fuctions before and after prolonged continuous positive airway pressure by mask. *Crit Care Med* 1984; 12:973-974.

12. Rusterholtz T, et al. Non-invasive pressure support ventilation with face mask in patients with acute cardiogenic pulmonary edema. *Int Care Med* 1995; 25:21-28.
13. Metha S, Jay GD, Woolard RH, Hipona RA, Connolly EM, Cimini DM, Drinkwine JH, Hill NS. Randomized prospective trial of bilevel versus continuous positive airway pressure in acute pulmonary edema. *Crit Care Med* 1997; 25:620-628.
14. Sullivan CE, Berthon-Jones M, Issa FQ, Eves L, Reversal of obstructive sleep apnoea by continuous positive airway pressure applied through the nares. *Lancet* 1981; 1:862-865.
15. Jenkinson C, Davies RJ, Mullins R, Stradling JR, Comparison of therapeutic and subtherapeutic nasal continuous positive airway pressure for obstructive sleep apnoea: a randomised prospective parallel trial. *Lancet* 1999; 353:2100–2105.
16. Visvanathan T, Kluger MT, Webb RK, Westhorpe RN. Crisis management during anaesthesia: obstruction of the natural airway. *Qual Saf Health Care* 2005; 14:e2.
17. Andersen JB, Qvist J, Kann T. Recruiting collapsed lung through collateral channels with positive end-expiratory pressure. *Scand J Respir Dis* 1979; 60:260-266.
18. Räsänen J, Heillilä J, Downs J, Nikki P, Väisänen IT, Viitanen A. Continuous positive airway pressure by face mask in acute cardiogenic pulmonary edema. *Am J Cardiol* 1985; 55:296-300.
19. Väisänen IT, Räsänen J. Continuous positive airway pressure and supplemental oxygen in the treatment of cardiogenic pulmonary edema. *Chest* 1987; 92:481-485.
20. Lin M, Chiang HT. The efficacy of early continuous positive airway pressure therapy in patients with acute cardiogenic pulmonary edema. *J Formos Med Assoc* 1991; 90:736-743.
21. Bersten AD, Holt AW, Vedig AE, Skowronski GA, Baggoley CJ. Treatment of severe cardiogenic pulmonary edema with continuous positive airway pressure delivered by face mask. *N Engl J Med* 1991; 325:1825-1830.

22. Lin M, Yang YF, Chiang HT, Chang MS, Chiang BN, Cheitling MD. Reappraisal of continuous positive airway pressure therapy in acute cardiogenic pulmonary edema. *Chest* 1995; 107:1379-1386.
23. MacIntyre NR, Cook DJ, Ely EW Jr, Epstein SK, Fink JB, Heffner JE, Hess D, Hubmayer RD, Scheinhorn DJ; American College of Chest Physicians; American Association for Respiratory Care; American College of Critical Care Medicine. Evidence-based guidelines for weaning and discontinuing ventilatory support: a collective task force facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine. *Chest.* 2001; 120:375S-395S.
24. Wiseman NE, Duncan PG, Cameron CB. Management of tracheobronchomalacia with continuous positive airway pressure. *J Pediatr Surg* 1985; 20:489-493.
25. Maitre B, Jaber S, Maggiore SM, Bergot E, Richard JC, Bakthiari H, Housset B, Boussignac G, Brochard L: Continuous positive airway pressure during fiberoptic bronchoscopy in hypoxemic patients. A randomized double-blind study using a new device. *Am J Respir Crit Care Med* 2000; 2:1063-1067.
26. Moritz F, Benichou J, Vanheste M, Richard JC, Line S, Hellot, MF Bonmarchand G, Muller JM: Boussignac continuous positive airway pressure device in the emergency care of acute cardiogenic pulmonary oedema: a randomized pilot study. *Eur J Emerg Med* 2003; 10:204-208.
27. Templier F, Dolveck F, Baer M, Chauvin M, Fletcher D. 'Boussignac' continuous positive airway pressure system: practical use in a prehospital medical care unit. *Eur J Emerg Med* 2003; 10:87-93.

Part I

Boussignac continuous positive airway pressure for the treatment of acute cardiogenic pulmonary edema *(chapter 2-5)*

Chapter 2

Implementation of continuous positive airway pressure on the coronary care unit: experiences and attitudes

Willem Dieperink
Maarten W.N. Nijsten
Mark van de Stadt
Iwan C.C. van der Horst
Leon P.H.J.Aarts
Felix Zijlstra
Tiny Jaarsma

Submitted

ABSTRACT

Background: Boussignac continuous positive airway pressure (BCPAP) delivered by face mask is useful for patients with acute cardiogenic pulmonary edema (ACPE). Although medically effective, we observed that not all suitable patients received BCPAP.

Aim: In this descriptive, prospective, cohort study we explored the experiences and attitudes of both patients and staff with BCPAP.

Methods: Patients were interviewed 12h to 48h after treatment with BCPAP. Nurses on the coronary care unit (CCU) were interviewed on their knowledge, skills, experiences and opinions concerning BCPAP.

Results: Of 117 patients with ACPE, 87 patients (74%) received BCPAP treatment. It was decided not to administer BCPAP in 30 ACPE patients (26%). Patients who received BCPAP found that the reduction of dyspnea outweighed any discomfort. Barriers for the use of BCPAP were not related to nurses' skills but to the nurses' belief that BCPAP created major discomfort, lack of guidelines, the ultimate improvement of oxygenation without BCPAP and the more labor-intensive treatment.

Conclusion: Overestimation of patient discomfort by nurses and system-related factors impeded the use of BCPAP for all ACPE patients.

INTRODUCTION

Acute cardiogenic pulmonary edema (ACPE) due to chronic heart failure is a common medical emergency that frequently manifests itself with sudden dyspnea and hypoxemia. When treatment with oxygen, opiates, diuretics and vasodilators do not result in sufficient improvement, additional ventilatory support may be required [1,2]. Traditionally ventilatory support has been effected via endotracheal intubation and mechanical ventilation, an approach that usually requires admission to the intensive care unit (ICU). Several randomized clinical trials demonstrated a decrease in the rate of intubation and hospital length of stay for patients assigned to CPAP compared with conventional therapy with oxygen alone [3-6]. International heart failure guidelines mention that CPAP treatment is an effective and accepted treatment option in these patients [7,8]. Coronary care units (CCU) in the

Netherlands are usually not equipped for applying respiratory support with mechanical ventilators. Most nurses on the CCU are not trained to ventilate patients and have limited expertise and experience in the field of conventional mask-CPAP. Therefore we introduced the Boussignac CPAP (BCPAP) system (Figure 2.1) in the CCU.

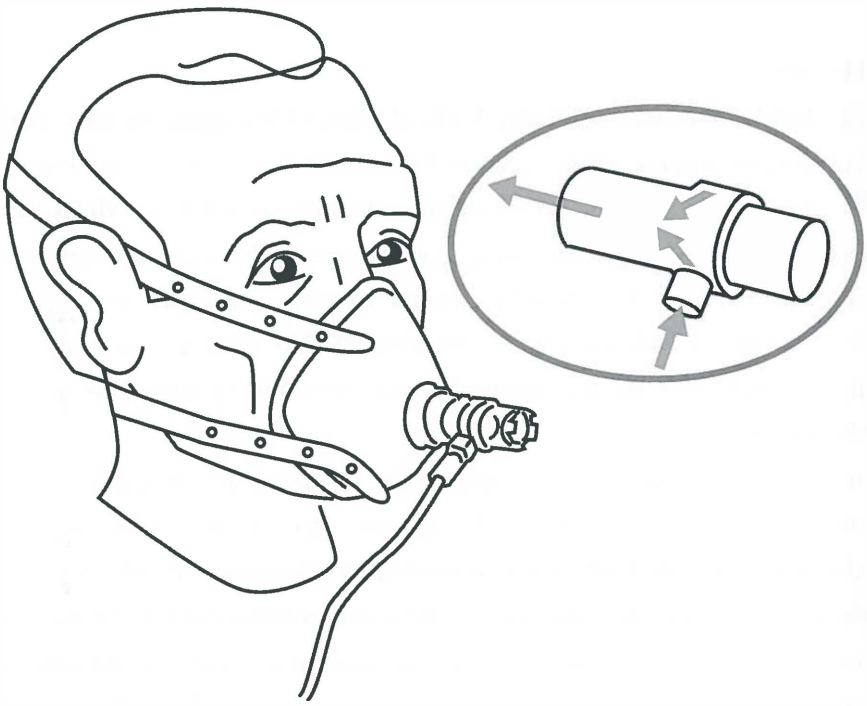


Figure 2.1 BCPAP system
Face mask and BCPAP device. Due to the geometry by which the compressed gas is injected into the hollow Boussignac tube (inner diameter 1.2 cm or 0.5 in.), continuous positive pressure (5 cm H_2O at a flow of 15 L/min) is created

The BCPAP system is a simple disposable cylindrical plastic device that only requires an O_2 source and a flow meter to generate face mask CPAP. This easy to handle system can be used outside the ICU and in pre-hospital settings and has made it feasible to implement nurse-centered CPAP in the CCU. ACPE patients show significant improvement when treated with CPAP. The BCPAP system has already been proven to be as effective as more complicated CPAP devices in the

management of ACPE [9-11]. Therefore it is important that patients with ACPE receive CPAP.

Identifying hindrances in implementation may be important to ensure that patients receive optimal treatment. The goal of our study was to identify factors that hinder successful use of BCPAP in suitable patients. For this purpose we focused on the experiences and attitudes of patients and staff with regard to this new technology.

METHODS

On a 12 bed CCU of the University Medical Center Groningen, we introduced the BCPAP system (Vygon, 95440 Ecouen, France) for the treatment of patients with ACPE. During a two year period all patients admitted to our CCU with ACPE were studied. ACPE was defined according to established criteria [1]: a respiratory rate >25 breaths/min and a peripheral arterial oxygen saturation of <95% while receiving oxygen. Candidate patients received BCPAP as displayed in figure 2.1. During treatment patients are monitored and motivated by nurses to maintained BCPAP treatment.

Quantitative clinical data and descriptive data of diagnosis, clinical interventions, treatment and nursing care were collected and recorded in a case record form. Introduction of the BCPAP system consisted of preparation in which CCU staff members were trained and subsequently the actual implementation in patient care.

The current study was part of a prospective study that compared the cost-benefit differences of conventional treatment without any form of CPAP in the CCU (retrospective control group) with a prospective group that received BCPAP. The prospective arm of the study was designed to last two years. Therefore our current study on experiences and attitudes also covered the same period. The institutional review board of the hospital approved the study. (METc 2004.195)

Preparation consisted of theoretical education, practical training and evaluation of confidence in applying BCPAP.

Education included a 1 hour session in which principles of BCPAP, indications and contra-indications, definition of terms, examples regarding treatment and application of the actual treatment protocol were taught (Figure 2.2). Practical training consisted of setting up the BCPAP system, choosing the right face mask,

good mask-fitting and altering alarms according to a written scenario. Both education and training were given by the same intensive care nurse according to a standardized teaching package to ensure consistency. Immediately after the training session, nurses received a (first) questionnaire in which they could point out whether they felt competent applying BCPAP safely and self-sufficiently.

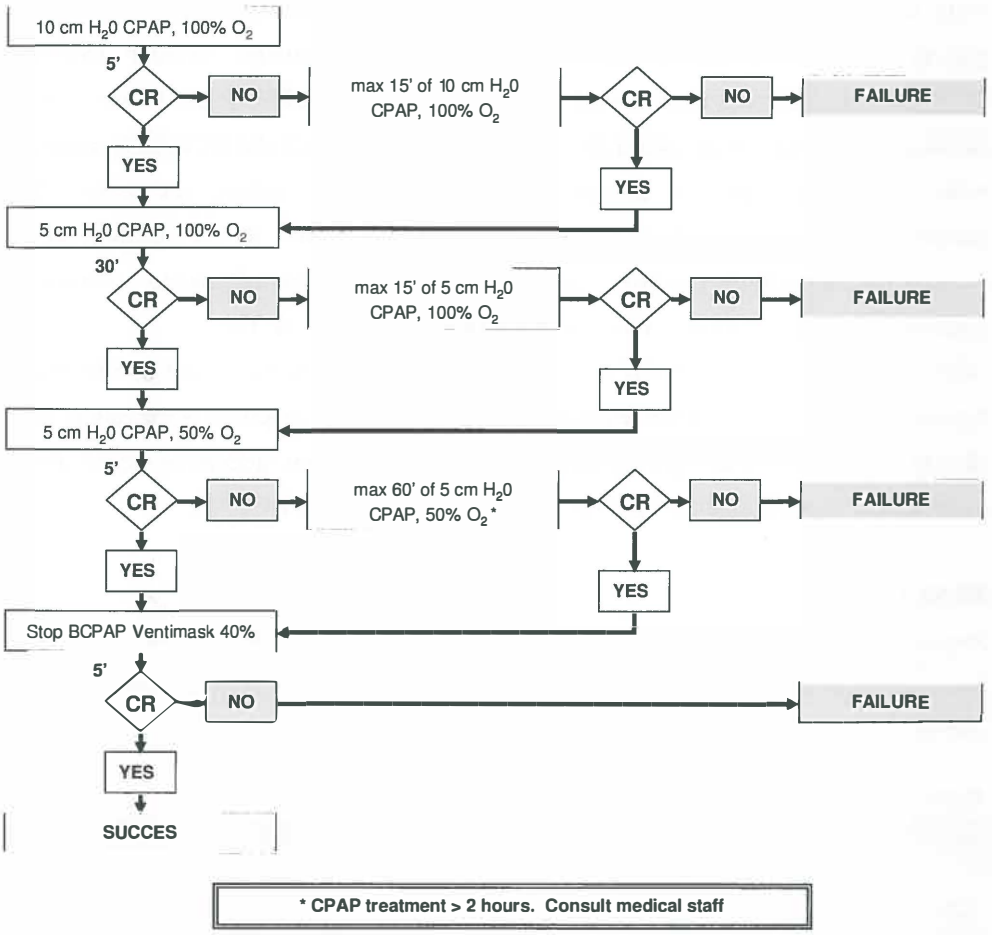


Figure 2.2 Protocol for Boussignac CPAP treatment.
The flowchart displays the protocol of BCPAP treatment in patients with ACPE. Clinical response is defined as an improvement in heart rate and transcutaneous oxygen saturation.
Note that according to this protocol CPAP should not last for more than 2 hours. In case of failure medical staff was immediately consulted.
CPAP: Continuous positive airway pressure, CR: clinical response

New incoming nurses received theoretical and practical training concerning BCPAP treatment. If one component of the training session would be judged as insufficient or there was doubt about the ability applying BCPAP, extended education and instruction was provided. Once application proficiency was assured, patients with ACPE were assessed for treatment with BCPAP using a protocol. Data were collected from patients who were treated with BCPAP. To evaluate patient experiences that might have influenced the nurses' attitude towards BCPAP, patients were interviewed 12 to 48 hours after BCPAP treatment. Semi-structured questions were asked about their experiences with the BCPAP treatment, with specific attention to dyspnea relief, face mask comfort and noise. All questionnaires were developed specifically for this study, as no questionnaires existed for this patient category. The questions were generated during a series of research meetings involving three of the authors (WD, MN & TJ).

After 2 years, we sent all CCU staff a second questionnaire by e-mail in which we repeated the questions about education and instruction, practical application and directed protocol. This questionnaire also included open questions about their experiences as well as their opinion about the usefulness of BCPAP.

RESULTS

Implementation of BCPAP

In a 2 year period, 117 patients were admitted to the CCU with ACPE and an SpO_2 <95%.

Table 2.1 Patient characteristics of patients with ACPE and a SpO_2 <95% (N=117)

	BCPAP	No-BCPAP
N	87	30
Age (yrs) , mean, ± SD	70 ± 11	71 ± 11
Male %	69	60
$SpO_{2\ at}$ CCU admission, median, (IQR)	85 (78-89)	89 (84-92)
SpO_2 2 hr after CCU admission, median, (IQR)	96 (93-97)	93 (90-96)
Heart rate CCU admission, bpm, mean ± SD	110 ± 20	111 ± 32
Heart rate 2 hr after CCU admission, bpm, mean ± SD	89 ± 19	104 ± 33
CCU Length of stay, median, (IQR)	1 (1-3)	1 (0-2)
Hospital Length of stay, median (IQR)	7 (1-14)	7 (2-14)

Thirty (26%) patients did not receive BCPAP as prescribed by the protocol but were treated with oxygen alone. Patient characteristics did not differ substantially between patients that did and did not receive BCPAP except for the median SpO_2 which was significantly lower in the BCPAP patients ($p<0.05$) (Table 2.1). Patients were treated with BCPAP for a median period of 105 minutes with a maximum period of 2 hours. In the questionnaires, 84% of the nurses confirmed that not all patients with ACPE and an SpO_2 <95% were treated with BCPAP.

Table 2.2 Experiences of nurses who had applied BCPAP.

		N (%)
I have experience with BCPAP	Yes	27
As far as I know patients with acute pulmonary edema and an SpO_2 <95% are		
- always treated with BCPAP		2 (7)
- sometimes not treated with BCPAP		28 (93)
Patients who received BCPAP were always treated according the operation protocol	Yes	28 (93)
Why did suitable patients not receive BCPAP?	Not thought of	0
	Decision physician	16 (53)
	Decision nurse	7 (23)
	Mild ACPE	10 (33)
	Non-cooperative patient	5 (17)
Was the alternative treatment (without BCPAP) successful?	Yes	17 (57)
	No	2 (7)
	Don't know	9 (30)
How often did you work with BCPAP	Once	3 (10)
	2-4	13 (43)
	More than 4	14 (47)
BCPAP treatment is labor-intensive	Yes	20 (67)
	Uncertain	3 (10)
	No	7 (23)
Which aspects of the BCPAP system deserve to be improved? (several answers possibly)	Comfort	23 (77)
	Noise	14 (47)
	Fragrance of mask	10 (33)
	Measurement of generated pressure.	16 (53)
	Other	1 (3)

Although nurses believed BCPAP treatment was useful, they reported that ACPE in some patients was considered too mild for BCPAP treatment by either the doctor or the nurses (Table 2.3).

In total 56 (67%) of the 87 patients treated with BCPAP were interviewed (Table 2.4). Some patients (38-41%) could not remember specific details of the treatment. Nonetheless, 41% stated that BCPAP treatment immediately reduced dyspnea. The discomfort of face mask or headstrap was mentioned by 20% of the interviewed patients (Table 2.4).

Table 2.3 Patient experiences with BCPAP (N=56)

	N (%)			
	Agree	Uncertain	Disagree	Don't know
Directly after BCPAP was started I felt better.	23 (41)	7 (13)	3 (5)	23 (41)
The face mask was comfortable	15 (27)	9 (16)	11 (20)	21 (38)
I the sound produced by the BCPAP system did not annoy me	33 (59)	1 (2)	1 (2)	21 (38)
The vanilla fragrance of the face mask was not bothersome	32 (57)	1 (2)	0	23 (41)

Directly after BCPAP education and instruction, 34 of the instructed 35 nurses (97%) completed and returned the first questionnaire. In general nurses judged all aspects of these sessions as good, comprehensive, sufficient, easy and uncomplicated (Table 2.4). Five nurses were not confident in their ability to apply BCPAP. Nevertheless, none of them found it necessary to complete an extra training session.

In the second questionnaire, at most 2 years after introduction of BCPAP, 94% (33) of the nurses responded. There was limited (12%) staff turnover during the study period. Three of them were junior nurses who received theoretical education and practical training, but had not worked with the BCPAP system. Of the remaining 30 nurses, 29 (97%) reported that education and training for applying BCPAP was sufficient in combination with the BCPAP protocol. They also reported that the application of BCPAP did not pose technical problems.

