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Prophylactic nasal continuous positive airway pressure after major vascular surgery: results of a prospective randomized trial

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Abstract *Background:* The efficacy of nasal continuous positive airway pressure (nCPAP) as a prophylactic method for preventing cardiopulmonary complications after major vascular surgery has not been investigated. *Patients/methods*: In a prospective randomized trial, 204 patients undergoing elective midline laparotomy for vascular surgery were randomized to receive standard therapy (n=105) or additional prophylactic nCPAP (n=99) for the first postoperative night. Postoperative oxygenation, incidence of severe cardiac, and pulmonary complications, length of intensive care surveillance and length of total postoperative hospital stay (LOS) were compared. *Results*: Prophylactic nCPAP significantly reduced the number of patients with severe oxygenation disturbances defined as paO_2<70 mmHg with FiO_2≥ 0.7 (5 versus 17, P=.01). There were no differences with respect to death, cardiac and pulmonary complications, length of intensive care surveillance or LOS. *Conclusion*: Prophylactic 12 h nCPAP significantly reduces the occurrence of postoperative oxygenation disturbances but has no effect on cardiac or pulmonary complications, need for intensive care, LOS or mortality after major vascular surgery.

Keywords Nasal CPAP · Vascular surgery · Cardiopulmonary complications · Prevention · Noninvasive ventilation

Introduction

Cardiac events such as myocardial ischemia or congestive heart failure (CHF) and pulmonary complications are the most frequent causes of mortality and morbidity after major vascular surgery [1]. Postoperative pain, immobilization, and shallow breathing may decrease ventilation in the lower parts of the lung, leading to obstruction, dystelectasis and atelectasis. While in the early postoperative course these causes reduce pulmonary oxygen transfer resulting in hypoxemia, secondary infection clinically presenting as nosocomial pneumonia may follow. Routine strategies in preventing the development of pulmonary complications include sufficient analgesia, mucolytic medication, physiotherapy and early mobilization [2, 3, 4].

Nasal continuous positive airway pressure (nCPAP) is a well-known therapy for chronic obstructive sleep disorders [5] and gastroesophageal reflux disease [6]. A nose mask is fixed to the patient's face, a high-flow gas source is required to apply more than 50 l flow per minute with the help of a PEEP valve, continuous positive airway pressure is induced. Even with the mouth opened, 50–75% of the pressure applied is transmitted

into the trachea [7, 8]. By increasing intrathoracic pressure, nCPAP improves pulmonary oxygen transfer and blood oxygenation. It is effective in acute pulmonary failure due to acute exacerbations of obstructive pulmonary disease [9, 10]. It can effectively be used to treat dystelecstasis and atelectasis that have already occurred [11, 12]. In patients with acute congestive heart failure, nCPAP reduces cardiac preload and afterload [10, 13], leading to clinical improvement. In this study we investigated whether nCPAP applied prophylactically for at least 12 h after midline laparotomy for major vascular surgery is effective in preventing postoperative pulmonary and/or cardiac complications.

Patients and methods

Inclusion criteria

The protocol of the study was approved by the Ethics Committee of the Medical Faculty of Heinrich-Heine University. Included were patients undergoing midline laparotomy for elective vascular surgery who were scheduled to be extubated in the operation room. It included patients undergoing abdominal aortic aneurysm (AAA) repair, surgery for occlusive diseases of visceral, renal, and iliac arteries, and laparotomy for thrombectomy of the inferior vena cava. Not included were patients undergoing emergency surgery, those who had repair of thoracoabdominal aneurysm, and patients with an exclusively retroperitoneal approach, e.g., for renal transplant or unilateral iliac artery surgery.

Intraoperative management was standardized and did not include pulmonary artery catheters. The anesthesiologists at the operation site did not receive any information about the results of randomization.

Randomization and interventions

After informed consent, patients were randomized using a random list. In both groups intermediate care surveillance was performed for at least 24 h after surgery and extubation. Standard treatment included crystalloid fluid supplementation of 2500–4000 ml/day, perioperative antibiotics (amoxicillin plus sulbactam, once preoperatively and twice postoperatively), opioid analgesics (piritramide 5–7.5 mg as necessary), ranitidine and mucolytic therapy (ambroxol and n-acetylcystein) intravenously. In the control group, oxygen was administered at ambient pressure via a nonoccclusive face mask, including mouth and nose or nose cannulas to keep arterial oxygen saturation >95%. FiO_2 was chosen at a previously calibrated oxygen blender and was documented each time blood gas analyses were performed. Additional drugs were administered according to comorbidity and acute abnormalities, e.g., in blood pressure. Arterial blood gases were determined every 4–6 h.

Patients randomized to the study group received prophylactic nCPAP. On admission to the intermediate care unit, a nCPAP mask (Resp. Inc., Pittsburgh, USA) was put in place. A high-flow gas source (>50 l/min) and a standard PEEP valve resulting in a positive mask pressure of 10 cm H_2O were used. Air/oxygen was applied with an initial FiO_2 of 0.4 and thereafter it was adjusted according to the arterial blood gas analyses to achieve oxygen saturation >95%. The mask was left in place until the next morning but should have been in place for at least 12 h, unless the patient did not tolerate the mask. Patients ending prophylactic nCPAP before this time were included in the study group for further analysis (intention-to-treat).

Measurements

The parameters analyzed included specific complications of nCPAP as patients' intolerance or nose ulcers. Other general postoperative complications included severe disturbances in oxygenation which we defined as a PaO_2 <70 mmHg at an FiO_2 of 0.7 or higher in either mode of oxygen application, readmission to intermediate or intensive care units, or intubation for cardiopulmonary complications, cardiac events (congestive heart failure, myocardial ischemia, arrhythmia), pulmonary complications including pneumonia, and death. Pneumonia was defined according to Centers for Disease Control (CDC) criteria [14]. Pulmonary oxygen transfer was compared using the PaO_2/FiO_2 ratio.

The length of stay in intensive care units (ICU) or intermediate care units (IMC) and the duration of total postoperative hospitalization (LOS) was documented.

Statistical analysis

A case number calculation and power analysis was not performed because the number of all the clinically relevant potential complications we investigated has not been evaluated prospectively in vascular patients before this study.

Statistical analysis was performed using the SPSS software package. Chi-squared tests, the Mann-Whitney-Wilcoxon test and Fisher's exact test were used; $P<.05$ was considered significant.

Results

From May 1998 to August 1999, 237 patients undergoing laparotomy for elective vascular surgery were included after giving verbal informed consent. 33 patients (17 study, 16 control) were excluded postoperatively, either because mechanical ventilation had to be continued or because eventually a decision was made not to perform laparotomy and an extraperitoneal approach had been chosen for surgery. 204 patients (99 study, 105 control) remained for further analysis.

Preoperative data

The two groups did not differ with respect to the patients' age, body mass index, comorbidity, ASA classification (Table 1) or preoperative medication. As indicated by the preoperative blood gases and the lung function tests which were performed only if pulmonary abnormalities were suspected, the patients' pulmonary function did not differ between the two groups. The spectrum of the diseases leading to vascular surgery is shown in Table 2.