Nurses cited the following reasons for not applying BCPAP: decision of the physician, lack of guidelines, the ultimate improvement of oxygenation without BCPAP, the more intensive nature of BCPAP and their belief that BCPAP treatment creates major discomfort (Table 2.3).

Table 2.4 Responses of nurses to education and instruction of BCPAP (N=34)

	N (%)				
	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
I received sufficient education and instructions during the BCPAP education program.	7 (21)	24 (71)	1 (3)	2 (6)	0
The instruction and education was clear.	10 (30)	21 (62)	3 (9)	0	0
If I need to administer BCPAP independently I know what to do.	4 (12)	25 (74)	4 (12)	1(3)	0
The BCPAP protocol is clear.	3 (9)	30 (88)	0	1 (3)	0

DISCUSSION

This study found that nurses understood the benefits of BCPAP treatment and had the knowledge and skills to play a central role in the treatment of patients with ACPE. Despite the recognition that patients with ACPE may benefit from BCPAP treatment nurses did not always use BCPAP.

Nurses mentioned that the ACPE in some patients was so mild that BCPAP treatment was not necessary in combination with factors such as: BCPAP is more labor-intensive, lack of national guidelines for CPAP treatment in patients with ACPE and the perception that BCPAP treatment is less comfortable for patients.

Firstly, it is possible that CCU nurses underestimated the clinical benefit of BCPAP in patients with ACPE in which oxygenation was already somewhat improving. Probably the CCU nurses in such cases refer to their experiences with titrated therapy, with a main focus on the improvement of patients' peripheral arterial oxygen saturation and less on hemodynamic parameters. Nevertheless, patients with ACPE have a high mortality and morbidity and patients with "mild" ACPE might also benefit from BCPAP [12], since BCPAP can also improve

hemodynamics in addition to improving oxygenation [12,13]. Extended education of the CCU nurses concerning this aspect is necessary.

Secondly, BCPAP is more labor-intensive than conventional treatment with oxygen. Nevertheless, the duration of BCPAP treatment should be no more than 2 hours according to the protocol and more labor-intensive treatment should not limit the more favorable outcome of BCPAP treatment.

Thirdly, although in some international guidelines CPAP is advised as treatment [3], in the Netherlands no national guidelines exist for CPAP treatment in patients with ACPE. It is recommended to include CPAP in these guidelines

Finally, the nurses' perception was that BCPAP was not comfortable for patients. Surprisingly, objective and subjective perceptions of patients and nurses turned out to be very different. In contradiction to nurses impression patients in general did not suffer from mask discomfort, noise or the vanilla fragrance of the mask as stated by those patients who remembered BCPAP treatment when they were interviewed 1 or 2 days later. Far more important the reduction of dyspnea seemed to outweigh any discomfort.

It has been recognized that it is difficult to adopt new techniques or new research evidence in a complex environment such as the CCU. Taylor-Piliae applied Rogers' innovation-diffusion theory to analyze the barriers that impede implementation of new ideas in critical care practice [14,15]. Rogers' theory describes five factors on stages that are necessary before innovations are solidly embedded in practice: knowledge, persuasion, decision, implementation and confirmation.

Lack of knowledge about new techniques or research evidence could slow down successful implementation. So, adequate education, evidence based practice, understandable literature and clinical guidelines are important. In our study, nurses seemed to be trained adequately on the use of BCPAP. In future education the improvement of hemodynamic parameters probably needs more emphasis.

Persuasion can influence beliefs, attitude and behaviour. The opinion formed will be used to adopt or reject the new technique or research evidence. Changing attitudes is difficult. A positive attitude from medical and nursing staff towards the innovation together with relevant arguments could influence prejudices. We

devoted considerable effort to persuade nurses on the importance of the use of CPAP.

In the decision stage, innovations are evaluated and then either accepted or rejected. Aspects that lead to a positive decision include: evidence of improved outcome, limited workload and support from all involved disciplines. All these factors have played a part in our study and should be taken into account if BCPAP is introduced into other environments.

Implementation itself can be impeded by issues such as inadequate administrative facilities and lack of rewards for nursing staff for the effort made for implementing new innovation in practice. In implementing CPAP on the CCU it is recommended that the facilities are optimal and the efforts of nurses should be acknowledged.

In the confirmation stage, with acceptance and integration into routine clinical practice, the innovation process is nearly completed. Compliance should be measured in order to ensure that the new innovations are effective. Although not all eligible patients were treated as prescribed in the protocol, BCPAP treatment on our CCU is now integrated into routine clinical practice. Ongoing evaluation of this new treatment is necessary to ensure that BCPAP treatment will remain fully implemented for all relevant patients.

CONCLUSION

Although it was feasible to implement nurse-centered BCPAP on a CCU this study highlights some of the complexities that accompany its implementation. We observed that the main barriers that prevented the administration of BCPAP were underestimation of the clinical significance of BCPAP, lack of consistent guidelines and overestimation of patient discomfort.

ACKNOWLEDGEMENT

We thank Michael Rodgers for editorial assistance

REFERENCES

1. Rasanen J, Heikkla J, Downs J, Nikki P, Vaisanen I, Viitanen A. Continuous positive airway pressure by face mask in acute cardiogenic pulmonary edema. *Am J Cardiol* 1985; 55:269–300.
2. Pingleton SK. Complications of acute respiratory failure. *Am Rev Respir Dis* 1988; 137:1463-1493.
3. Bersten AD, Holt AW, Vedig AE, Skowronski GA, Baggoley CJ. Treatment of severe cardiogenic pulmonary edema with continuous positive airway pressure delivered by face mask. *N Engl J Med* 1991; 325:1825-1830.
4. Lin M, Yang YF, Chiang HT, Chang MS, Chiang BN, Cheitlin MD. Reappraisal of continuous positive airway pressure therapy in acute cardiogenic pulmonary edema. Short-term results and long-term follow-up. *Chest* 1995; 107:1379-1386.
5. Winck JC, Azevedo LF, Costa-Pereira A, Antonelli M, Wyatt JC. Efficacy and safety of non-invasive ventilation in the treatment of acute cardiogenic pulmonary edema - a systematic review and meta-analysis. *Crit Care* 2006; 10:R69.
6. Ho KM, Wong K. A comparison of continuous and bi-level positive airway pressure non-invasive ventilation in patients with acute cardiogenic pulmonary oedema: a meta-analysis. *Crit Care* 2006; 10:R49.
7. Nieminen MS, Bohm M, Cowie MR, Drexler H, Filippatos GS, Jondeau G, Hasin Y, Lopez-Sendon J, Mebazaa A, Metra M, Rhodes A, Swedberg K, Priori SG, Garcia MA, Blanc JJ, Budaj A, Cowie MR, Dean V, Deckers J, Burgos EF, Lekakis J, Lindahl B, Mazzotta G, Morais J, Oto A, Smiseth OA, Garcia MA, Dickstein K, Albuquerque A, Conthe P, Crespo-Leiro M, Ferrari R, Follath F, Gavazzi A, Janssens U, Komajda M, Morais J, Moreno R, Singer M, Singh S, Tendera M, Thygesen K; ESC Committe for Practice Guideline (CPG). Executive summary of the guidelines on the diagnosis and treatment of acute heart failure: the Task Force on Acute Heart failure of the European Society of Cardiology. *Eur Heart J*. 2005; 26:384-416.

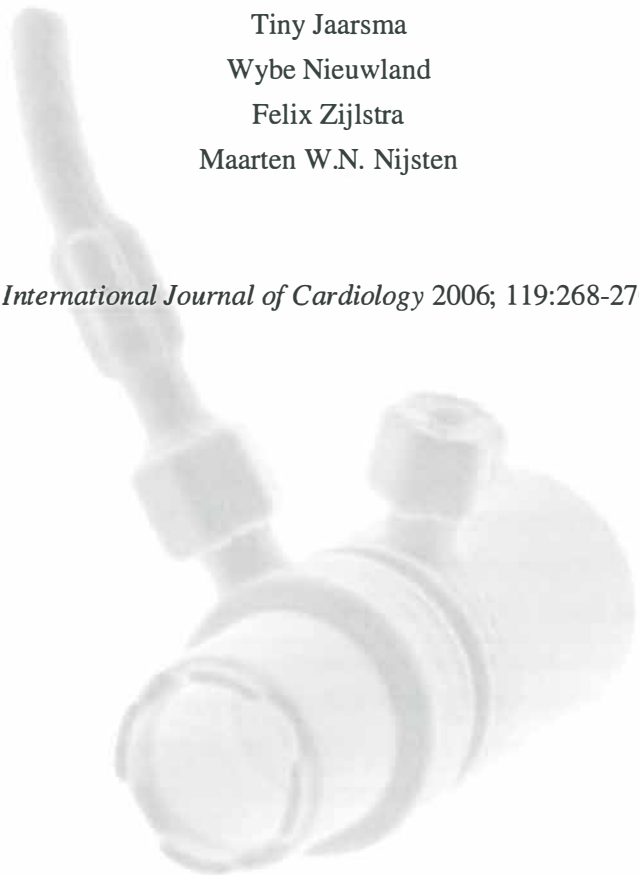
8. Heart Failure Society Of America. Nonpharmacologic management and health care maintenance in patients with chronic heart failure. *J Card Fail.* 2006; 12:e29-37.
9. Dieperink W, van der Horst ICC, Nannenberg-Koops JW, Brouwer HW, Jaarsma T, Nieuwland W, Zijlstra F, Nijsten MWN. A 64-year old man who sustained many episodes of acute cardiogenic pulmonary edema successfully treated with Boussignac continuous positive airway pressure: a case report. *Int J Cardiol* 2007; 119:268-270.
10. Moritz F, Benichou J, Vanheste M, Richard JC, Line S, Hellot MF, Bonmarchand G, Muller JM. Boussignac continuous positive airway pressure device in the emergency care of acute cardiogenic pulmonary oedema: a randomized pilot study. *Eur J Emerg Med* 2003; 10:204-208.
11. Leman P, Greene S, Whelan K, Legassick T. Simple lightweight disposable continuous positive airways pressure mask to effectively treat acute pulmonary oedema: Randomized controlled trial. *Emerg Med Australas* 2005; 17:224-230.
12. Bendjelid K, Schutz N, Suter PM, Fournier G, Jacques D, Fareh S, Romand JA. Does continuous positive airway pressure by face mask improve patients with acute cardiogenic pulmonary edema due to left ventricular diastolic dysfunction? *Chest* 2005; 127:1053-1058.
13. Agarwal R, D. Gupta D. Is the Decrease in LVEDV the Mechanism of Action of Continuous Positive Airway Pressure in Diastolic Heart Failure? *Chest* 2005; 128:1891-1892.
14. Taylor-Piliae RE. Establishing evidence-based practice: issues and implications in critical nursing. *Intensive Crit Care Nurs* 1998; 14:30-37.
15. Rogers EM. Lessons for guidelines from the diffusion of innovations. *Jt Comm J Qual Improv* 1995; 21:324-328.

Chapter 3

A 64-year old man who sustained many episodes of acute cardiogenic pulmonary edema successfully treated with Boussignac continuous positive airway pressure: a case report.

Willem Dieperink
Iwan C.C. van der Horst
Jaqueline W. Nannenberg-Koops
Henk W. Brouwer
Tiny Jaarsma
Wybe Nieuwland
Felix Zijlstra
Maarten W.N. Nijsten

International Journal of Cardiology 2006; 119:268-270



ABSTRACT

Continuous positive airway pressure (CPAP) is standard treatment for patients with acute cardiogenic pulmonary edema. We describe a patient who had 21 episodes of acute cardiogenic pulmonary edema due to very poor patient compliance. This 64-year old man had end-stage congestive heart failure based on systolic left ventricular dysfunction following two myocardial infarctions. In addition to routine medical treatment 15 episodes of pulmonary edema were successfully treated with Boussignac continuous positive airway pressure (BCPAP). The BCPAP system is a simple, disposable, FDA-approved device that delivers positive pressure without a ventilator. This extraordinary case underscores the utility of the BCPAP system to avoid repeated intubation and mechanical ventilation in patients with cardiogenic pulmonary edema.

Acute cardiogenic pulmonary edema usually starts with the sudden onset of hypoxemic respiratory failure, which requires rapid assessment and treatment. When conventional treatment consisting of oxygen therapy, opiates, diuretics and vasodilators has failed, intubation and mechanical ventilation with the associated potential complications is usually required [1]. Nowadays, continuous positive airway pressure (CPAP) applied by a face mask is available to avoid intubation. Several studies showed a decrease of both the rate of intubation and of the hospital length of stay for patients assigned to CPAP compared with conventional therapy [2].

The Boussignac CPAP (BCPAP) system (Vygon, 95440 Ecouen, France) is an FDA-approved face mask CPAP system (Figure 3.1). BCPAP uses a simple, safe, and lightweight (10 gram) disposable cylindrical plastic device without moving parts and without heavy tubing. Thus this system can be used outside the intensive care unit (ICU) and in pre-hospital settings. A jet flow of air and/or oxygen generated in this plastic tube creates a flow-dependent pressure [3]. BCPAP can generate a fraction of inspired oxygen (FiO_2) that approaches 100 %. The BCPAP system contains no mechanical valves or sensors.

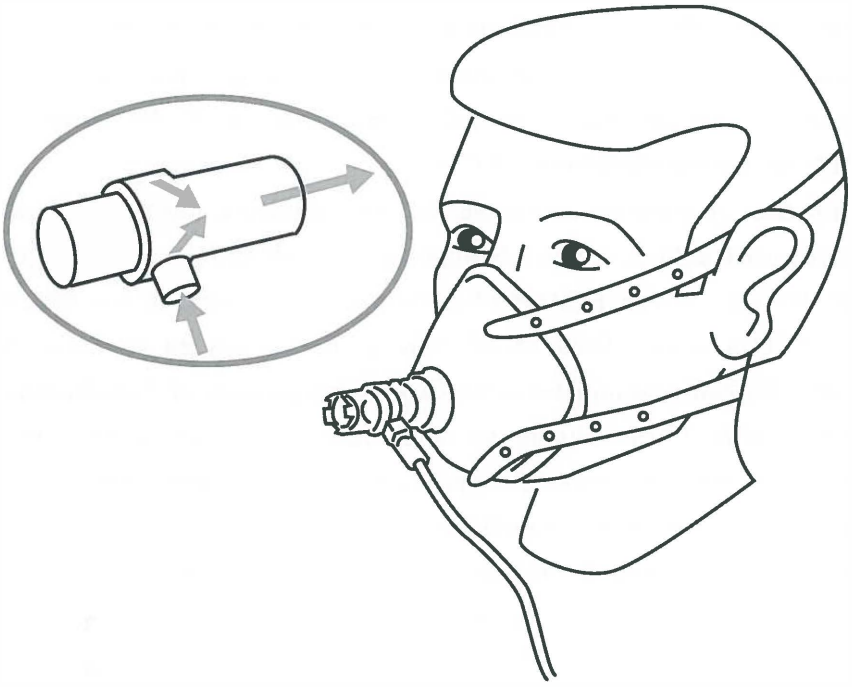


Figure 3.1 Face mask and BCPAP device.
Due to the geometry by which the compressed gas is injected into the hollow Boussignac tube (inner diameter 1.2 cm or 0.5 in.) continuous positive pressure (5 cm H_2O at a flow of 15L/min) is created.

CASE REPORT

A 64-year-old man had a cumulative history of twenty-one coronary care unit (CCU) admissions over a nine-month period (January 2004 - September 2004) with acute dyspnea resulting from pulmonary edema. His medical history included a cardiac arrest in 1998 of which exact data were not available. Two and a half weeks before his first admission to our CCU the patient was resuscitated because of an anterior myocardial infarction. He required intubation and mechanical ventilation. He was immediately transferred to the catheterization laboratory for percutaneous transluminal coronary intervention. During catheterization a significant stenosis of the LAD, CX and RDP was diagnosed. Successful revascularization of the LAD was obtained with stenting. At the end of the procedure an intra-aortic balloon pump was placed, which was removed after 4 days. The stenosis in the CX and RDP were not considered suitable for

revascularization. Physical examination and the X-ray of the thorax revealed persistent signs of left ventricular failure. Echocardiography revealed a poor left ventricular function with a left ventricular ejection fraction of 24%. After 11 days at the ICU he was transferred to the CCU.

When titration of diuretics, morphine and nitro-glycerine together with a non-rebreathing mask did not sufficiently improve his condition, it was decided to start BCPAP. We started with BCPAP when conventional therapy of non-rebreathing mask with 100% oxygen failed in achieving peripheral oxygen saturation (SpO_2) above 90%. BCPAP was initiated at the CCU with a pressure of 5 centimeters H_2O and an FiO_2 of 80-100%. Initially the patient had difficulty in accepting BCPAP. However with intensive nursing support he quickly accepted treatment. After BCPAP treatment his dyspnea rapidly improved. Two days after the first BCPAP treatment a second treatment with mask-CPAP was needed, and again his condition improved. After 42 days he was discharged home.

Table 3.1 Effect of Boussignac mask CPAP.

	Before	**After**	***P-value***
SpO_2	83 (53-99)	96 (64-98)	<0.001
Heart rate (/min)	112 (88-120)	88 (64-106)	0.012
Respiratory Rate (/min)	40 (45-33)	23 (30-22)	0.034
Arterial			
pH	7.27 (7.16-7.33)	7.39 (7.31-7.45)	0.002
PCO_2 (kPa)	7.2 (5.8-7.8)	5.5 (4.6-6.0)	0.017
PO_2 (kPa)	8.1 (6.9-8.8)	13.0 (10.1-14.0)	<0.001
Saturation (%)	86 (83-92)	97 (95-98)	0.001
HCO_3- (mmol/L)	21 (19-26)	23 (21-27)	0.011

Acute therapeutic effect of 15 courses of Boussignac CPAP in a single patient. The median duration of BCPAP administration was 2 hours (range 0.5 to 4.5 hour). Data are medians and ranges. *P*-values were determined with the paired Student's *t*-test.

However, as result of non-compliance of the patient with regard to salt and fluid restriction as well as with regard to medication he had a total of 21 episodes of severe hypoxemia. All fifteen episodes managed by BCPAP (median duration 2 hours) were successful. The median minimal SpO_2 at the start of BCPAP was 83%. In addition, five episodes of pulmonary edema were managed without BCPAP, one

with intubation. In each of the BCPAP courses arterial blood gases improved and the heart rate decreased (Table 3.1). Once BCPAP was stopped, the patient received a Ventimask set at an FiO_2 of 40 to 60%. With intensive supportive measures the patient is currently in a stable condition that is managed by his general practitioner. He has not been admitted to the hospital for the last 16 months.

This case report only concerns a single patient treated among many others. Nevertheless, thanks to his nature to recur frequently, we were able to perform before-after comparisons with statistically significant and clinically relevant differences. The improvement was observed within two hours. Our case also underscores the importance of adequate coaching by the nursing staff during the administration of mask CPAP. BCPAP was easy to implement and provided an effective alternative to CPAP generated by a mechanical ventilator or even intubation.

The treatment of acute pulmonary edema with CPAP was already described in 1938 by Barach [4]. CPAP increases lung volume, improves oxygenation and reduces the work of breathing. CPAP can also reduce venous return, decreasing ventricular filling pressures and improving cardiac performance [5]. Several studies indicate that CPAP in patients with acute hypoxemia due to heart failure may decrease the need for intubation [2]. Compared with oxygen therapy, treatment with CPAP is associated with significant improvement in the PaO_2/FiO_2 ratio, subjective dyspnea score, and respiratory and heart rates. CPAP produces a rapid physiological and symptomatic improvement in these patients, especially within the first hour. We repeatedly observed the same phenomenon in our patient. It has been demonstrated that BCPAP can also be used in pre-hospital settings [6].

Although there are other methods of non-invasive ventilatory support in heart failure, as recently described in this journal, e.g. high-frequency jet ventilation and positive pressure support, mask-CPAP is the simplest, safest and most commonly used technique to treat patients with acute cardiogenic edema [7,8].