Intraoperative data

There were no differences between the groups during surgery. The operation and anesthesia times, all necessary medication, including vasopressors and antihypertensive drugs, the blood loss, the amount of autotransfu-

Table 1 Preoperative data (unless mentioned mean values and standard deviation indicated). *nCPAP* nasal continuous positive airway pressure, *ASA* American Society of Anesthesia, *FVC* functional vital capacity, *FV1* one second capacity

	Prophylactic nCPAP (*n*=99)	Control (*n*=105)	*P*
Age	64.1±12.3	64.5±11.3	0.821
Male:female	84:15	82:23	0.280
Body mass index	25.4±3.5	25.0±3.3	0.858
Smokers (%)	54.9	50.6	0.652
Coronary heart disease (%)	85.9	91.4	0.269
Pulmonary disease (%)	28.3	29.5	0.878
ASA classification	2.80±0.43	2.85±0.44	0.453
FVC (% of normal)	80.6±17.1[a]	78.4±17.1[b]	0.451
FV1 (% of normal)	78.3±22.2[a]	74.9±21.8[b]	0.361
PaO_2 preop. (mmHg)	73.6±13.2	74.0±11.2	0.810
$PaCO_2$ preop. (mmHg)	40.7±5.3	40.4±4.3	0.726
Preoperative base excess	1.3±2.0	1.3±2.8	0.952

[a] *n*=60 [b] *n*=79

Table 2 Number of surgical diagnoses. Other diagnoses include mesenteric ischemia and thrombosis of the inferior vena cava. *nCPAP* nasal continuous positive airway pressure

Diagnosis	Prophylactic nCPAP	Control
Infrarenal aortic aneurysm	68	66
Renal artery stenosis	13	16
Atherosclerosis	9	11
Fibromuscular dysplasia	4	5
Aortoiliac occlusive disease	12	16
Others	6	7
Total	99	105

sion, which was used in most of the cases, the cumulative fluid balance including crystalloid volume and the amount of red blood cell units and fresh frozen plasma administered, did not differ (Table 3). The operative procedures did not differ between the groups.

Table 3 Intraoperative data (unless indicated otherwise, mean and SD are noted)

	Prophylactic nCPAP (*n*=99)	Control (*n*=105)	*P*
Time of surgery (min)	163±84	168±82	0.638
Blood loss (ml)	1910±1547	1831±1316	0.818
Cristalloid infusion	3313±1772	3410±1514	0.676
Transfusion (red cells) (ml)	699±385	726±412	0.631
Hypotension (n/%)[a]	10/10.1	19/18.1	0.113
Hypertension (n/%)[b]	14/14.1	8/7.6	0.176
Autotransfusion (ml)	515±557	515±535	0.818
FiO_2 [c]	0.38±0.11	0.35±0.07	0.371
PaO_2 (mmHg)[c]	144±70	141±50	0.783
$PaCO_2$ (mmHg)[c]	46±6	45±5	0.306
Base excess[c]	–0.8±3.3	–1.5±9.0	0.143

[a] Hypotension was stated when systolic blood pressure was <90 mmHg and vasopressors had to be given.
[b] Hypertension was stated when systolic blood pressure was >170 mmHg and antihypertensive medication had to be given.
[c] All intraoperative arterial blood gas analyses were pooled for comparison.

Table 4 Postoperative data, first day after surgery (unless indicated otherwise, mean and SD are noted). *nCPAP* nasal continuous positive airway pressure

	Prophylactic nCPAP (*n*=99)	Control (*n*=105)	*P*
Blood pressure systolic (mmHg)	161±18	164±20	0.437
Blood pressure diastolic (mmHg)	90±11	91±13	0.537
Transfusion (*n*/%)	6/6.1	6/5.8	1.0
Hemoglobin (g/dl)	11.8±1.5	11.6±1.6	0.626
Lactate (mg/dl)	2.17±2.75	1.82±2.33	0.527
Temperature (°C)	38.2±0.7	38.0±0.6	0.08
PaO_2/FiO_2, day of operation (mmHg)[a]	320±156	285±123	0.03
PaO_2/FiO_2 (mmHg)[a]	255±94	269±122	0.543
$paCO_2$ (mmHg)[a]	42±4	42±5	0.832
Base excess (IU)[a]	3.2±2.3	3.2±3.3	0.965

[a] All arterial blood gas analyses were pooled for comparison.