In conclusion, our case underscores the feasibility and effectiveness of BCPAP in environments where support with mechanical ventilators is not possible.

REFERENCES

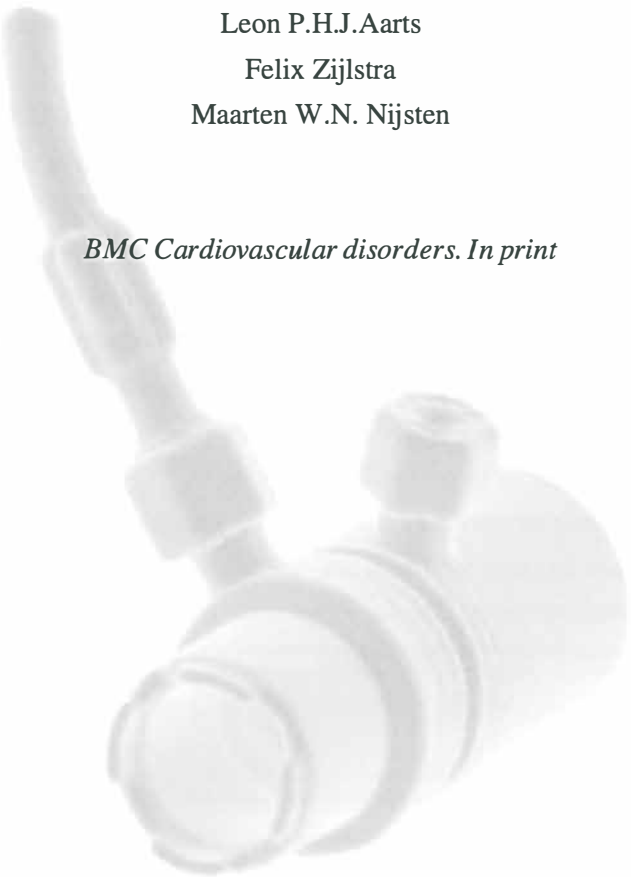
1. Rasanen J, Heikkla J, Downs J, Nikki P, Vaisanen I, Viitanen A. Continuous positive airway pressure by face mask in acute cardiogenic pulmonary edema. *Am J Cardiol* 1985; 55:269–300.
2. Bersten AD, Holt AW, Vedig AE, Skowronski GA, Baggoley CJ. Treatment of severe cardiogenic pulmonary edema with continuous positive airway pressure delivered by face mask. *N Engl J Med* 1991; 325:1825-1830.
3. Moritz F, Benichou J, Vanheste M, Richard JC, Line S, Hellot MF, Bonmarchand G, Muller JM. Boussignac continuous positive airway pressure device in the emergency care of acute cardiogenic pulmonary oedema: a randomized pilot study. *Eur J Emerg Med* 2003; 10:204-208.
4. Barach AL. Positive pressure respiration and its application to the treatment of acute pulmonary edema. *Ann Intern Med* 1938; 12:754-795.
5. Park M, Sangean MC, Volpe M de S, Feltrim MI, Nozawa E, Leite PF, Passos Amato MB, Lorenzi-Filho G. Randomized, prospective trial of oxygen, continuous positive airway pressure, and bilevel positive airway pressure by face mask in acute cardiogenic pulmonary edema. *Crit Care Med* 2004; 32:2407-2415.
6. Templier F, Dolveck F, Baer M, Chauvin M, Fletcher D. 'Boussignac' continuous positive airway pressure system: practical use in a prehospital medical care unit. *Eur J Emerg Med* 2003; 10:87-93.
7. Hu K, Li QQ, Yang J, Chen XQ, Hu SP, Wu XJ. The role of high-frequency jet ventilation in the treatment of Cheyne-Stokes respiration in patients with chronic heart failure. *Int J Cardiol* 2006; 106:224-231.
8. Nadar S, Prasad N, Taylor RS, Lip GY. Positive pressure ventilation in the management of acute and chronic cardiac failure: a systematic review and meta-analysis. *Int J Cardiol* 2005; 99:171-185.

Chapter 4

Boussignac CPAP for the management of acute cardiogenic pulmonary edema: prospective study with a retrospective control group

Willem Dieperink
Tiny Jaarsma
Iwan C.C. van der Horst
Wybe Nieuwland
Karin M Vermeulen
Hanka Rosman
Leon P.H.J.Aarts
Felix Zijlstra
Maarten W.N. Nijsten

BMC Cardiovascular disorders. In print



ABSTRACT

Background: Continuous positive airway pressure (CPAP) treatment for acute cardiogenic pulmonary edema can have important benefits in acute cardiac care. However, coronary care units are usually not equipped and their personnel not adequately trained for applying CPAP with mechanical ventilators. Therefore we investigated in the coronary care unit setting the feasibility and outcome of the simple Boussignac mask-CPAP (BCPAP) system that does not need a mechanical ventilator.

Methods: BCPAP was introduced in a coronary care unit were staff had no CPAP experience. All consecutive patients transported to our hospital with acute cardiogenic pulmonary edema, a respiratory rate >25 breaths/min and a peripheral arterial oxygen saturation of <95% while receiving oxygen, were included in a prospective BCPAP group that was compared with a historical control group that received conventional treatment with oxygen alone.

Results: During the 2-year prospective BCPAP study period 108 patients were admitted with acute cardiogenic pulmonary edema. Eighty-four of these patients (78%) were treated at the coronary care unit of which 66 (61%) were treated with BCPAP. During the control period 66 patients were admitted over a 1-year period of whom 31 (47%) needed respiratory support in the intensive care unit. BCPAP treatment was associated with a reduced hospital length of stay and fewer transfers to the intensive care unit for intubation and mechanical ventilation. Overall estimated savings of approximately € 3,800 per patient were achieved with the BCPAP strategy compared to conventional treatment.

Conclusions: At the coronary care unit, BCPAP was feasible, medically effective, and cost-effective in the treatment of acute cardiogenic pulmonary edema. Endpoints included mortality, coronary care unit and hospital length of stay, need of ventilatory support, and cost (savings).

INTRODUCTION

Many cases of acute cardiogenic pulmonary edema (ACPE) are treated with an oxygen mask and pharmacologic treatment including diuretics and vasodilators [1,2]. When such treatment is not sufficient, additional ventilatory support may be

useful [3,4]. Traditionally this has been achieved via endotracheal intubation and mechanical ventilation, an approach that usually requires intensive care unit (ICU) admission. Continuous positive airway pressure (CPAP) applied by a face mask is a feasible alternative. Several randomized clinical trials [5-8] report a decreased rate of intubation and decreased hospital length of stay for patients assigned to mask-CPAP compared with conventional therapy with oxygen alone. These trials were performed either at the emergency department or at the ICU and not in an environment such as a coronary care unit (CCU) which is often not suited to use mechanical ventilators that are normally necessary for CPAP.

A simple CPAP device which does not require a ventilator might therefore be useful to treat patients with ACPE in the CCU and reduce the need for more invasive treatment in the ICU. The Boussignac CPAP (BCPAP) system is a small lightweight plastic cylinder that is directly connected to face mask which has been shown to be effective for ACPE in the emergency department and in prehospital care [9,10]. Although no data are available on the effectiveness of BCPAP in the CCU we found no convincing medical arguments why BCPAP could not be effective in the CCU. We hypothesized that the major obstacle in treating patients with BCPAP in the CCU would be organizational. We studied if implementation of BCPAP in the CCU was practically feasible, medically effective and cost reducing. For this purpose all patients to our hospital with ACPE were studied.

METHODS

Boussignac CPAP system

The BCPAP face masksystem (Vygon, 95440 Ecouen, France) which is CE-approved and approved by the Food and Drug Administration is a simple and lightweight (10 g) disposable cylindrical plastic device without sensors, mechanical valves and without heavy tubing. A jet flow of air and or oxygen generated in this plastic tube creates a flow dependent pressure [9-14]. We used an air/oxygen blender (Bird 3800™ Microblender, Palm Springs, USA) for full control of the inspired oxygen fraction (FiO_2). BCPAP can generate a fraction of FiO_2 that approaches 100% [11]. The generated pressure is proportional to the flow applied: 3 cm H_2O at a flow of 8 L/min, 5 cm H_2O at a flow of 15 L/min and 10 cm H_2O at

a flow of 23 L/min. This was measured during CPAP treatment with a handheld electronic pressure analyzer (Testo 505-P1, Almere, the Netherlands).

Patients

This study was conducted in a regional university hospital with a 12 bed CCU and 4 ICU's with 47 beds. ACPE was defined as acute dyspnea associated with a past of ischemic heart disease or cardiomyopathy and physical signs consistent with pulmonary edema including respiratory rate >25 breath/min and a peripheral arterial oxygen saturation (SpO_2) <95% while receiving oxygen [3].

We studied all adult patients admitted to our hospital with respiratory failure due to ACPE. Exclusion criteria were known evidence of severe pulmonary pathology, Glasgow coma scale <9 and in the prospective group the inability to wear a facemask (facial deviations, non-cooperative patient). The first ten patients treated with BCPAP on the CCU were observed by the medical and nursing staff of the ICU to ensure a safe and sufficient CPAP treatment.

The institutional review board of the hospital approved the study design that compared a historical control group with a prospective BCPAP group. Verbal consent was obtained and recorded from patients to use their medical data. (METc 2004.195).

BCPAP group and control group

Patients in the intervention group received BCPAP with an initial pressure of 10 cm H_2O and an FiO_2 of 80-100%. BCPAP pressure and FiO_2 were decreased when there was a clinical improvement in SpO_2 and heart rate. Patients were preferably kept in a sitting position during BCPAP. In order to facilitate successful implementation of BCPAP both medical and nursing staff was involved in the implementation process. During a training session of 45 minutes we introduced the BCPAP system as well as a protocol (Figure 4.1) for applying CPAP. The training session included theory and practical use of CPAP and was distributed to all staff by an experienced ICU nurse according a standardized teaching package to ensure consistency. CCU staff was instructed to use BCPAP not for other indications than ACPE.

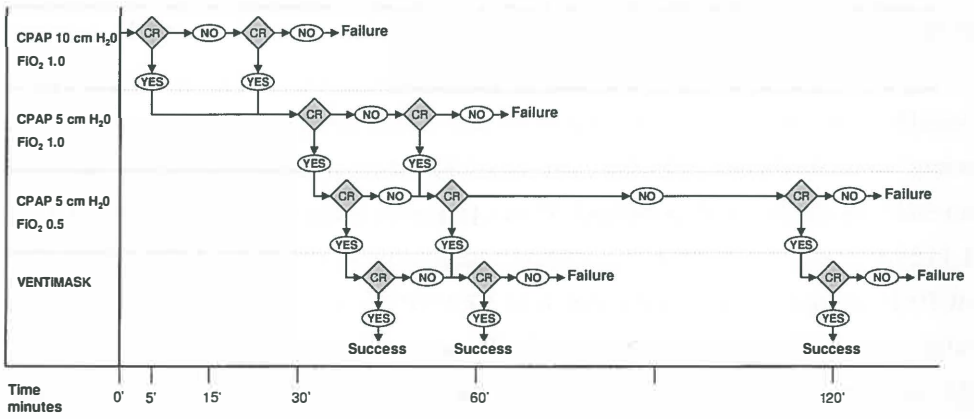


Figure 4.1 Algorithm for BCPAP treatment in patients with ACPE in the CCU.
Protocol as used for patients treated with BCPAP in the CCU. Since ACPE should respond within 30 minutes to BCPAP therapy, this protocol required early and frequent assessments of the patients' response. From left to right the duration of BCPAP treatment is displayed and from top to bottom the decreasing level of respiratory support. CR: clinical response is defined as an improvement in respiration rate and SpO_2 to at least >95%. Success was defined as achievement of CR with breathing oxygen through a ventimask. Note that depending on the patients' response the protocol leads to a minimal duration of BCPAP of 30 minutes and a maximal duration of 2 hours.

Data from the prospective BCPAP cohort of patients were compared with the data from a historical control group. The prospective part of the study was conducted over a period of 24 months. Patients in the control group were admitted in the same CCU and hospital in a previous 12 month period and treated with oxygen through non-rebreathing mask (FiO_2 approximately 100%), ventimask (FiO_2 40-60%) or nasal catheter (3 L/min; FiO_2 30%) on ICU admissions and endotracheal intubation. For this purpose we evaluated all records from patients admitted to the CCU and the ICU's for ACPE.

Data on pharmacological treatment with diuretics, opioids and nitroglycerine as well as patient acceptance, complications, SpO_2, heart rate, CCU length of stay, hospital length of stay hospital mortality and long term mortality were collected.

An economic evaluation was carried out to estimate costs of the strategy including BCPAP therapy compared with conventional treatment. This evaluation was

performed from a hospital perspective, and all relevant costs made between admission and discharge from the hospital were taken into account. Where possible, costs were valued according to Dutch standard prices [15]; if no standard prices were available, costs were estimated based on true resources used and time invested by the hospital personnel. Cost categories included were: stay in CCU (€ 1,112/day), stay in ICU (€ 1,733/day), admission to hospital ward (€ 490/day), BCPAP therapy (€ 42), personnel cost BCPAP therapy (€ 23) and endotracheal intubation (€ 377). Based on costs of both conventional treatment and BCPAP, and the percentages of patients admitted to the CCU and ICU, total costs for both strategies were calculated and compared.

Statistical analysis

Data are presented as medians and associated interquartile ranges (IQR) or means with standard deviation (SD) for continuous variables, or as group percentages for categorical variables. Statistical analysis was performed using Student's t, Mann Whitney, Wilcoxon signed rank test, Fisher exact or Chi-square test. Overall comparisons were based on intention-to-treat: all patients treated at the CCU or ICU for ACPE were compared between the control and the BCPAP period, irrespective of whether they actually received BCPAP. All statistical analyses were performed using commercially available software (SPSS 14.0, SPSS, Chicago, Illinois, USA).

RESULTS

Sixty-six patients were included in the control group and 108 patients in the BCPAP group (Figure 4.2). Patients in both study groups were predominantly male and had a mean age of 72 years. Table 4.1 shows the characteristics of both groups on an intention-to-treat basis. Pharmacological treatment did not differ between the groups. Eighty-four (78%) of the patients in the BCPAP group were admitted to the CCU, of which 66 were actually treated with BCPAP. No problems in the practical use of the BCPAP system were identified. Eighteen patients who were admitted to the CCU were eligible for BCPAP but did not receive this treatment and received oxygen alone. The main reason was because there were insufficient signs of serious

respiratory distress and staff believed that the patients (baseline SpO_2 91%. IOR 88-93) showed adequate spontaneous improvement.

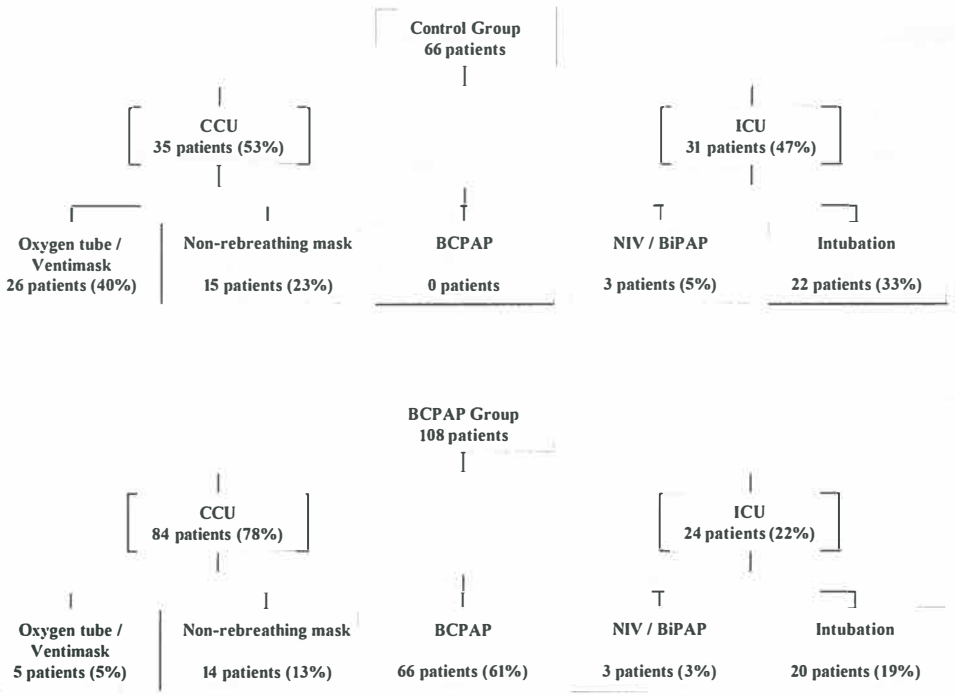


Figure 4.2 Study design.
First all patients were examined at the emergency department by a cardiologist and depending on his findings transferred to CCU or ICU. The control group consists of all patients admitted to our hospital with ACPE over a one year period. The BCPAP group covers all patients with ACPE over a two year period.
Note the considerable shift of ICU admissions to CCU admissions in the BCPAP group ($p<0.001$). The number of patients treated with BCPAP in the control group was zero since this option was not available.

The median duration of BCPAP treatment was 105 minutes (IQR 60-172 minutes). Pressure measurements showed a predicted CPAP level in 76% of the BCPAP patients. In only two patients a flow of more than 23 L/min was given to achieve the desired BCPAP level. Sixty-four of 66 patients maintained stable gas exchange after BCPAP was stopped. Two of the 66 patients required follow-up respiratory support in the ICU after BCPAP treatment in the CCU. One patient with a large

myocardial infarction and support with an intra-aortic balloon pump had to be intubated and the other received ventilator mask-CPAP. No other complications of the BCPAP treatment were reported and 88% of the staff assessed the implementation of BCPAP as simple and uncomplicated.

Table 4.1 Patient characteristics

	Control	BCPAP	P-value
N	66	108	
Duration of the study	1 year	2 years	
Age in yrs, mean, ± SD	72 ± 11	72 ± 11	-
Male, n (%)	46 (70)	69 (64)	-
Medication, n (%)			
Loop-diuretics	56 (85)	97 (90)	-
Opioids	34 (51)	47 (44)	-
Nitroglycerine	29 (44)	39 (36)	-
Admission CCU, n (%)	35 (53)	84 (78)	<0.01
Admission ICU, n (%)	31 (47)	24 (22)	<0.01
CCU stay in days, median (IQR)	3 (2-5)	2 (2-3)	-
CCU stay in days, mean (SD)	2.0 (2.3)	2.3 (2.7)	-
ICU stay in days, median (IQR)	2 (2-5)	4 (2-7)	<0.01
ICU stay in days, mean (SD)	2.0 (3.5)	1.3 (3.4)	-
Hospital stay in days, median (IQR)	16 (8-24)	8 (2-16)	<0.01
Hospital stay in days, mean (SD)	20.2 (23.5)	13.9 (17.9)	0.047
Hospital survivors, n of total (%)	50 (76)	84 (78)	-
6 month survival, n of total (%)	49 (74)	81 (75)	-

Comparison of the two patients groups studied with intention-to-treat analysis The median CCU and ICU stay is only given for those patients who were admitted to the CCU and ICU respectively. In contrast, the mean CCU and ICU stay are calculated for the whole group. Comparisons were performed with the Fisher exact test, Chi-square test, Student-t test and the Mann Whitney test. IQR = Interquartile range.

Saturation and heart rate

Baseline median SpO_2 was lower in the BCPAP group than in the control group (88% versus 91%, p<0.01). Both groups showed a significant increase in SpO_2 after 2 hours (Table 4.2). Nevertheless the increase of SpO_2 was higher in the BCPAP group compared to the control group (+8% versus +3%, p<0.01) with a

similar SpO_2 after 2 hours. Heart rate in the BCPAP group was significantly decreased after 2 hours of treatment (median 104/min to 86/min) this in contrast to the unchanged heart rate in the control group (median 102). In the 2 to 6 hours after discontinuation of BCPAP, the saturation or heart rate did not deteriorate again.

Table 4.2 Physiological responses before and after BCPAP in subgroup of CCU patients

	Control	BCPAP	p-value
N	35	84	
Heart rate baseline	102 (83-125)	104 (86-119)	-
Heart rate after 120 min	102 (82-117)	86 (76-99)*	0.03
Mean arterial pressure baseline	101 (85-118)	103 (79-123)	-
SpO_2 baseline	91 (88-94)	88 (82-92)	<0.01
SpO_2 after 120 min	94 (92-95)*	95 (92-97)*	-

Data are median (IQR), SpO_2 = peripheral arterial oxygen saturation. The Wilcoxon signed rank test was used to test difference scores of data collected at baseline and after 120 minutes.
* Significant $p<0.05$ improvement at 120 minutes compared to baseline.

Intubations, length of stay and outcome

After implementing BCPAP on the CCU, the number of intubations showed an absolute decrease of 14% ($p<0.001$) compared to the control period with conventional treatment. Likewise the number of ICU admissions showed an absolute decrease of 25% ($p<0.001$) compared to the control period.

The median CCU-stay in de BCPAP group was 1 day and a median hospital length of stay of 6 days. In the control group the median CCU-stay was 2 days and the median hospital length of stay was 14 days. There was no significant difference between the mortality rates in both groups (BCPAP 22% versus control 24%).

Costs

As a shift was found in route of admittance, resulting in more patients in the BCPAP group admitted to the CCU compared to the ICU, costs changed accordingly. In the control group, mean total costs for ACPE patients were € 13,754 per patient.

In the BCPAP group (where 61% of the patients actually received BCPAP) mean total costs were € 9,968. This resulted in a saving of € 3,787 per candidate for the new treatment strategy compared to the traditional strategy.

DISCUSSION

We demonstrated that for patients with acute cardiogenic pulmonary edema it is possible to use a simple form of mask-CPAP. The introduction of BCPAP at our CCU decreased endotracheal intubations and the related ICU admissions. Our study also underscores that CPAP, as delivered by mask, is superior to conventional oxygen treatment in improving oxygenation and decreasing heart rate. Moreover, no complications were observed with the use of the BCPAP system on our CCU. The decreasing number of endotracheal intubations with related ICU admissions after implementation of BCPAP on our CCU led to notable cost reductions. Savings were approximately € 3,800 per candidate for the strategy that included BCPAP compared to the conventional strategy.

The treatment of ACPE with non-invasive CPAP was already described in de first half of the previous century by both Poulton [16] and Barach [17]. Nowadays there is extensive evidence that supports the use of non-invasive CPAP [7,1]. CPAP delivered by mask has shown to be beneficial in several randomized clinical trials [5-8] as stated in the introduction. However, these studies were not performed at a CCU or a likewise environment. In general CPAP together with pharmalogical therapy achieves rapid clinical improvement, but heart failure of which ACPE is a cardinal manifestation is still associated with high in-hospital mortality and a poor long-term prognosis [18], as also is seen in our patients (Table 4.1).

ACPE patients show significant improvement in the PaO_2/FiO_2 ratio, subjective dyspnea score, and respiratory and heart rates with CPAP [19,20]. At the same time CPAP can reduce venous return, decrease ventricular filling pressures and improve cardiac performance. In our patients, CPAP produced a rapid physiological and symptomatic improvement in patients with ACPE, especially within the first hours, as also been observed with other CPAP modalities [21]. More complicated forms of non-invasive ventilation, as bilevel ventilation, showed no additional benefits in the treatment of ACPE compared to CPAP [7,22]. Therefore, clinicians must be

aware that if a rapid physiological and symptomatic improvement does not occur, the etiology of respiratory insufficiency might not be acute cardiogenic pulmonary edema. In fact our protocol allowed no more than 120 minutes of BCPAP treatment because other causes for respiratory distress may then be present and intubation might be more appropriate in this setting.

A tight fitted facemask can cause serious discomfort but it is fundamental for achieving adequate positive pressure in the airways during CPAP. The patients at our CCU were systematically queried about their experiences with BCPAP treatment and they found that the reduction of dyspnea outweighed any discomfort of the facemask. These findings were exemplified by a patient who was successfully treated during many episodes of ACPE with BCPAP: although initially wary about a facemask he subsequently easily accepted it for many times [23]. Although most nurses in our CCU had limited expertise and experience in the field of mask-CPAP they could apply BCPAP effectively after a short instruction period.

The effectiveness of BCPAP has also been demonstrated in prehospital settings [9]. Future studies focusing on the early administration of BCPAP in patients with ACPE - in a pre-hospital setting such as an ambulance - would add insight into the clinical advantages and cost benefits of early CPAP treatment of patients with ACPE.

There are some limitations of the present study. First, the data from the control group is retrospective and ACPE is not always easy to diagnose. Based on the evaluation of all patient records great care was taken to include all patients who were admitted to our hospital with ACPE according to established criteria [3]. Second, in the prospective BCPAP group the treatment of patients might have differed slightly due to ongoing advances in treatment of patients with ACPE. For comparison, treatment of patients with ST-elevation myocardial infarction improved because of more widespread and rapid use of percutaneous coronary intervention. But in the treatment of ACPE no major or minor changes in the treatment have occurred in our institution. Finally, calculated savings were based on assumptions that are related with the reimbursement system in the Netherlands

and therefore should be interpreted with caution when transposed to other institutions.

CONCLUSION

The results of this study underscore the utility of the Boussignac CPAP system as a simple, effective and cost saving modality on a CCU for patients with ACPE.

REFERENCES

1. Nieminen MS, Bohm M, Cowie MR, Drexler H, Filippatos GS, Jondeau G, Hasin Y, Lopez-Sendon J, Mebazaa A, Metra M, Rhodes A, Swedberg K, Priori SG, Garcia MA, Blanc JJ, Budaj A, Cowie MR, Dean V, Deckers J, Burgos EF, Lekakis J, Lindahl B, Mazzotta G, Morais J, Oto A, Smiseth OA, Garcia MA, Dickstein K, Albuquerque A, Conthe P, Crespo-Leiro M, Ferrari R, Follath F, Gavazzi A, Janssens U, Komajda M, Morais J, Moreno R, Singer M, Singh S, Tendera M, Thygesen K; ESC Committe for Practice Guideline (CPG). Executive summary of the guidelines on the diagnosis and treatment of acute heart failure: the Task Force on Acute Heart failure of the European Society of Cardiology. *Eur Heart J* 2005; 26:384-416.
2. Heart Failure Society of America. Nonpharmacologic management and health care maintenance in patients with chronic heart failure. *J Card Fail* 2006; 12:e29-37.
3. Rasanen J, Heikkla J, Downs J, Nikki P, Vaisanen I, Viitanen A. Continuous positive airway pressure by face mask in acute cardiogenic pulmonary edema. *Am J Cardiol* 1985; 55:269-300.
4. Pingleton SK. Complications of acute respiratory failure. *Am Rev Respir Dis* 1988; 137:1463-1493.
5. Bersten AD, Holt AW, Vedig AE, Skowronski GA, Baggoley CJ. Treatment of severe cardiogenic pulmonary edema with continuous positive airway pressure delivered by face mask. *N Engl J Med* 1991; 325:1825-1830.
6. Lin M, Yang YF, Chiang HT, Chang MS, Chiang BN, Cheitlin MD. Reappraisal of continuous positive airway pressure therapy in acute cardiogenic pulmonary edema. Short-term results and long-term follow-up. *Chest* 1995; 107:1379-1386.
7. Winck JC, Azevedo LF, Costa-Pereira A, Antonelli M, Wyatt JC. Efficacy and safety of non-invasive ventilation in the treatment of acute cardiogenic pulmonary edema - a systematic review and meta-analysis. *Crit Care* 2006; 10:R69.

8. Ho KM, Wong K. A comparison of continuous and bi-level positive airway pressure non-invasive ventilation in patients with acute cardiogenic pulmonary oedema: a meta-analysis. *Crit Care* 2006; 10:R49.
9. Leman P, Greene S, Whelan K, Legassick T. Simple lightweight disposable continuous positive airways pressure mask to effectively treat acute pulmonary oedema: Randomized controlled trial. *Emerg Med Australas* 2005; 17:224-230.
10. Templier F, Dolveck F, Baer M, Chauvin M, Fletcher D. 'Boussignac' continuous positive airway pressure system: practical use in a prehospital medical care unit. *Eur J Emerg Med* 2003; 10:87-93.
11. Moritz F, Benichou J, Vanheste M, Richard JC, Line S, Hellot MF, Bonmarchand G, Muller JM. Boussignac continuous positive airway pressure device in the emergency care of acute cardiogenic pulmonary oedema: a randomized pilot study. *Eur J Emerg Med* 2003; 10:204-208.
12. Dieperink W, Goorhuis JF, de Weerd W, Hazenberg A, Zijlstra JG, Nijsten MWN. Walking with continuous positive airway pressure. *Eur Respir J* 2006; 27:853-855.
13. Templier F, Dolveck F, Baer M, Chauvin M, Fletcher D. Laboratory testing measurement of FIO_2 delivered by Boussignac CPAP system with an input of 100% oxygen. *Ann Fr Anesth Reanim* 2003; 22:103-107.
14. Cigada M, Elia G, UmbrelloM , Giacomini M, Mistraletti G, Tommasino C, Iapichino G. Novel indications for the Boussignac CPAP valve. *Intensive Care Med* 2007; 33:374-375.
15. Oostenbrink JB, Koopmanschap MA, Rutten FFH, Guidelines for cost studies; methods and unit prices for economic evaluations in health care (in Dutch). *Dutch Health Care Insurance Board (CVZ)* 2004.
16. Poulton EP, Oxon DM, Left-sided heart failure with pulmonary oedema its treatment with the "pulmonary plus pressure machine". *Lancet* 1936; 228:981-983.
17. Barach AL. Positive pressure respiration and its application to the treatment of acute pulmonary edema. *Ann Intern Med* 1938; 12:754-795.

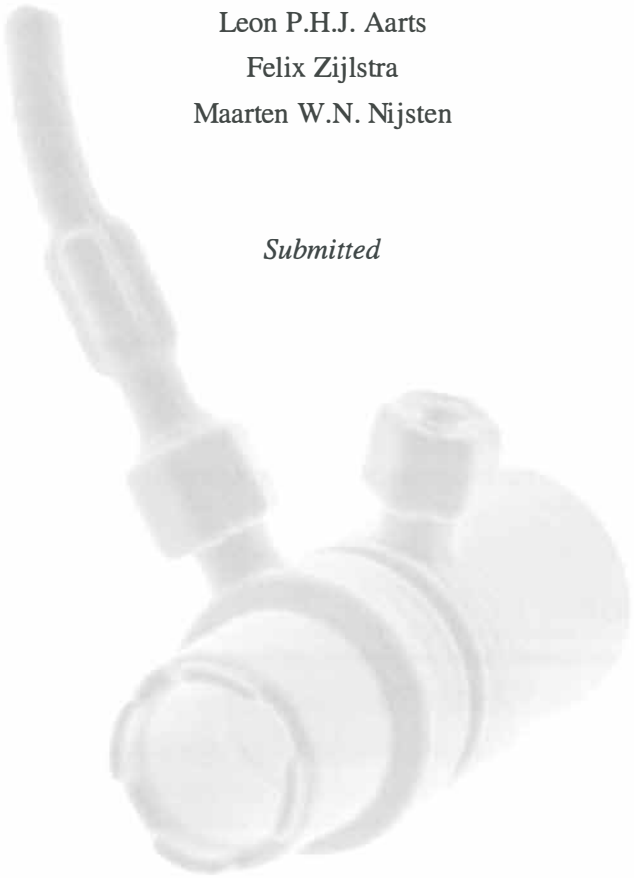
18. Adnet F, Le Toumelin P, Leberre A, Minadeo J, Lapostolle F, Plaisance P, Cupa M. In-hospital and long-term prognosis of elderly patients requiring endotracheal intubation for life-threatening presentation of cardiogenic pulmonary edema. *Crit Care Med* 2001; 29:891-895.
19. Bendjelid K, Schutz N, Suter PM, Fournier G, Jacques D, Fareh S, Romand JA. Does continuous positive airway pressure by face mask improve patients with acute cardiogenic pulmonary edema due to left ventricular diastolic dysfunction? *Chest* 2005; 127:1053-1058.
20. Agarwal R, Gupta D, Bendjelid K. Is the Decrease in LVEDV the Mechanism of Action of Continuous Positive Airway Pressure in Diastolic Heart Failure? *Chest* 2005; 128:1891- 1892.
21. Park M, Sangean MC, Volpe M de S, Feltrim MI, Nozawa E, Leite PF, Passos Amato MB, Lorenzi-Filho G. Randomized, prospective trial of oxygen, continuous positive airway pressure, and bilevel positive airway pressure by face mask in acute cardiogenic pulmonary edema. *Crit Care Med* 2004; 32:2407-2415.
22. Peter JV, Moran JL, Philips-Hughes J, Graham P, Bersten AD. Effect of non-invasive pressure ventilation (NIPPV) on mortality in patients with acute cardiogenic pulmonary oedema: a meta-analysis. *Lancet* 2006; 367:1155-1163.
23. Dieperink W, van der Horst ICC, Nannenberg-Koops JW, Brouwer HW, Jaarsma T, Nieuwland W, Zijlstra F, Nijsten MWN. A 64-year old man who sustained many episodes of acute cardiogenic pulmonary edema successfully treated with Boussignac continuous positive airway pressure: a case report. *Int J Cardiol* 2007; 119:268-270.

Chapter 5

Treatment of acute cardiogenic pulmonary edema in the ambulance with Boussignac continuous positive airway pressure

Willem Dieperink
Ellen E.M. Weelink
Iwan C.C. van der Horst
Ronald de Vos
Tiny Jaarsma
Leon P.H.J. Aarts
Felix Zijlstra
Maarten W.N. Nijsten

Submitted



ABSTRACT

Background: Early initiation of continuous positive airway pressure applied by facemask benefits patients with acute cardiogenic pulmonary edema (ACPE). The simple disposable Boussignac continuous positive airway pressure system (BCPAP) has been used in ambulances by physicians. In the Netherlands Ambulances are manned by nurses and not physicians. We hypothesized that ambulance nurses are able to identify patients with ACPE and can successfully apply BCPAP.

Patients and methods: After training, all 33 ambulances in our region were equipped with BCPAP. ACPE was diagnosed on clinical signs and a pulse-oxymetry saturation (SpO_2) <95%. BCPAP (5 cm H_2O; FiO_2>80%) was generated with an oxygen flow of 15 L/min. Patients' physiological responses, experiences and clinical outcome were collected from ambulance and hospital records. Ambulance nurses and patients received a questionnaire.

Results: From March 2006 till December 2006 32 patients (ages ranging from 61 to 94) received BCPAP during transport to six different regional hospitals. In 26 patients (81%) the diagnosis ACPE was confirmed. With BCPAP median (IQR) SpO_2 increased from 79% (69%-94%) to 96% (89%-98%) within 20 min. The median (IQR) duration of BCPAP treatment was 26 min (21-32 min). No complications occurred during BCPAP. The patients had no negative recollection of the treatment. Ambulance personnel were satisfied about the BCPAP therapy.

Conclusion: BCPAP was feasible and effective as treatment for ACPE in the ambulance applied by nurses, and can be implemented in all ambulances in the Netherlands.

INTRODUCTION

The benefit of continuous positive airway pressure (CPAP) applied by facemask as an adjuvant treatment for acute cardiogenic pulmonary edema (APCE) is well established [1]. Several studies indicate that early administration of CPAP in ACPE reduces the number of endotracheal intubations and shortens intensive care unit (ICU), coronary care unit (CCU) and hospital length of stay [1-4]. The effectiveness of CPAP has also been demonstrated in prehospital settings when

applied by attending emergency physicians [5,6]. In the Netherlands the ambulance service network is manned by well-trained nurses, not by physicians. These are all registered nurses, often specialised in intensive care, emergency care, or anaesthesiology, with additional ambulance training for one year. The ambulance nurses are extensively trained in diagnosing and initiating treatment for different conditions that are set out in protocols.

The application of CPAP by nurses in ambulances has not been described before. The administration of CPAP has been proven effective with the Boussignac CPAP (BCPAP) system in the treatment of ACPE in the emergency department [7]. Given the experiences with non-physicians on ambulances in identifying ST-elevation myocardial infarction (STEMI), we hypothesized that diagnosis of ACPE could also be made by ambulance nurses [8].

Our aim was to demonstrate that ACPE can be identified by trained nurses and treated with BCPAP during emergency transportation by ambulance.

METHODS

This study was performed by the Department of Cardiology of the University Medical Center Groningen (UMCG) and AmbulanceZorg Groningen in the setting of a regional cooperation between the Emergency Departments and Departments of Cardiology in six hospitals in our region. The study was approved by the Institutional Review Board (METc 2006.232) of the UMCG.

Before BCPAP was implemented for the treatment of patients with ACPE on the ambulance all ambulance nurses received training of 1 hour on applying BCPAP on the ambulance, by means of lecture and an e-learning program. (The e-learning program is freely available at "www.bcpap.umcg.nl") All 33 ambulances in our region (AmbulanceZorg Groningen) were equipped with the disposable BCPAP system, with 4 different sizes of face mask and a BCPAP instruction manual. The BCPAP system (Vygon, 95440 Ecouen, France) is a light weight (10 g) FDA and CE approved, disposable, cylindrical plastic device. Oxygen is supplied by the means of an integrated oxygen tube with a length of 2 meters that is connected to an oxygen cylinder. A jet flow of oxygen that accelerates to nearly the speed of sound through four micro-channels generates a flow-dependent pressure in the

BCPAP system [9-11]. The BCPAP system was directly connected to a small mobile 2L oxygen cylinder (Linde Gas Therapeutics Benelux, Eindhoven, the Netherlands) pressurized at 200 bar. Once in the ambulance, the BCPAP system was connected to larger (2 x 5L) oxygen cylinders pressurised at 200 bar. Depending of the oxygen flow administered (5 to 20 L/min) a CPAP of 2-8 cm H_2O was created.

When the ambulance nurse triaged a patient for treatment with BCPAP, the severity of ACPE, prior history of heart disease as well as the respiratory condition including peripheral oxygen saturation (SpO_2), were carefully considered. Criteria for BCPAP were defined as: clinical signs of ACPE, respiratory rate of more than 25 breaths/min and an SpO_2<95% while receiving oxygen. If deemed necessary the treatment with the disposable BCPAP system could be continued without interruption in the emergency department, the CCU or the ICU. In addition to BCPAP, patients were also treated with morphine, frusemide and nitroglycerin.

Patient demographic information, medical history and physiological information from the ambulance monitoring system as well as data from hospital admission and subsequent outcome were retrieved. For this purpose the investigators visited all hospitals. Informed consent was obtained from patients to use their clinical data. Surviving patients were queried about their experiences. Eight months after introduction we queried the ambulance nurses about their experiences with respect to BCPAP treatment in patients with ACPE.

Data are presented as medians and associated interquartile ranges (IQR) or means with standard deviation (SD) for continuous variables, or as group percentages for categorical variables. All statistical analyses were performed using commercially available software (SPSS 14.0, SPSS, Chicago, Illinois, USA).