Postoperative data

Physiologic parameters on the day of the operation and the first postoperative day, including hemoglobin concentration and arterial blood gases, are shown in Table 4. Only PaO_2/FiO_2 on the day of the operation were significantly higher in the study group (330±156 versus 285±123 mmHg, *P*=.03).

Nine patients did not tolerate nCPAP because of claustrophobia (9.1%) and refused to continue prophylactic nCPAP after 5.75±4.80 h. Superficial nose ulcers appeared in four patients (4.1%); other side effects were not seen. These four ulcers appeared in an early phase of the study, after using a hydrocolloid coverage for the nose; no ulcers developed within the study. The average time during which nCPAP was applied prophylactically was 14.0±4.3 h.

More control group patients developed oxygenation disturbances (17 versus 5, *P*=.01, see Table 5). Patients with oxygenation disturbances mainly contributed to other complications; three of the five study group patients (one pneumonia, one reintubation, one readmission) and 11 of the 17 control group patients (two pneumonia, two reintubation, seven readmission) with oxygenation disturbances developed secondary complications (*P*=.06).

Postoperative cardiac and pulmonary complications did not differ between the groups. Reintubation and pneumonia occurred more frequently in the control group; however, the difference did not reach statistical

Table 5 Postoperative data, complications (unless indicated otherwise *n*/% shown). *nCPAP* nasal continuous positive airway pressure, *ICU* intensive care unit; *IMC* intermediate care unit

	Prophylactic nCPAP (*n*=99)	Control (*n*=105)	*P*
Nose ulcer	4/4.1	–	–
Intolerance to prophylactic nCPAP	9/9.1	–	–
Time of nCPAP (hours±SD)	14.0±4.3	–	–
Reoperation	5/5.1	4/3.8	0.742
Cardiac arrest	1/1.0	2/1.9	1.0
Severe oxygenation disturbance[a]	5/5.1	17/16.2	0.012
Renal failure	3/3.0	3/2,9	1.0
Severe postoperative delirium	6/6.1	12/11.4	0.220
Pneumonia	2/2.0	5/4.8	0.446
Reintubation	1/1.0	5/4.8	0.213
Death	4/4	–	0.06
Readmission to ICU/IMC	6/6.1	14/13.3	0.21
Stay ICU/IMC (days±SD)	1.91±1.63	2.83±7.09	0.199
Total stay postoperatively (days±SD)	9.45±6.79	11.81±18.61	0.236

[a] A severe oxygenation disturbance was defined as paO_2 <70 mmHg despite a FiO_2 of 0.7 or more applied via a face mask without CPAP.

significance. Analysis of other clinical parameters showed no statistical differences between the groups, including readmission rate to ICU/IMC (14 versus 6, *P*=.10) stay on ICU/IMC (2.8 versus 1.9 days, *P*=0.20) and total postoperative hospitalization (11.8 versus 9.5 days, *P*=.24) (Table 5).

Four patients in the study group died, but there were no deaths in the control group (*P*=.06). Two patients died after surgical complications on days 2 and 3 after surgery, one from cardiac failure on day 6 and one from septic shock with unproven focus on day 10 after surgery.

The total number of cardiac and pulmonary complications, including death, readmission rate to ICU/IMC, cardiac events (congestive heart failure, myocardial infarction), but excluding oxygenation disturbances, was not significantly higher in the control group (26 versus 14, *P*=.08).

Discussion

Nasal CPAP is a support device for patients breathing spontaneously. It is easy to implement and the technical requirements are simple: a high-flow gas source, an air/oxygen blender, a reservoir, and a commercially available nose mask plus a standard PEEP valve. It has been proven effective in acute respiratory distress due to cardiogenic pulmonary edema [10], acute exacerbation of chronic obstructive pulmonary disease (COPD) [11, 15], and chest wall diseases, including neurogenic diseases [16].

Its positive effect in treating atelectasis [12], acute respiratory failure due to COPD [17], and in postoperative hypoxemia, has been described [18].