RESULTS

From March 2006 until December 2006, 32 patients were identified as having ACPE and received treatment with the BCPAP according to the protocol. Median patient age was 82 (IQR 73-86) years, with 15 females and 17 males (Table 5.1). The patients were transported to one of six hospitals in our region. For 26 (81%) patients the diagnosis ACPE was confirmed by the hospital physicians and the

study investigators (EEMW, ICCvdH and MWNN), on the basis of physical examination, chest X-ray and other available data. Of the other 6 patients, three had COPD exacerbations, two had pneumonia and one intracranial hemorrhage. Three patients were admitted to the ICU, two of them had to be intubated and one was treated with non-invasive bilevel positive pressure ventilation. One patient (3%) died in the ambulance, 10 patients (31%) died during their hospital stay and within a median observation period of 4 months, another three patients (9%) had died (Table 5.2). The cause of death was heart failure in all but 1 case.

Table 5.1. Patient characteristics

N	32
Age in yrs, mean, ± SD	80 ± 9
Male (%)	17 (53)
Treatment time, minutes	26
Diagnoses in hospital	
ACPE, n of total (%)	26
COPD, n of total (%)	3
Pneumonia, n of total (%)	2
Intracranial hemorrhage, n of total (%)	1

Table 5.2 Outcome

N	32
CCU stay in days, median (IQR)	1 (0-1)
Hospital stay in days, median (IQR)	6 (3-9)
Died during transport, n of total (%)	1 (3)
Died in hospital, n of total (%)	10 (31)
6 month survival, n of total (%)	18 (56)

After initiation of BCPAP, median (IQR) SpO_2 increased from 79% (69%-94%) to 96% (89%-98%) within 20 min (Figure 5.1). The median heart rate in the same interval did not change.

Four patients were interviewed about their experiences with BCPAP directly after treatment by one of the investigators (WD). We also queried 14 patients after a

mean interval of 4 months about their experiences with BCPAP. None of the patients had a negative recollection of the treatment. Eleven patients (61%) could not remember specific details of the treatment. The other seven patients (39%) reported that the BCPAP treatment immediately reduced dyspnea. No discomfort was reported by the patients. 20 of the 22 (91%) queried ambulance nurses were positive about practical feasibility and medical effectiveness of BCPAP treatment for ACPE. No technical or logistical problems were reported.

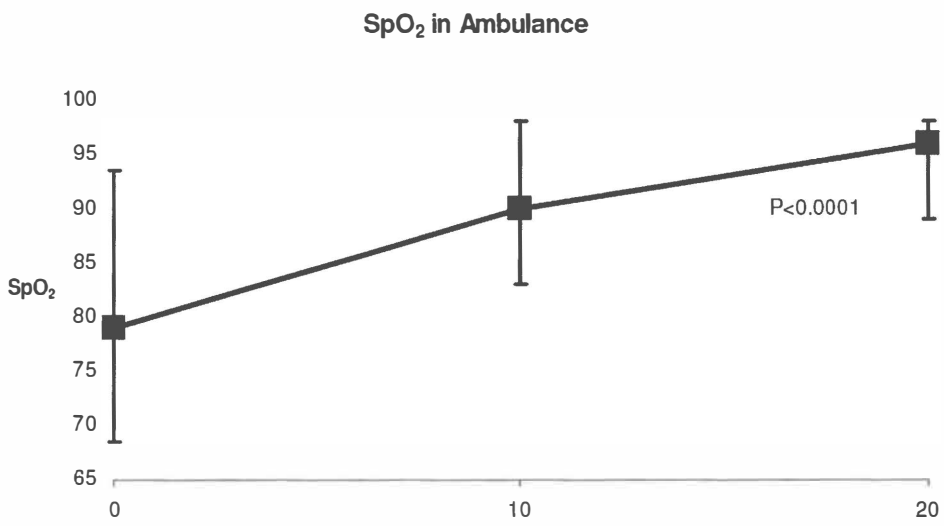


Figure 5.1 SpO_2 in ambulance
Changes in median peripheral oxygen saturation (SpO_2) before, after 10 and 20 minutes of BCPAP treatment in 32 patients with acute cardiogenic pulmonary edema.

DISCUSSION

To our knowledge this is the first study in which BCPAP is used in ambulances by nurses for the treatment of patients with ACPE. The study shows that BCPAP could be applied on the ambulance by trained ambulance nurses. They can recognize ACPE equally well as physicians, who correctly diagnosed ACPE in 77% of cases [7]. The treatment of ACPE with BCPAP on the ambulance has been described before[7]. However, in that study BCPAP was applied by physicians.

The treatment of ACPE with CPAP was already described by Alvan Barach in 1938 [12]. CPAP can increase lung volume, improve oxygenation and reduce the work of breathing [13]. CPAP can also reduce venous return, decreasing ventricular filling pressures and improve cardiac performance [14,15]. Several studies indicate that CPAP in patients with acute hypoxemia due to heart failure may decrease the need for intubation [1,3,16]. Compared with oxygen therapy, treatment with CPAP is associated with significant improvement in the PaO_2/FiO_2 ratio, subjective dyspnea score, and respiratory and heart rates. CPAP produces a rapid physiological and symptomatic improvement in these patients, especially within the first hour. Interestingly, non-invasive ventilation is equivalent to CPAP alone [17]. The use of CPAP as well as many other interventions performed by non-physicians on the ambulance, with the exception of thrombolysis in patients with ST-Elevation Myocardial Infarction (STEMI) [18], has been poorly investigated.

The rise in life expectancy and the improved survival after myocardial infarction have led to an increase of predominantly elderly patients with heart failure and ACPE. This is underscored by a mean age of 80 years in our patients. Our patients had a high mortality in-hospital as well as after hospital discharge. In recent studies on the use of CPAP after hospital admission for ACPE patients, similar mortality rates were found [19,20].

In our study we have also shown that SpO_2 in patients with hypoxemia due to ACPE rapidly improved when treated with BCPAP. Similar benefits were reported with in-hospital treatment of patients with ACPE treated with CPAP from more sophisticated CPAP systems or mechanical ventilators [1,3,4]. The utility of early aggressive therapy for ACPE is underscored by the results seen after introduction of a mobile coronary care unit in Sweden. With this mobile unit, CPAP was used in 91% of 158 patients. This resulted in marked clinical improvement upon hospital arrival in comparison with a control group of 158 patients who did not receive CPAP [21].

Since four years we have also designated a pivotal role for the ambulance nurses in diagnosing STEMI for immediate transport to our catheterization laboratory for primary percuntaneous intervention (PCI). The feasibility, safety and speed of paramedic-referred primary PCI has recently been demonstrated in a Canadian

study [8]. As with STEMI and primary PCI, the ambulance nurses were well motivated to diagnose ACPE and initiate treatment with BCPAP. Undoubtedly an important motivation for nurses to apply BCPAP will be the rapid clinical improvement that this therapy induces in patients who are in severe distress.
Our study has a number of limitations. This study is an observational study, with a limited number of patients. Nevertheless, we demonstrated that the BCPAP system is well suited for use in the ambulance. After admission to one of the six hospitals, different treatment protocols may have been used. We hypothesize that it may also be possible to use the BCPAP system in air ambulances for patients with ACPE. The low weight and the small size of the system is very relevant in this respect. Future studies with the BCPAP system must be done to confirm this hypothesis. We are currently in the process of implementing BCPAP in other ambulance regions, with the goal of implementation in the whole of the Netherlands.

CONCLUSION

This study showed that immediate treatment of ACPE with BCPAP both indicated by and administrated by ambulance nurses was feasible and effective in our ambulance region. We believe that BCPAP can be implemented in ambulances in countries with similar emergency systems for the treatment of patients with ACPE.

ACKNOWLEDGEMENTS

We wish to thank the ambulance personnel of the AmbulanceZorg Groningen, the cardiologists and staff from the Delfzicht Hospital in Delfzijl, Refaja Hospital in Stadskanaal, St. Lucas Hospital in Winschoten, Martini Hospital in Groningen and Nij Smellinge Hospital in Drachten for their support of this study. This study was partly supported by a grant from the Office for Medical Technology Assessment and the Thoraxcenter, Department of Cardiology of the University Medical Center Groningen, University of Groningen, The Netherlands.

REFERENCES

1. Lin M, Yang YF, Chiang HT, Chang MS, Chiang BN, Cheitlin MD. Reappraisal of continuous positive airway pressure therapy in acute cardiogenic pulmonary edema. Short-term results and long-term follow-up. *Chest* 1995; 107:1379-1386.
2. Pang D, Keenan SP, Cook DJ, Sibbald WJ. The effect of positive pressure airway support on mortality and the need for intubation in cardiogenic pulmonary edema: a systematic review. *Chest* 1998; 114:1185-1192.
3. Bersten AD, Holt AW, Vedig AE, Skowronski GA, Baggoley CJ. Treatment of severe cardiogenic pulmonary edema with continuous positive airway pressure delivered by face mask. *N Engl J Med* 1991; 325:1825-1830.
4. Rasanen J, Heikkla J, Downs J, Nikki P, Vaisanen I, Viitanen A. Continuous positive airway pressure by face mask in acute cardiogenic pulmonary edema. *Am J Cardiol* 1985; 55:269-300.
5. Kosowsky JM, Stephanides SL, Branson RD, Sayre MR. Prehospital use of continuous positive airway pressure (CPAP) for presumed pulmonary edema: a preliminary case series. *Prehosp Emerg Care* 2001; 5:190-196.
6. Hubble MW, Richards ME, Jarvis R, Millikan T, Young D. Effectiveness of prehospital continuous positive airway pressure in the management of acute pulmonary edema. *Prehosp Emerg Care*. 2006; 10:430-439.
7. Templier F, Dolveck F, Baer M, Chauvin M, Fletcher D. 'Boussignac' continuous positive airway pressure system: practical use in a prehospital medical care unit. *Eur J Emerg Med* 2003; 10:87-93.
8. Le May MR, Davies RF, Dionne R, Maloney J, Trickett J, So D, Ha A, Sherrard H, Glover C, Marquis JF, O'Brien ER, Stiell IG, Poirier P, Labinaz M. Comparison of early mortality of paramedic-diagnosed ST-segment elevation myocardial infarction with immediate transport to a designated primary percutaneous coronary intervention center to that of similar patients transported to the nearest hospital. *Am J Cardiol* 2006; 98:1329-1333.
9. Moritz F, Benichou J, Vanheste M, Richard JC, Line S, Hellot, MF Bonmarchand G, Muller JM. Boussignac continuous positive airway

pressure device in the emergency care of acute cardiogenic pulmonary oedema: a randomized pilot study. *Eur J Emerg Med* 2003; 10:204-208.

10. Leman P, Greene S, Whelan K, Legassick T. Simple lightweight disposable continuous positive airways pressure mask to effectively treat acute pulmonary oedema: Randomized controlled trial. *Emerg Med Australas* 2005; 17:224-230.
11. Dieperink W, van der Horst ICC, Nannenberg-Koops JW, Brouwer HW, Jaarsma T, Nieuwland W, Zijlstra F, Nijsten MWN. A 64-year old man who sustained many episodes of acute cardiogenic pulmonary edema successfully treated with Boussignac continuous positive airway pressure: a case report. *Int J Card*iol 2007; 119:268-270.
12. Barach AL. Positive pressure respiration and its application to the treatment of acute pulmonary edema. *Ann Intern Med* 1938; 12:754-795.
13. Duncan AW, Oh TE, Hilman DR. PEEP and CPAP. *Anaesth Intens Care* 1986; 14:236-250.
14. Bendjelid K, Schutz N, Suter PM, Fournier G, Jacques D, Fareh S, Romand JA. Does continuous positive airway pressure by face mask improve patients with acute cardiogenic pulmonary edema due to left ventricular diastolic dysfunction? *Chest* 2005; 127:1053-1058.
15. Agarwal R, Gupta D, Bendjelid K. Is the Decrease in LVEDV the Mechanism of Action of Continuous Positive Airway Pressure in Diastolic Heart Failure? *Chest* 2005; 128:1891-1892.
16. Kelly CA, Newby DE, McDonagh TA, Mackay TW, Barr J, Boon NA, Dargie HJ, Douglas NJ. Randomised controlled trial of continuous positive airway pressure and standard oxygen therapy in acute pulmonary edema. *Eur Heart J* 2002; 23:1379-1386.
17. Winck JC, Azevedo LF, Costa-Pereira A, Antonelli M, Wyatt JC. Efficacy and safety of non-invasive ventilation in the treatment of acute cardiogenic pulmonary edema - a systematic review and meta-analysis. *Crit Care* 2006; 10:R69.
18. Pitt K. Prehospital selection of patients for thrombolysis by paramedics. *Emerg Med J* 2002; 19:260-263.

19. Adnet F, Le Toumelin P, Leberre A, Minadeo J, Lapostolle F, Plaisance P, Cupa M. In-hospital and long-term prognosis of elderly patients requiring endotracheal intubation for life-threatening presentation of cardiogenic pulmonary edema. *Crit Care Med* 2001; 29:891-895.
20. L'Her E, Duquesne F, Girou E, de Rosiere XD, Le Conte P, Renault S, Allamy JP, Boles JM. Noninvasive continuous positive airway pressure in elderly cardiogenic pulmonary edema patients. *Intensive Care Med* 2004; 30:882-888.
21. Gardtman M, Waagstein L, Karlsson T, Herlitz J. Has an intensified treatment in the ambulance of patients with acute severe left heart failure improved the outcome? *Eur J Emerg Med* 2000; 7:15-24.

Part II

Novel applications for the Boussignac continuous positive airway pressure system *(chapter 6-8)*

Chapter 6

Walking with continuous positive airway pressure

Willem Dieperink
Joanne F. Goorhuis
Willemien de Weerd
Anda Hazenberg
Jan G. Zijlstra
Maarten W.N. Nijsten

European Respiratory Journal 2006; 27:853-855

ABSTRACT

A ventilator-dependent child had been in the paediatric intensive care unit (PICU) ever since birth. As a result, she had fallen behind considerably in her development. After 18 months, continuous positive airway pressure was successfully administered via a tracheostomy tube with a novel lightweight device. This enabled her to walk in the PICU. With this device, the child was discharged home where she could walk with an action range of 10 m. Subsequently, her psychomotor development improved remarkably. To the authors' knowledge, this is the first case report of a patient, adult or paediatric, who could actually walk with a sufficient radius of action while receiving long-term respiratory support.

INTRODUCTION

The current study presents a case of a child with chronic lung disease (CLD) of infancy and tracheobronchomalacia (TBM). TBM with or without CLD is associated with prolonged ventilator dependency, even when only continuous positive airway pressure (CPAP) is needed [1,2]. Usually a general-purpose ventilator, a dedicated noninvasive ventilator or a CPAP machine applies CPAP. Regardless of whether CPAP is applied via a full-face mask, nasal mask, nasal prongs or a tracheostomy tube, patients who are otherwise awake and mobile will be bound to their bed or wheelchair. In children especially, this immobilisation will impede the development of motor skills as well as many other skills.

Recently, a CPAP device (Boussignac system; Vygon, Ecouen, France) has become available that can be directly connected to the tracheostomy tube and is driven only by compressed air. The present study describes the successful application of the Boussignac CPAP, which enabled the patient to become mobilised and walk.

CASE REPORT

Pentalogy of Cantrell was diagnosed, in a female born at 36 weeks gestational age and with a birthweight of 2,000 g. This is a rare congenital malformation characterised by: 1) a lower sternum defect; 2) an anterior diaphragm defect; 3) a pericardium defect; 4) an omphalocele; and 5) cardiovascular abnormalities. She

had been ventilator dependent since birth due to TBM and developed CLD due to a complicated abdominal closure with need for mechanical ventilation at high pressures. At the age of 4 months, a tracheostomy was performed because prolonged ventilatory support and weaning was expected. In the months following the tracheostomy, weaning attempts failed repeatedly due to recurrent hypoxaemia and hypercapnia. Assessment at the age of 13 months showed a psychomotor development compatible with the age of 6 months.

During weaning with conventional CPAP apparatus, the heavy tubing severely restricted the patient's mobility. For that reason, Boussignac CPAP (Figure 6.1) was introduced at the age of 18 months to stimulate psychomotor development. Pressurised air and oxygen with a final oxygen fraction of 30% and a flow of 15 L-min^{-1} was used to deliver 5 cmH_2O of CPAP to the tracheostomy tube. Humidification was supplied with an ordinary syringe infusion pump supplying 3 mL-h^{-1} of sterile water to the Boussignac CPAP device. Boussignac CPAP, combined with extended tubing, offered the child an action range of 10 m so she could play and develop motor skills. Over a period of 6 months, Boussignac CPAP was gradually extended to all hours that the patient was awake. During sleep, the child was mechanically ventilated. Supplemental oxygen was gradually decreased to zero. In the same period, the child was fully mobilised with Boussignac CPAP and her psychomotor and mental development improved dramatically.

Finally, after an admission of 2 yrs at the current authors' paediatric intensive care unit, the child was discharged home. She was still receiving Boussignac CPAP during the day and pressure-controlled ventilation (18/4 cm of H_2O; frequency 25-min^{-1}; inspiratory oxygen fraction 0.3) during the night. Pressurised air was generated at home by a medically certified compressor (Jun-air, Nørresundby, Denmark). At home, the time spent on Boussignac CPAP was gradually tapered over 1 yr. No technical problems were encountered, and especially no obstructions of the tracheostomy tube occurred. At the age of 2.5 yrs, new testing showed that the child's psychomotor development had returned to normal according to calendar age. At the age of 3 yrs, the child could breathe adequately via a tracheostomy tube without additional support while awake. At present (3.5 yrs), she is being weaned from ventilatory support during the night.

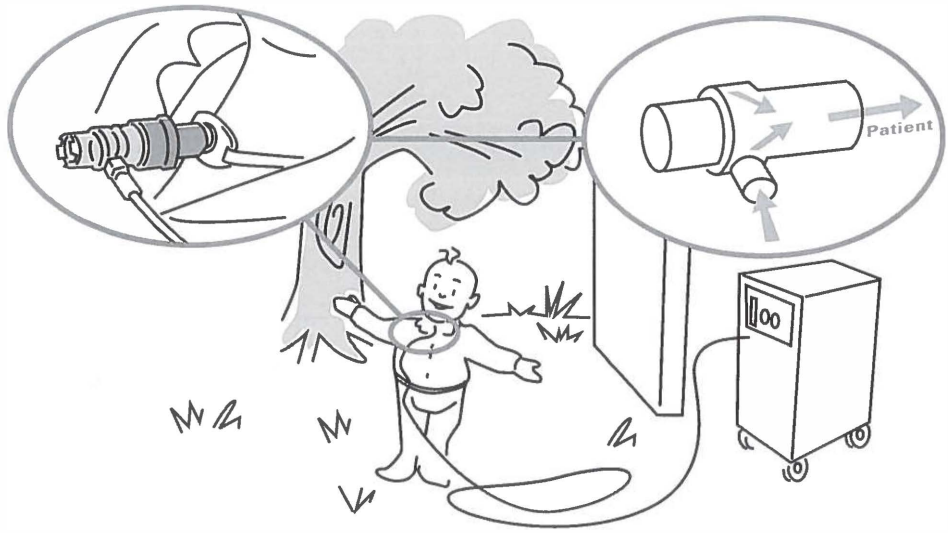


Figure 6.1 Schematic diagram showing the delivery of continuous positive airway pressure (CPAP) to an infant at home.
The child learned to walk while on long-duration daytime CPAP support with a novel system. Pressurised air was generated by a transportable air compressor powered by electricity from the mains connection (height 0.85 m) and transported through thin tubing with a length of 10 m. CPAP (4 cmH_2O) was generated in situ by the Boussignac valve that was connected to the tracheal canula. Due to the geometry with which the compressed air is injected into the hollow tube (inner diameter 0.5 inches or 1.2 cm), a virtual ''valve'' is created.

NOVEL CPAP DELIVERY SYSTEM

The Boussignac CPAP system is a Food and Drug Administration approved, simple and lightweight (10 g) disposable plastic device without moving parts. It was developed to deliver CPAP for face masks [3]. In addition to generating positive pressure, the system also allows the administration of high inspiratory oxygen fractions and humidification. Since CPAP is generated in situ, the system only needs compressed air or oxygen delivered through thin tubing that can be of any length. CPAP varies linearly when the flow is applied. This contrasts with the short and heavy tubing that characterises other CPAP systems. Although marketed for application to face masks, Boussignac CPAP can be easily applied to tracheostomy tubes as well. In adult patients who are weaned from respiratory

support with a tracheostomy tube, Boussignac CPAP is already frequently used. The unique properties of the Boussignac system result in more freedom of movement for these patients. The low weight of the overall system also reduces mechanical forces on the trachea and surrounding structures. Since the Boussignac ''valve'' is only a virtual valve with no moving parts, it cannot be obstructed by sputum, a common problem in tracheostomy patients. Moreover, given the open design of the Boussignac valve, the patient can still breathe freely without any resistance if flow is interrupted.

The Boussignac CPAP system has one major disadvantage, which is the noise that is produced (55 dB measured at 1 m at a CPAP level of 5 cmH_2O). The noise is related to the flow that is applied.

DISCUSSION

With Boussignac CPAP, it was possible to allow a patient on long-term ventilatory support to walk with a sufficient radius of action. With the combination of TBM and CLD, CPAP was applied 24/24 as treatment for the TBM to splint the airways. Ventilation with additional oxygen during the night served as treatment for CLD. Children who are ventilator dependent due to CLD and/or TBM have a good chance to ultimately become independent of long-term ventilatory support, albeit after 1.6–2.3 yrs [4].

Thus, CLD and TBM are associated with a great impact on intensive care resources and healthcare utilisation [5]. Therefore, it is important to consider and develop alternative techniques that allow early mobilisation and discharge of these patients. Although the hospital, and especially the intensive care unit, is an unsuitable environment for the developing child, discharging these patients is difficult [1,4]. In the present study, a significant delay occurred before the patient could be discharged, in part as a result of the process of obtaining certification of the equipment for use at home.

With the Boussignac CPAP system, the child was successfully mobilised and discharged home. Although a direct relationship between mobilisation with the Boussignac CPAP and the improved psychomotor development cannot be proven, it is obvious that the freedom to move stimulates psychomotor development in

children. Assisted ventilation during exercise has been applied in adult chronic obstructive pulmonary disease patients [6]. However, these studies have been carried out on a treadmill or bicycle ergometer. In these cases, the patient cannot be considered to be mobile. Although portable ventilators have been evaluated in adults [7], and might be used under parental guidance, such systems are too heavy to be used by a playing child. The possibility to mobilise CPAP-dependent patients may improve the quality of life of children and adults. The relative safety of the open design of the Boussignac system is reflected by the fact that no tube obstructions occurred over a period of 18 months. Boussignac CPAP may be of use for the temporal support of adult patients with reversible respiratory insufficiency. Engoren *et al.* [8] described that out of 429 adult patients who received a tracheostomy in a tertiary care centre, as many as 143 were discharged while ventilator dependent. Although the authors do not describe the percentage of patients who had reversible CPAP dependency, in the current authors' experience this number may be considerable.

In conclusion, the Boussignac system was successfully used to treat a continuous positive airway pressure-dependent patient with a tracheostomy. This allowed the patient to walk and achieve a normal level of development. Children especially may benefit from this therapy so they can develop in a more normal way.

REFERENCES

1. Allen J, Zwerdling R, Ehrenkranz R, Gaultier C, Geggel R, Greenough A. Kleinman R, Klijanowicz A, Martinez F, Ozdemir A, Panitch HB, Nickerson B, Stein MT, Tomezsko J Van den akker J, American Thoracic Society. Statement on the care of the child with chronic lung disease of infancy and childhood. *Am J Respir Crit Care Med* 2003; 168:356-396.
2. Wiseman NE, Duncan PG, Cameron CB. Management of tracheobronchomalacia with continuous positive airway pressure. *J Pediatr Surg* 1985; 20:489-493.
3. Maitre B, Jaber S, Maggiore SM, Bergot E, Richard JC, Bakthiari H, Housset B, Boussignac G, Brochard L. Continuous positive airway pressure during fiberoptic bronchoscopy in hypoxemic patients. A randomized double-blind study using a new device. *Am J Respir Crit Care Med* 2000; 162:1063-1067.
4. Edwards EA, O'Toole M, Wallis C. Sending children home on tracheostomy dependent ventilation: pitfalls and outcomes. *Arch Dis Child* 2004; 89:251-255.
5. Fraser J, Mok Q, Tasker R. Survey of occupancy of paediatric intensive care units by children who are dependent on ventilators. *BMJ* 1997; 315:347-348.
6. van 't Hul A, Kwakkel G, Gosselink R. The acute effects of noninvasive ventilatory support during exercise on exercise endurance and dyspnea in patients with chronic obstructive pulmonary disease: a systematic review. *J Cardiopulm Rehabil* 2002; 22:290-297.
7. Revill SM, Singh SJ, Morgan MD. Randomized controlled trial of ambulatory oxygen and an ambulatory ventilator on endurance exercise in COPD. *Respir Med* 2000; 94:778-783.
8. Engoren M, Arslanian-Engoren C, Fenn-Buderer N. Hospital and long-term outcome after tracheostomy for respiratory failure. *Chest* 2004; 125:220-227.

Chapter 7

Boussignac CPAP for weaning with tracheostomy tubes

Willem Dieperink
Leon P.H.J. Aarts
Michael G.G. Rodgers
Hans Delwig
Maarten W.N. Nijsten

Respiration 2007
Published online 25 July 2007

ABSTRACT

Background: In patients who are weaned with a tracheostomy tube (TT), continuous positive airway pressure (CPAP) is frequently used. Dedicated CPAP systems or ventilators with bulky tubing are usually applied. However, CPAP can also be effective without a ventilator by the disposable Boussignac CPAP (BCPAP) system that is normally used with face masks. *Objective:* It was the aim of this audit to evaluate the feasibility of low-level BCPAP in patients who were weaned with a TT.

Methods: All patients at our surgical intensive care unit who received a TT for weaning were considered for application of BCPAP. Once patients received minimal pressure support from the mechanical ventilator, the BCPAP device was connected to the TT three times a day for 30 minutes with pressure set to 3 to 5 cm H_2O, FiO_2 at 0.4 and with humidification. BCPAP was then gradually extended to 24 hours/day. Patient acceptance, complications and outcome were recorded.

Results: 58 patients received a TT to facilitate weaning. They had a median stay of 52 days in the intensive care unit during which they had an endotracheal tube for 22 days and a TT for 28 days. 50 of these patients (86%) received BCPAP for a median of 16 days. The lightweight BCPAP system was well tolerated without tube obstructions or accidental decanulations and may have contributed to patient mobility. No patients remained on ventilatory support after hospital discharge. In-hospital and 1-year survival were 86 and 71%, respectively.

Conclusions: BCPAP is a feasible and safe method for weaning tracheostomy patients.

INTRODUCTION

Weaning patients from long-term ventilation is an important clinical issue [1]. A fundamental motive to place a tracheostomy tube (TT) in such patients is the potential of more gradual weaning from ventilatory support as it constitutes an intermediate step between endotracheal intubation and spontaneous breathing. Perceived benefits of tracheostomy are improved patient comfort with the ability to speak, better oral hygiene, more effective airway suctioning, decreased gas resistance, less tube dead space, less need for sedation and a lower incidence of

tube obstruction [2,3]. An additional medical and economic advantage may be the earlier discharge of tracheostomy patients from the intensive care unit (ICU) [4,5].
Several strategies can be used to wean patients with a TT. Once or thrice daily, temporary disconnections, T-Piece trials or continuous positive airway pressure (CPAP) have all been described, with no clinical evidence on the superiority of any particular method [6,7]. At our ICU, we have the policy that for patients on minimal pressure support, the next weaning step is to apply intermittent low-level CPAP. Mechanical ventilators or dedicated CPAP systems are normally used for this purpose. Patients who are fit for CPAP are often awake and can be mobilized, although it may be difficult due to the large and heavy tubing of these systems. The forces exerted on the TT by the heavy tubing can also cause tracheal wall damage [8]. Moreover, when the patient is disconnected from the ventilator, adequate humidification becomes very important as dried mucus can easily obstruct a TT [9].
With the lightweight Boussignac CPAP system (BCPAP) connected to a TT it is possible to provide oxygen, CPAP and humidification without a ventilator (Figure 7.1) [10]. We recently reported on an infant with a TT who was successfully weaned and mobilized with BCPAP for nearly 2 years [11]. In the current study, we investigated the advantages and disadvantages of the BCPAP in a cohort of adult patients weaned with a TT at the ICU.

PATIENTS AND METHODS

This audit was conducted in a 12 bed closed-format surgical ICU at a university regional hospital over a period of 36 months (from March 2002 until February 2005). All patients at our ICU who received a tracheostomy to facilitate weaning were studied. The timing of tracheostomy depended on various clinical factors. Most tracheostomies were percutaneous tracheostomies according to one of four main criteria [1]: marginal respiratory mechanics, to decrease the high levels of sedation, to improve the patient's psychological condition and to enhance mobility. The percutaneous procedures were performed by an experienced staff intensivist (H.D. or M.G.G.R.) after informed consent of the patient or the patient's family-members was obtained.

BCPAP system

The BCPAP system (Vygon, Ecouen, France) is an FDA-approved lightweight (10 g) disposable cylindrical plastic device (Figure 7.1) with an inner diameter of 1.2 cm. It contains no sensors or mechanical valves and was developed to deliver CPAP for face masks. A jet flow of air and/or oxygen that accelerates through four parallel microchannels creates a flow-dependent pressure in this plastic tube. Due to the geometry by which the compressed gas is injected into the hollow tube a turbulent virtual "valve" is created [12-15].

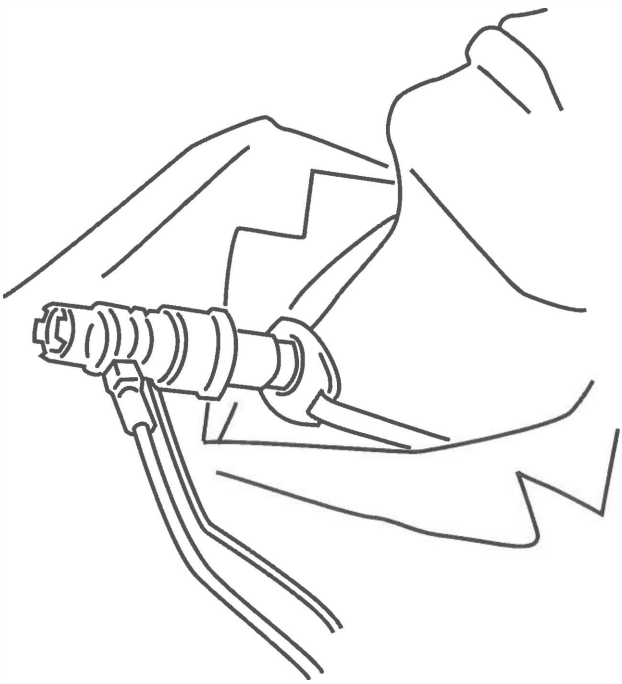


Figure 7.1 Boussignac CPAP system and tracheostomy tube.
CPAP is generated in situ by the BCPAP connected with an adapter to the TT. Two thin flexible tubes deliver air/oxygen (left tube Ø 3 mm) and humidification (right tube 1.5 mm). Due to the geometry with which air-oxygen is injected into the hollow tube (Ø 1.2 cm) a positive pressure with a "virtual" valve is created.

The BCPAP system can be lightweight because pressure is generated in situ, which makes large-bore tubing unnecessary. In our patients, the BCPAP valve was

attached to the TT with a small and lightweight disposable adapter. A second port on the BCPAP device (more proximal to the patient) allows humidification or application of additional oxygen if desired. Humidification was titrated with a standard 50-ml-syringe infusion pump that delivered normal saline at 4-8 ml/hour. We used an air/oxygen blender (Bird 3800™ Microblender, Palm Springs, USA) for full control of the FiO_2. The generated pressure was proportional to the flow applied: 3 cm H_2O at a flow of 8 L/min and 5 cm H_2O at a flow of 15 L/min.

Since BCPAP with a TT is a new technical combination of two accepted therapies, informed consent was not necessary. According to Dutch legislation (Medical Research Involving Human Subject Act), an audit does not need the approval of the Institutional Review Board.

Weaning

Weaning with BCPAP was initiated when mechanical pressure support was 15/5 cm H_2O (i.e. 10 cm H_2O pressure support above 5 cm H_2O PEEP) with a frequency <20/min and an FiO_2 of 0.4, over a period of at least 24 h with a stable haemodynamic status, controlled infection, sufficient oxygenation and no need for further interventions. Patients then initially received 30 minutes of low-level BCPAP at a pressure level of 3-5 cm H_2O 3 times a day at an FiO_2 of 0.4 [7]. When patients displayed an oxygen saturation <95% while on BCPAP, with apparent adequate ventilation or even increased inspiratory flow, the FiO_2 was set at 0.5 or higher to provide a sufficient effective FiO_2. If the 30-minutes BCPAP weaning trial was successful, time on BCPAP was gradually increased to 24 hours/day. The next step was slowly decreasing the pressure level to zero so that the Boussignac system at this point only provided oxygen and humidification. Once zero-positive end-expiratory pressure was achieved, we tapered the FiO_2 to 0.21. The course of all weaning trials with BCPAP was recorded in detail. We also recorded age, gender, reason for admission, the acute physiologic and chronic health evaluation (APACHE II) score on ICU-admission, technique of tracheostomy, duration of endotracheal intubation before tracheostomy, and of mechanical ventilation after tracheostomy, incidence of tube obstruction, length of ICU and hospital stay, ICU and in-hospital mortality, ventilatory support after ICU or hospital-discharge and 1-year survival after hospital discharge.

Table 7.1 Tracheostomy patients characteristics

	BCPAP	no BCPAP
N	50	8
Age in yrs, mean, ± sd	63 ± 15	48 ± 14 *
Male/female, N	32/18	6/2
APACHE II	22 ± 7	25 ± 10
SAPS	47 ± 14	54 ± 21
Kind of admissions, n, (%)		
Surgical		
Vascular	8 (16)	
Oncology	2 (4)	
Abdominal	32 (64)	2 (25)
Liver transplantation	3 (6)	3 (38)
Thorax	2 (4)	
Trauma	3 (6)	3 (38)
Reason for ICU admission, n, (%)		
Surgery	8(16)	4 (50)
Acute respiratory failure	32 (64)	3 (38)
Neurologic	1 (2)	
Sepsis	8 (16)	1 (13)
Metabolic disorders	1 (2)	
Median duration of the endotracheal tube before tracheostomy, days (IQR)	22 (14-30)	17 (1-34)
Median duration of canulation, days (IQR)	31 (20-44)	17 (9-20) *
Tracheostomy techniques		
Percutaneous/surgical	45/5	6/2
Median ICU stay, days (IQR)	64 (42-77)	34(10-50) *
Median duration of hospitalization, days, IQR	83 (62-120)	53 (30-100)
Hospital survivors, n of total (%)	44 (88)	6 (75)
Discharge from ICU	45 (90)	7 (88)
Alive after 1 yr	35 (70)	6 (75)

APACHE = Acute physiology and chronic health evaluation score; SAPS = simplified acute physiological score; IQR = interquartile range. * $P<0.05$ vs. BCPAP.

Statistical Analysis

Data are presented as medians and associated interquartile ranges or means ± SD for continuous variables, or as group percentages for categorical variables. All statistical analyses were performed with commercially available software (SPSS 12.0, SPSS, Chicago, Illinois, USA)

RESULTS

Fifty-eight patients admitted on the surgical ICU received a tracheostomy to facilitate weaning during the 3-year study period. Surviving patients were followed-up for 1-4 years. Overall demographic data and outcome information for the 58 patients are summarized in table 7.1.

There were 38 (66%) men; median age was 65 years, and 34 (59%) of the 58 patients underwent abdominal surgery. The majority (47 patients; 81%) received a TT because of marginal respiratory mechanics including 6 patients with a critical illness polyneuropathy and 6 patients who developed a late adult respiratory distress syndrome. Eleven patients (19%) received a TT for at least one of the following criteria: need to decrease the high levels of sedation, to gain psychological benefits and to enhance mobility. Four patients were immediately tracheostomized upon arrival at the ICU for the following reasons: transfer from another ICU, severe overweight, spinal cord transection and severe mediastinitis. Two patients were tracheomized in another ICU before transfer to our ICU.

Figure 7.2 displays the distribution of the various individual weaning times for the 50 patients (86%), who were weaned with BCPAP. This group was weaned from mechanical ventilation with a median duration of BCPAP of 16 days (interquartile range: 11-25 days). Eight (14%) of the 58 were not weaned with BCPAP because weaning was expected to be brief. This is underscored by the significantly lower duration of cannulation and shorter ICU stay in patients who were weaned without BCPAP.

BCPAP was well tolerated by the patients without tube obstructions and contributed to comfort and mobility since patients were able to sit in a chair during weaning. Humidification of the BCPAP device was apparently effective because TT's were not obstructed in patients on BCPAP. The sound produced by the BCPAP system was related to the flow that was applied: a flow of 15 L/min produced 55 dB at 1-meter distance whereas a flow of 5 L/min produced <40 dB, which constitutes a strong reduction in the sound level.

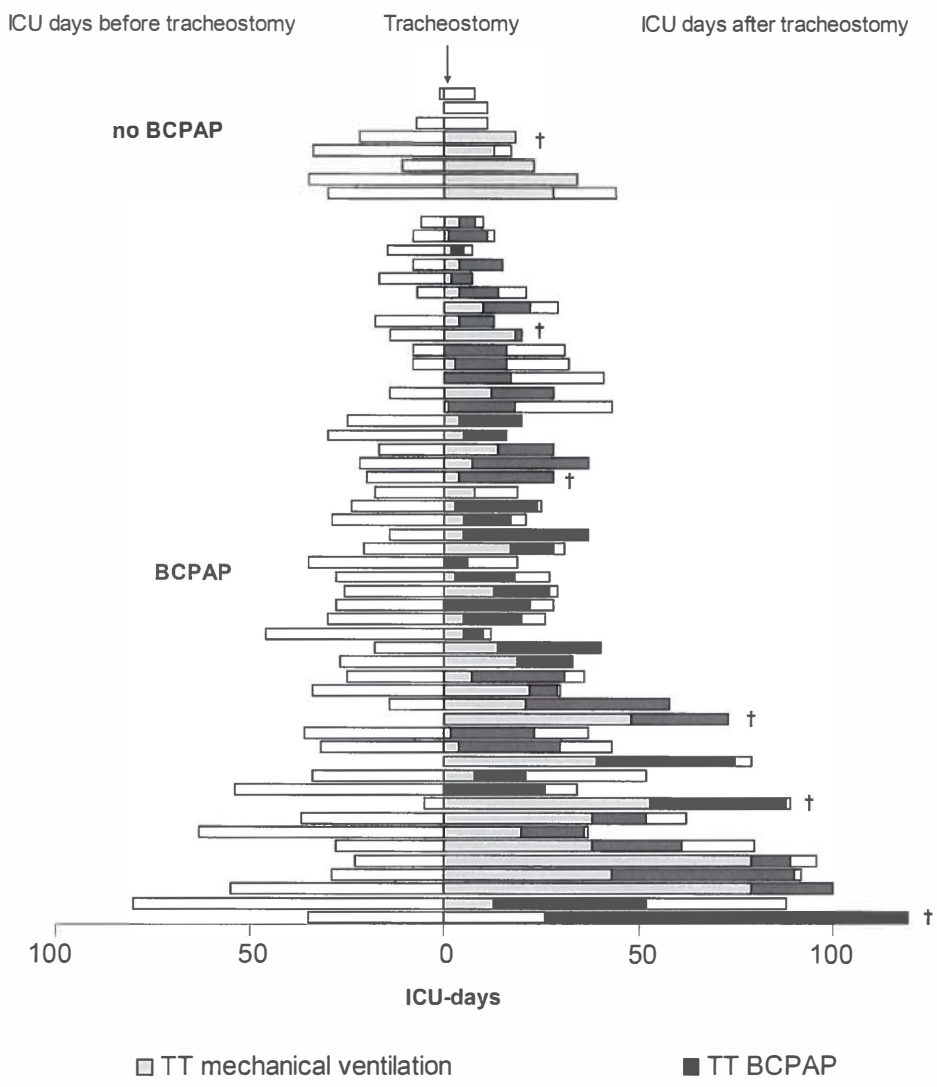


Figure 7.2 Weaning phases in tracheostomy patients.
The diagram displays the distribution of the individual weaning phases during ICU stay. ICU days before (left side) and after tracheostomy (right side) are displayed. Patients who died in the ICU are marked (†). Tracheostomies were and BCPAP was administered for a median period of 16 days. Three patients in the no-BCPAP group did not need any form of mechanical ventilation since they rapidly improved after tracheostomy.