Barratz [19] showed that about half of the patients with congestive heart failure responded positively to nasal CPAP. Responders have a slightly higher cardiac index and a lower heart rate, but no hemodynamic parameter reliably predicts response before CPAP therapy. The hemodynamic studies performed show that the effect is mainly due to reduction in cardiac preload and afterload [13]. Furthermore, the work of breathing is reduced by CPAP, which is specifically beneficial in patients with impaired left ventricular function [20]. These findings show that patients with a moderate to severe reduction of left ventricular function (a group of patients frequently found in vascular surgery) may benefit from nasal CPAP.

A few studies have investigated the role of noninvasive ventilation as a breathing support in preventing complications in general [3, 21, 22, 23, 24] and cardiothoracic surgery [2, 25, 26]. After general surgery, short-term CPAP of 1–4 h was used (90% open cholecystectomies). The authors were not able to prove that their results (reduction in radiological changes, improvement of functional residual capacity) lead to a reduction in clinical relevant variables such as the incidence of pneumonia or a reduction in the duration of stay in the ICU/IMC care or total LOS.

To our knowledge, this study is the first prospective randomized trial on the prophylactic use of nCPAP in vascular surgery patients who have a high rate of cardiopulmonary risk factors, and in whom cardiac and pulmonary complications account for the majority of postoperative complications, including death [1]. It is also the first study using a continuous 12-h regimen of prophylactic CPAP. The low incidence of pre-term cessation of prophylactic nCPAP and the experience with long-term therapeutic nCPAP, which is tolerated up to 72 h in patients with severe postoperative hypoxemia [8], show that the nasal application of CPAP is superior to other modes, such as full face masks [2], with respect to the patient's comfort. The occurrence of nose ulcers as early as after only 12 h of nCPAP underlines the importance of a protective coverage to avoid ulcers.

We have shown that a 12-h prophylactic application of nCPAP has significantly improved oxygenation and reduced the number of patients who developed oxygenation disturbances. In general, these patients represent a large group of those patients who develop secondary, clinically important complications that lead to readmission on ICU/IMC.

We were not able to show a significant benefit of 12-h prophylactic nCPAP with respect to other clinically important cardiac and pulmonary complications, nor could we show its effect on the length of ICU/IMC treatment or the total length of hospital stay. This might be partly due to the low incidence of complication in the entire

study group. For example, the average incidence of pneumonia after major vascular surgery is 5–15% [1], whereas in our study only seven patients (3.4%) developed pneumonia. On the other hand, the investigated groups' sample size might have been too small to discover slight but significant differences.

Although four patients in the study group died, we do not think this can be related to nCPAP. Findings during reoperation of the two patients revealed that the surgical complication was decisive for the patients' death, so this cannot be attributed to nCPAP. The other two patients died on days 6 and 10 after surgery, but in their cases an influence from nCPAP applied until day 1 after surgery seems very unlikely.

More control patients required readmission to ICU/IMC, although this difference fails to reach statistical significance. The readmission rate is not generally accepted as a measurement of the quality of medical care [27], but patients readmitted to ICU/IMC are older, more seriously ill, and more likely to die [28]. In surgical patients, cardiac and pulmonary complications are the main causes leading to readmission [28], findings that we could confirm in our patients. The possibility of reducing clinically relevant cardiac and/or pulmonary complications after major vascular surgery, and therefore reducing the need for intensive care and shortening of postoperative stay, may help to overcome the shortage of intensive care capacity and could help to reduce costs.

In conclusion, a 12-h prophylactic nCPAP treatment significantly reduces the number of postoperative severe oxygenation disturbances after major vascular surgery. However, we did not find evidence for a reduction in overall cardiac or pulmonary complications or in LOS in the patient group we investigated. Further studies are necessary to investigate whether subgroups with specifically high risks of postoperative pulmonary or cardiac failure may benefit from prophylactic nasal CPAP.

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