Although we did not quantify the effect, earplugs appeared effective in improving the comfort of the few patients who were bothered by the noise. However, in most cases it was possible to decrease the CPAP level within a few days.

DISCUSSION

This study showed that BCPAP was a feasible and effective method for weaning patients with a TT from mechanical ventilation. The simple BCPAP system achieved oxygenation, CPAP and humidification safely with no obstructions of the TT. Humidification with conventional means [16] may be an important cause of the canula obstructions observed with many other systems.

A limitation of this audit is its observational design, which does not allow any conclusions regarding the superiority of one type of weaning over another. We performed our tracheostomies relatively late, whereas recently the benefits of early tracheostomy with respect to delayed tracheostomy have been demonstrated [3]. Tracheostomies were performed in difficult-to-wean patients who were already mechanically ventilated for a considerable time. Therefore the patients first had to reach a sufficiently low level of ventilator support before BCPAP could be started. This is reflected by a median duration of cannulation of 31 days and a BCPAP duration of 16 days. The BCPAP system was specifically constructed for the application to face masks, but apparently it worked satisfactorily with TT as well. The noise produced may be the biggest disadvantage of the BCPAP-system, although noise is decreased at lower flow levels, and earplugs may be effective. Another theoretical disadvantage may be the possibility of unprotected sputum emission. Yet this also applies to a TT in general and many other open systems. The same open design that makes the BCPAP so safe from cannula obstructions - a common problem in tracheostomy patients [9] - allows the patient with forceful sputum evacuation to cough sputum out of the BCPAP system. For these patients we put an ordinary disposable surgical mouth-mask in front of the BCPAP system that functions as an effective 'sputum-shield'.

To our knowledge, the only study on the combination of BCPAP with TT has been in abstract form and included only 8 adult patients followed for a limited time period [17]. To our knowledge there are no other reports applying BCPAP systems

on tracheostomy tubes. Yet, we could not identify intrinsic objections for the application of BCPAP on TT patients. Regarding weaning in TT patients, we found it also very practical that positive end –expiratory pressure, FiO_2 as well as humidification could be independently and continuously adjusted. Moreover, given the open design of the BCPAP system, the patient can still breathe freely without any resistance if flow is interrupted. Although there are several alternative systems for applying CPAP, only the BCPAP system results in more freedom of movement for tracheostomy patients.

An important complication of TT's has been described by Polderman et. al. [8]. They observed a chronic irritation of the posterior tracheal wall due to conventional heavy tubing systems that move, because of their weight, the outside part of the tracheal cannula downwards with the result that the inside part of the cannula moves upwards and damages the tracheal wall. Traction problems were especially observed in sitting patients. Although we have not compared or measured traction forces in our patients, the force exerted by conventional 22-mm tubing will obviously be larger than 3 mm tubing. The lightweight BCPAP system may considerably reduce these detrimental forces on the tracheal cannula.

CONCLUSION

Although marketed for application on facemasks, the BCPAP device is able to provide pressure, oxygen and humidification in TT patients. BCPAP was used for prolonged periods and allowed us to discharge all patients without ventilatory support. To apply low-level CPAP in tracheostomized patients, the BCPAP system seems to be a feasible option. Prospective studies will be needed to determine the potential of this therapy in the weaning process.

ACKNOWLEDGEMENTS

The authors wish to thank Henk van Plateringen from the Surgical Intensive Care Unit of the University Medical Center Groningen for his assistance. This study was partly supported by a grant from the Health Care Insurance Board, Association of University Hospitals and the University Medical Center Groningen.

REFERENCES

1. MacIntyre NR, Cook DJ, Ely EW Jr, Epstein SK, Fink JB, Heffner JE, Hess D, Hubmayer RD, Scheinhorn DJ: American College of Chest Physicians; American Association for Respiratory Care; American College of Critical Care Medicine. Evidence-based guidelines for weaning and discontinuing ventilatory support: a collective task force facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine. *Chest* 2001; 120:375s-395s.
2. Durbin CG Jr. Indications for and timing of tracheostomy. *Respir Care* 2005; 50:483-487.
3. Rumbak MJ, Newton M, Truncale T, Schwartz SW, Adams JW, Hazard PB. A prospective, randomized, study comparing early percutaneous dilational tracheotomy to prolonged translaryngeal intubation (delayed tracheotomy) in critically ill medical patients. *Crit Care Med* 2004; 32:1689-1694.Erratum p 2566.
4. Pierson DJ. Tracheostomy from A to Z: historical context and current challenges. *Respir Care* 2005; 50:473-475.
5. Heffner JE. The role of tracheotomy in weaning. *Chest* 2001;120:477s-481s.
6. Shneerson JM. Are there new solutions to old problems with weaning? *Br J Anaesth* 1997; 78:238-240.
7. Meade M, Guyatt G, Sinuff T, Griffith L, Hand L, Toprani G, Cook DJ. Trials comparing alternative weaning modes and discontinuation assessments. *Chest* 2001; 120:425s-437s.
8. Polderman KH, Spijkstra JJ, de Bree R, Christiaans HM, Gelissen HP, Wester JP, Girbes AR. Percutaneous dilatational tracheostomy in the ICU: optimal organization, low complication rates, and description of a new complication. *Chest* 2003; 123:1595-1602.
9. Forbes A.R. Humidification and mucus flow in the intubated trachea. *Br J Anaesth* 1973; 45:874-878.

10. Dieperink W, Delwig H, Nijsten MWN. Application of Boussignac CPAP-system on tracheostomy tubes during weaning. *Intensive Care Med* 2005; 31:suppl.1 S193.
11. Dieperink W, Goorhuis JF, de Weerd W, Hazenberg A, Zijlstra JG, Nijsten MWN. Walking with continuous positive airway pressure. *Eur Respir J* 2006; 27:853-855.
12. Maitre B, Jaber S, Maggiore SM, Bergot E, Richard JC, Bakthiari H, Housset B, Boussignac G, Brochard L. Continuous positive airway pressure during fiberoptic bronchoscopy in hypoxemic patients. A randomized double-blind study using a new device. *Am J Respir Crit Care Med* 2000; 162:1063-1067.
13. Moritz F, Benichou J, Vanheste M, Richard JC, Line S, Hellot, MF Bonmarchand G, Muller JM. Boussignac continuous positive airway pressure device in the emergency care of acute cardiogenic pulmonary oedema: a randomized pilot study. *Eur J Emerg Med* 2003; 10:204-208.
14. Templier F, Dolveck F, Baer M, Chauvin M, Fletcher D. 'Boussignac' continuous positive airway pressure system: practical use in a prehospital medical care unit. *Eur J Emerg Med* 2003; 10:87-93.
15. Leman P, Greene S, Whelan K, Legassick T. Simple lightweight disposable continuous positive airways pressure mask to effectively treat acute pulmonary oedema: Randomized controlled trial. *Emerg Med Australas* 2005; 17:224-230.
16. Liener K, Durr L, Leiacker R, Rozsasi A, Keck T. Measurement of tracheal humidity and temperature. *Respiration* 2006; 73:324-328.
17. Lavrentieva A, Setzis D, Giannakou M, Tsotsolis V, Ourailogloy V, Theodosiadis P, Skourtis X, Sofanos E. Use of Boussignac-Vygon CPAP system in ICU patients with tracheostomy. *Resuscitation* 2000; 48:1 P28.

Chapter 8

Combination of heliox and CPAP without a ventilator: bench test and clinical observations

Willem Dieperink
Johan A. Knol
Hans J. Boersma
G. Boukes Eindhoven
Joanne F Goorhuis
Leon P.H.J. Aarts
Maarten W.N. Nijsten

European Journal of Anaesthesiology 2007

EDITOR:

Failure to restore an adequate airway in patients with acute upper airway obstruction can rapidly lead to hypoxic injury or even death. Helium–oxygen mixtures (heliox) are less dense than air–oxygen mixtures and can improve the flow of gas through partially obstructed airways. Since Barach described this principle 70 years ago, heliox has at times been applied in spontaneously breathing patients with acute upper airways obstruction [1]. Heliox has also been combined with (non-) invasive mechanical ventilation, often with specifically adapted apparatus [2]. However, the correct function of ventilators relies on the precise measurement of flow, pressure, temperature and oxygen fraction for which the necessary sensors are calibrated for use with air–oxygen. The unique physical properties of heliox have an important impact on all these measurements. Thus the correct application of heliox in ventilators is far from trivial [3]. This technical problem becomes especially relevant under emergency circumstances.

Continuous positive airway pressure (CPAP) by face mask can reduce upper airway collapse [4] and the combination of mask CPAP and heliox might be useful. The Boussignac continuous positive airway pressure (BCPAP) system (Vygon, 95440 Ecouen, France) for mask CPAP is a simple and lightweight (10 g) disposable plastic device without moving parts [5]. This device may thus avoid the problems with ventilators and heliox.

In a bench test, we evaluated whether heliox works with the BCPAP system and how much more heliox flow was needed compared to oxygen to achieve similar pressures. We then evaluated the effect of this combination in selected patients with acute upper airways obstruction. We chose a helium–oxygen mixture of 60/40 to ensure a sufficient oxygen delivery under all circumstances.

For the bench test we used 10 randomly selected, commercially available BCPAP systems and an analyser specifically designed to measure pressure or flow for helium–oxygen mixtures (VT Plus, Fluke Biomedical, Carson City, NV, USA) Since the variable orifice flow meters mounted on the heliox cylinders were oxygen-calibrated, we first recalibrated these meters by comparing the indicated flow of oxygen or heliox with the true flow as measured with the VT-plus analyser. This was done 10 times for each of the following levels of indicated flow: 5, 10,

15, 20, 25 and 30 L min^{-1}. The observed relation between indicated and actual flow was also compared to the theoretically predicted flow [6]. After this flow-calibration, we then measured the pressures generated by the BCPAP system for the various indicated flows (Figure 8.1). The measured flow rates (true flow) of the variable orifice flow meters showed a 25± 6% (SD) higher flow for heliox compared to oxygen. When we calculated the predicted actual flow for the variable orifice flow meters for heliox 60/40 based on the gas laws and assuming fully turbulent conditions with densities (ρ=rho) of 1.33 and 0.17 kg/m^{-3} for oxygen and heliox, respectively [6]: $(\rho O_2/\rho \text{Heliox } 60/40)^{0.5} \approx (1.33/0.63)^{0.5}$, the theoretically predicted actual flow was 145% of the indicated flow. Thus the behaviour of the variable orifice flow meter with heliox was not in accordance with the assumptions of the simplified gas law.

Flow–pressure measurements were performed at six levels of flow indicated by the orifice flow meters. At every flow level, pressure was measured 10 times. With regard to the generated pressure by the BCPAP system, both for oxygen and for heliox, an approximately linear flow–pressure relation was observed. Compared to oxygen, a true heliox flow of 178% (95% CI: 168–188%) was needed to achieve similar levels of CPAP.

For rapid transport to any patient in our hospital with acute upper airway obstruction, we put the heliox cylinders and the BCPAP system, as well as conventional non-rebreathing masks, on a small trolley (Figure 8.1). Over a 2-yr period, seven adult patients (aged 53–83 yr) and one infant aged 3 months with life-threatening obstruction and various degrees of inspiratory stridor were treated. Causes of the stridor included laryngeal cancer, vocal cord palsy, post extubation stridor or hygroma. Heliox and BCPAP were administered for a mean (SD) duration of 83 ± 42 (range 60–180) min. We used indicated flows from 20 to 30 L-min^{-1}, corresponding to true flow of 25–36 L-min^{-1} and pressures of 6–8 cm of H_2O. In all cases stridor typically decreased or disappeared within a few minutes. In four patients a definitive airway was established after intubation with an endotracheal tube and in four cases with a tracheostomy. In one patient we successfully performed flexible intubation through the BCPAP system.

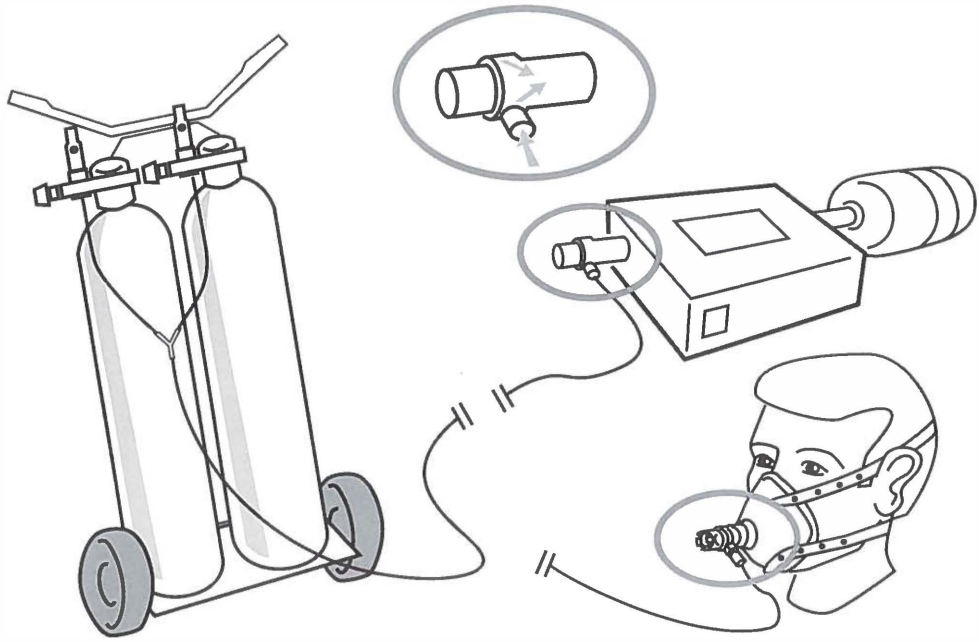


Figure 8.1.
In a bench test (upper right) the static pressures generated by the BCPAP system for various flows of heliox 60/40 were measured in a closed system. For this purpose the patient side of the BCPAP-system was connected to a pressure analyzer. For patients the BCPAP system was connected to a facemask.

We showed that heliox could effectively generate pressure in the BCPAP system. The simplicity of this system with no moving parts allowed us to put it on a trolley that could be brought to patients. The application of heliox and BCPAP was effective in creating clinical stabilization allowing time to create a final secure airway. Acute upper airway obstruction is often a life-threatening situation. Under such circumstances, establishing a safe definitive airway is crucial, but the procedure itself is one of the most dangerous actions in medicine. It should be stressed that neither CPAP nor heliox nor CPAP and heliox combined are intended to solve the airway obstruction, but to immediately relieve the work of breathing and buy some time. In the meantime, the precise cause of respiratory failure may be identified and an experienced team can prepare to establish a definitive airway. The considerable cost of heliox [1] is another reason to limit the duration of

treatment with heliox. There are several reports of clinical application of heliox and non-invasive ventilation [2]. It is known that non-invasive ventilation and also CPAP decrease the work of breathing in patients with upper airway obstruction [4]. Heliox also decreased the work of breathing in these patients. Obviously, CPAP alone or heliox without CPAP given by venturi mask or non-rebreathing mask may be the easiest and best solution for many patients. We assumed that combining heliox and BCPAP might have additive effects. Recently, a study showed the effectiveness of the combination nasal CPAP and heliox in infants [7]. To our knowledge there are no reports in adults of combining heliox specifically with CPAP devices, including the BCPAP system. The unique open design of the BCPAP system makes bronchoscopy [5] or even endotracheal intubation, through the system, possible with no loss of CPAP. As the true heliox flow differs both from the actual and from the theoretically predicted flow, recalibration of flow meters is mandatory, especially since the gas cylinders empty much faster than might otherwise be expected. The simple BCPAP system circumvents many of the disadvantages associated with the use of heliox with mechanical valves or ventilators. We think the BCPAP heliox combination may be of use as a bridging therapy in selected patients with acute upper airway obstruction. Prospective studies are needed before a final recommendation can be made about the benefit of this therapy.

REFERENCES

1. McGee DL, Wald DA, Hinchliffe S. Helium-oxygen therapy in the emergency department. *J Emerg Med* 1997; 15:291-296.
2. Jaber S, Fodil R, Carlucci A *et al.* Noninvasive ventilation with helium-oxygen in acute exacerbations of chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 2000; 161:1191-1200.
3. Tassaux D, Jolliet P, Thouret JM, Roeseler J, Dorne R, Chevrolet JC. Calibration of seven ICU ventilators for mechanical ventilation with helium-oxygen mixtures. *Am J Respir Crit Care Med* 1999; 16:22-32.
4. Visvanathan T, Kluger MT, Webb RK, Westhorpe RN. Crisis management during anaesthesia: obstruction of the natural airway. *Qual Saf Health Care* 2005; 14:e2.
5. Maitre B, Jaber S, Maggiore SM *et al.* Continuous positive airway pressure during fiberoptic bronchoscopy in hypoxemic patients. A randomized double-blind study using a new device. *Am J Respir Crit Care Med* 2000; 162:1063-1067.
6. Papamoschou D. Theoretical validation of the respiratory benefits of helium-oxygen mixtures. *Respir Physiol* 1995; 99:183-190.
7. Martinon-Torres F, Rodriguez-Núñez A, Martinon-Sánchez JM. Nasal continuous positive airway pressure with heliox in infants with acute bronchiolitis. *Respir Med* 2006; 100:1458-1462.

Chapter 9

Summary and conclusions

SUMMARY AND CONCLUSIONS

Continuous positive airway pressure, (CPAP) is a form of treatment to support patients with dyspnea. For the application of CPAP a mechanical ventilator or complex CPAP apparatus is mostly used. The Boussignac CPAP (BCPAP) system developed by George Boussignac does not need such apparatus. The BCPAP system is a simple, safe and cheap alternative for these modalities. This lightweight and disposable CPAP system without moving parts consist of nothing more than a hollow tube in which gas flow is blown under a specific angle through 4 micro-channels, as a result of which a pressure is generated.

In Chapter 1 a short historical overview is given of the development of CPAP and the mechanism by which CPAP exerts its positive therapeutic effects. Furthermore a number of its applications are described and an overview is given of the investigations that are described in this thesis.

Part I (chapter 2-5), describes of the use of BCPAP in the coronary care unit and on the ambulance.

In Chapter 2 the experiences and problems with the nurse-centered implementation of the BCPAP system on the coronary care unit are described. In spite of the fact that CPAP therapy was quite effective in the treatment of acute cardiogenic pulmonary edema not all potential patients were treated with CPAP. Lack of consistent guidelines, the underestimation of the clinical usefulness of CPAP and the belief of nurses that BCPAP was inconvenient for the patients obstructed more widespread use of BCPAP. Remarkably, the patients themselves did not consider BCPAP inconvenient.

Chapter 3 and 4 describe the outcome of BCPAP treatment in patients with pulmonary edema due to heart failure. The hypothesis that underpinned this study was that early treatment of patients with acute cardiogenic pulmonary edema as result of heart failure would have a favourable impact on the duration of coronary care unit, intensive care unit and hospital length of stay. In a particular case study (chapter 3) we describe a man of 64 years who received the extraordinary number of 15 successful BCPAP treatments over the course of 9 months. The recurring nature of acute cardiogenic pulmonary edema in this patient was rooted in a poor

compliance with salt and fluid restricted diet. Chapter 4 describes a prospective study of 108 patients with acute cardiogenic pulmonary edema treated with a BCPAP protocol. These patients were compared with a historical patient group of patients who were treated with oxygen alone. In patients who were treated with BCPAP, heart rate and arterial oxygenation normalized faster. Moreover, the fraction of patients who had to be transferred to the intensive care unit for intubation and mechanical ventilation was nearly halved. Thus, considerable costs savings (± € 3,800) were achieved.

The study described in Chapter 5 examined if BCPAP can be administered by nurses on the ambulance to patients with acute cardiogenic pulmonary edema acute cardiogenic pulmonary edema. The results of this study show that early treatment on the ambulance of acute cardiogenic pulmonary edema with BCPAP is both feasible and effective. On the basis of several other studies, as well as our observations as reported in chapter 3 and 4, we believe that BCPAP can be nurse-centered and implemented in all ambulances in the Netherlands.

A number of novel applications of the BCPAP system are described in Part II (chapter 6-8).

Chapter 6 is a case report of an infant who was ventilator dependent since her birth because of a chronic lung disease and tracheabronchomalacia. Her ventilator-dependency resulted in a retarded psychomotor development. At an age of 18 months the BCPAP system was introduced which was connected on her tracheostomy tube. Now she could be mobilised while she received ventilation support. In cooperation with several parties a medical certified compressor was assembled that generated pressurized air at home. Eventually, after an admission of 2 years at the pediatric intensive care unit she was discharged home with BCPAP during the day and full ventilatory support at night. At home she had an action range of 10 meters for walking and playing while on CPAP support. As result her psychomotor and mental development recovered remarkably.

In Chapter 7 we evaluated the feasibility and effectiveness of the BCPAP system in patients who were weaned from mechanical ventilation with a tracheostomy tube.

Over a 3 year period we studied 58 intensive care unit patients who were weaned with a tracheal canula and BCPAP. The patients tolerated the lightweight Boussignac system without complications. Weaning from mechanical ventilation with the BCPAP system allowed improved patient mobility and comfort. Remarkably, no tube obstructions were observed, a notorious problem when patients were weaned with conventional systems.

Chapter 8 describes research in which patients with an upper airway obstruction were treated with a helium oxygen mixture (heliox) combined with CPAP delivered by the BCPAP system. Heliox reduces the airway resistance and consequently the work of breathing. CPAP may also reduce obstructions as it "splints" the airways. However, combining heliox with ventilators is technically complex and expensive. After flow-calibration the Boussignac system was combined with heliox. The low weight of the BCPAP-heliox system allowed us to construct a mobile BCPAP-heliox trolley. In 8 cases the mobile BCPAP-Heliox system successfully served as a bridge to the establishment of a final safe airway by an experienced and well-prepared team.

FINAL COMMENTS AND FUTURE DIRECTIONS

CPAP-dependent patients with a tracheostomy can be weaned and mobilised without heavy tubing that restrict their freedom from mechanical ventilation with BCPAP. We have described a child who can walk with the BCPAP system with a positive impact on psychomotor development. Nevertheless, practical problems impede the use of the BCPAP system in patients with a tracheostomy tube. The unprotected sputum emission and the noise produced by the BCPAP system must be addressed before the system could be recommended for widespread use.

Combining heliox and CPAP is technically feasible with the BCPAP system. The combination shows potential benefits and can certainly still further be developed. Prospective studies are needed to prove the usefulness of this combination as a bridging therapy to a definitive airway for patients with acute upper airway obstruction.

When ventilatory support is needed on the intensive care or coronary care unit one tends to think of sophisticated and expensive techniques with the most complex apparatus. The opposite is proven by the BCPAP system which is cheap, intrinsically safe and simple to apply by nurses who have little or no experience with mechanical ventilation. BCPAP is a useful alternative for ventilator CPAP in the treatment of dyspnea due to acute cardiogenic pulmonary edema in the setting of a coronary care unit. Successful implementation in coronary care units in other hospitals will benefit from national guidelines in which CPAP is recommended for patients with acute cardiogenic pulmonary edema. Likewise it is important that nurses realise that in patients with acute cardiogenic pulmonary edema the more labor intensive BCPAP displayed more rapid improvement than the treatment with oxygen alone.
Thanks to the austere nature of the BCPAP device, it was also practically feasible to apply in an early stage BCPAP on the ambulance to treat patients with acute cardiogenic pulmonary edema. In 91% of the cases BCPAP treatment resulted in a rapid improvement in the clinical condition of the patient.

If possible patients should receive the best available treatment. This often involves advanced technology that complicates healthcare and has made healthcare even more expensive. But advanced and expensive technologies are not always necessary to provide good treatment. In several cases it is well possible to provide optimal treatment with less sophisticated and expensive technology. The BCPAP system is an example of a cheap and easy to use apparatus that has proven to be as effective as mechanical ventilators or CPAP apparatus for ventilatory support in selected patient groups. The effectiveness of BCPAP in the treatment of acute cardiogenic pulmonary edema has been well established. It can be applied outside ICU departments and also on the ambulance with small investments. The BCPAP system will in the near future be implemented on all ambulances in the Netherlands. This might contribute to a reduction in coronary care unit and hospital length of stay and especially fewer intensive care unit admissions for patients with acute cardiogenic pulmonary edema.

Chapter 10

Samenvatting en conclusies

SAMENVATTING EN CONCLUSIES

Een belangrijke vorm van ademhalingsondersteuning bij ernstige kortademigheid is continue positieve luchtwegdruk (continuous positive airway pressure, CPAP). Voor de toediening van CPAP wordt veelal een beademingsmachine of een ingewikkeld CPAP apparaat gebruikt. Het Boussignac CPAP (BCPAP) systeem dat door George Boussignac is ontwikkeld heeft geen machine nodig. Het BCPAP systeem is een eenvoudig, veilig en goedkoop alternatief voor de toediening van CPAP. Dit lichtgewicht en disposable CPAP systeem zonder bewegende delen bestaat in feite uit een holle buis waarin een gasflow onder een bepaalde hoek door 4 microkanalen wordt geblazen waardoor er een continue positie druk gegenereerd wordt.

In hoofdstuk 1 wordt een kort historisch overzicht gegeven van de ontwikkeling van CPAP. De werking en een aantal toepassingen van CPAP wordt hier beschreven. Verder wordt er een overzicht gegeven van de diverse onderzoeken die in dit proefschrift beschreven worden.
Deel I (hoofdstuk 2-5), beschrijft het gebruik van BCPAP op de coronary care unit en op de ambulance.

In hoofdstuk 2 worden de ervaringen en problemen beschreven bij het implementeren van het BCPAP systeem op de coronary care unit waarin er voor verpleegkundigen een centrale rol was weggelegd. Ondanks het feit dat CPAP therapie zeer effectief was met betrekking als onderdeel van de behandeling van astma cardiale, werden niet alle geschikte patiënten ermee behandeld. Goede richtlijnen, het juist beoordelen van de klinische betekenis van CPAP en de wetenschap dat patiënten de behandeling niet als ongemakkelijk ervaren kan een optimaal gebruik van BCPAP bevorderen.

Hoofdstuk 3 en 4 beschrijven de resultaten van BCPAP bij patiënten met astma cardiale tengevolge van hartfalen. De hypothese die aan de onderzoeken ten grondslag lag was dat vroegtijdige behandeling van astma cardiale ten gevolge van hartfalen een gunstig effect zou kunnen hebben op zowel de verblijfsduur op de coronary care unit, op de intensive care unit en in het ziekenhuis. Het nut van BCPAP wordt geïllustreerd door een bijzondere case studie (hoofdstuk 3) van een

aanmerkelijke reeks van 15 succesvolle BCPAP behandelingen bij een 64 jarige man. Het recidiverende karakter van astma cardiale was gelegen in een slechte naleving van zijn zout en vochtbeperkte dieet. Hoofdstuk 4 beschrijft een prospectieve studie bij patiënten met astma cardiale op de coronary care unit behandeld met BCPAP. Deze patiënten werden vergeleken werd met een historische patiëntengroep die alleen met zuurstof behandeld werden. Bij de groep patiënten behandeld met Boussignac CPAP normaliseerde hartslag en arteriële zuurstofspanning aanzienlijk sneller. Dit resulteerde in een halvering van het aantal intensive care opnames voor intubatie en bijbehorende beademing.

In de studie beschreven in hoofdstuk 5 is onderzocht of BCPAP ook op de ambulance door ambulanceverpleegkundigen kan worden toegediend bij patiënten met astma cardiale. De uitkomst van deze studie liet zien dat de vroegtijdige behandeling op de ambulance van astma cardiale met BCPAP haalbaar en effectief is. Op basis van verscheidene andere studies – als mede onze observaties zoals die in hoofdstuk 3 en 4 worden gerapporteerd – zijn wij stellig van mening dat BCPAP kan worden uitgevoerd door ambulance verpleegkundigen op alle ambulances in Nederland.

Een aantal nieuwe toepassingen van het BCPAP systeem wordt in deel II beschreven (hoofdstuk 6-8).

Hoofdstuk 6 is een case report van een meisje dat beademingsafhankelijk was vanaf haar geboorte vanwege een chronische long ziekte en tracheobronchomalacie. De langdurige beademingsafhankelijkheid resulteerde uiteindelijk in een forse achterstand in haar psychomotorische ontwikkeling. Bij een leeftijd van 18 maanden werd bij haar het BCPAP systeem geïntroduceerd welke werd aangesloten op haar tracheacanule. In samenwerking met diverse partijen werd er een medisch gecertificeerde compressor ontwikkeld die bij het kind thuis perslucht kon produceren. Uiteindelijk, na een intensive care opname van 2 jaar werd zij naar huis ontslagen terwijl ze overdag BCPAP kreeg. Dankzij de BCPAP had zij een actieradius van 10 meter om te lopen en spelen. Mede hierdoor kon zij zich beter ontwikkelden en de psychomotorische en geestelijke achterstand volledig inhalen.

In hoofdstuk 7 is de effectiviteit en uitvoerbaarheid van het ontwennen van beademing met behulp van het BCPAP systeem bij patiënten met een trachea canule geëvalueerd. In een periode van 3 jaar bestudeerden we 58 patiënten met een trachea canule, opgenomen op de intensive care unit die werden ontwend van de beademing met behulp van het BCPAP systeem. Het lichtgewicht BCPAP systeem werd goed verdragen zonder dat er complicaties optraden. Het bleek een veilige en goed uitvoerbare methode om te ontwennen van de beademing welke vooral een bijdrage leverde aan de mobiliteit van patiënten met een trachea canule.

Hoofdstuk 8 beschrijft onderzoek waarbij patiënten met een hoge luchtwegobstructie zowel een helium/zuurstof mengsel (heliox) als CPAP wordt toegediend via het BCPAP systeem. Heliox vermindert de luchtweerstand en bijgevolg ook het de ademarbeid terwijl CPAP de luchtwegobstructie kan reduceren. Het combineren van heliox en beademingsmachines is echter technisch complex en kostbaar. Aangezien het BCPAP systeem geen bewegende delen heeft zou het simpel met heliox kunnen worden gecombineerd. Met een door ons ontworpen en getest mobiel BCPAP/heliox systeem zouden patiënten met een hoge luchtweg obstructie van zowel van CPAP als van heliox kunnen profiteren. In 8 gevallen werd de BCPAP-heliox combinatie met succes toegediend als overbruggingstherapie totdat er een veilige en definitieve luchtweg gecreëerd kan worden door een ervaren en goed voorbereid team.

SLOTOPMERKINGEN EN TOEKOMSTIGE ONTWIKKELINGEN

Het ontwennen van mechanische beademing van patiënten met een trachea canule met behulp van BCPAP wordt gehinderd door een aantal praktische problemen. De ongehinderde sputumuitstoot bij hoesten en het lawaai van het systeem dienen eerst worden opgelost alvorens er aanbevelingen gedaan kunnen worden met betrekking tot algemeen gebruik.

De toepassing van BCPAP in combinatie met heliox toont potentiële voordelen maar zal zeker nog verder moeten worden ontwikkeld. Prospectieve studies zijn

nodig naar het nut van deze combinatie als overbruggingstherapie naar een definitieve luchtweg bij patiënten met een acute hoge luchtweg obstructie.

We denken al gauw aan geavanceerde en dure technieken met ingewikkelde apparaten wanneer ademhalingsondersteuning op een intensive care unit of coronary care unit nodig is. Het tegendeel wordt bewezen door het BCPAP systeem dat goedkoop, veilig en eenvoudig te bedienen is door verpleegkundigen die weinig of geen ervaring hebben met mechanische beademing. Het BCPAP systeem heeft bewezen een bruikbaar alternatief te zijn voor ventilator CPAP bij de behandeling van ernstige kortademigheid ten gevolge astma cardiale. Met betrekking tot de behandeling van astma cardiale op een coronary care unit bleek BCPAP een praktisch uitvoerbaar, medisch effectief en kosten besparend alternatief. Implementatie van het BCPAP systeem op vergelijkbare afdelingen van andere ziekenhuizen zou kunnen profiteren van nationale richtlijnen waarin CPAP wordt geadviseerd als behandeling voor patiënten met astma cardiale. Verpleegkundigen moeten zich ervan bewust zijn dat patiënten de vermindering van benauwdheid als belangrijker ervaren dan andere ongemakken. Evenzo is het belangrijk dat verpleegkundigen beseffen dat de meer arbeidsintensieve BCPAP behandeling voor patiënten met astma cardiale een gunstiger resultaat heeft dan de behandeling met alleen zuurstof.
Het bleek ook praktisch haalbaar om BCPAP op de ambulance toe te passen om patiënten met astma cardiale al in een vroeg stadium met CPAP te behandelen. In 91% van de gevallen resulteerde de behandeling met BCPAP in een snelle klinische verbetering van de patiënt.

Zo mogelijk moeten patiënten de best mogelijk voorhanden zijnde behandeling krijgen. Dit vereist vaak geavanceerde technologie welke de gezondheidszorg vaak complexer en duurder maakt. Het is in een aantal gevallen mogelijk om een goede behandeling te geven met minder geavanceerde technologie. Het BCPAP systeem is een voorbeeld van een goedkoop en gemakkelijk te bedienen apparaat dat in geselecteerde patiënten groepen bewezen heeft net zo effectief te werken als een mechanische beademingsmachine of speciaal CPAP apparaat. De effectiviteit van

BCPAP in de behandeling astma cardiale is al ruimschoots bewezen. Het BCPAP systeem zal hopelijk worden geïntroduceerd op ambulances in Nederland. Voor patiënten met astma cardiale zal dit resulteren in een vermindering van intensive care unit opnames en een kortere verblijfsduur in het ziekenhuis en coronary care unit.

Dankwoord

Dankwoord

Wanneer ik mijn passie zeilen als metafoor voor het promotie traject zou nemen zou ik zonder te overdrijven kunnen zeggen dat het een avontuurlijke en fantastische zeiltocht was. Toch verliep de reis, die veelal over onbekende zeeën voerde, niet altijd even voorspoedig. Gevaren zoals een voortijdige stranding of over boord geslagen te worden tijdens een hevige storm waren voortdurend aanwezig. Ook liet de wind het wel eens afweten of zat in de verkeerde hoek. Scheurbuik door proviand tekort, averij en zelf muiterij moesten overwonnen worden en op het laatst van de tocht werd de voortgang ernstig belemmerd door aangroei van het onderwaterschip. Echter de boot is blijven drijven en ik ben heelhuids, met voltallige bemanning, op mijn bestemming aangekomen. Hiervoor hulde aan de diverse reddingsmaatschappijen.

Het onderzoek beschreven in dit proefschrift werd verricht op de afdelingen Hartbewaking van het Thorax Centrum en de Intensive Care van de Chirurgische Kliniek van het Universitair Medisch Centrum Groningen alsook bij de ambulance dienst van AmbulanceZorg Groningen. Het onderzoek werd mogelijk gemaakt door zowel interne als externe subsidies.

Veel mensen hebben de afgelopen jaren een bijdrage geleverd aan de totstandkoming van dit proefschrift. Ik wil een ieder daarvoor hartelijk bedanken, maar een aantal mensen in het bijzonder noemen.

Allereerst mijn promotores prof. dr. L.P.H.J. Aarts en prof. dr. F. Zijlstra. Beste Leon en Felix, bedankt voor jullie bereidheid mijn promotieonderzoek als promotor te begeleiden. Het was vast even wennen om mij, als niet medicus, te begeleiden. Ik wil jullie bij deze dan ook bedanken voor het vertrouwen dat jullie in mij stelden.

Dr. M.W.N. Nijsten, beste Maarten, als iemand mijn dank verdient ben jij het wel. Jij bent eerst als onderzoeksleider en later als co-promotor met mij op pad gegaan in wetenschapsland. Jou kennis, vaardigheden, ideeën, scherpzinnigheid, niet aflatend enthousiasme en analytisch vermogen waren voor mij een grote inspiratie.

Mw. dr. T. Jaarsma, beste Tiny, jouw gedrevenheid en enthousiasme zijn niet te evenaren. Het was een voorrecht jou als co-promotor te mogen hebben. Ik dank je dan ook hartelijk voor alle inbreng.

Prof. dr. A.R.J. Girbes, beste Armand, jij leidde mij de wondere wereld van het doen van onderzoek binnen. Het motiveerde mij uiteindelijk zodanig dat ik aan een universitaire studie begon die uiteindelijk uitmondde in dit proefschrift. Ik beschouw het als een eer dat je in de beoordelingscommissie zitting hebt willen nemen om mijn wetenschappelijke arbeid te toetsen. Ook de andere leden van de beoordelingscommissie, prof. dr. D.J. van Veldhuisen en prof. dr. D. Zandstra, Dirk Jan en Durk, dank ik dat ze hun oordeel over dit proefschrift wilden geven.

Dr. J.W. Hesselink, beste Jan Willem, ik ben je zeer erkentelijk voor je inspanning met betrekking tot het verwerven van het vervolgonderzoek. Zonder dit vervolgonderzoek was dit boekje hoogstwaarschijnlijk niet tot stand gekomen.

Hans Boersma, jou wil ik bedanken voor de samenwerking en technische ondersteuning. De vele metingen die we samen aan het Boussignac systeem verricht hebben vormde de basis voor degelijk klinisch onderzoek.

De artsen, verpleegkundigen, en secretaressen van de Chirurgische IC, Hartbewaking en AmbulanceZorg Groningen wil ik bedanken voor de ondersteuning van het onderzoek. In het bijzonder Bauk Dijkstra voor de bereidwillige medewerking van het opvragen van de honderden medische statussen en Henk Brouwer voor zijn assistentie gedurende het onderzoek op de hartbewaking.

Mijn paranimfen, dr. D.J. Kleijer en drs. G.C. Niemeijer, Dick en Gerard, wil ik danken voor de jarenlange samenwerking. Ik ben dan ook erg verheugd met het feit dat jullie mij willen begeleiden bij de gang door het Academiegebouw.

Verder wil ik alle patiënten en hun familieleden bedanken voor de bereidheid om mee te doen aan het onderzoek.

Lieve Hinke, ik weet dat ik je geen plezier doe met deze passage maar zonder jou was het allemaal zeker niet gelukt. Dit onderzoek is zeker een gezamenlijke inspanning geweest. Mijn onvergetelijke dank hiervoor en vanaf nu gaan weer echt leuke dingen doen.

The publication of this thesis was financially supported by Vygon Nederland BV.

and

KP Care BV / KP Medical BV
Medtronic Bakken Research Center
Pfizer BV