

# Non-invasive ventilation in elderly patients with acute hypercapnic respiratory failure: a randomised controlled trial

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## Abstract

**Objective:** older patients usually receive less invasive and costly hospital care, even if they meet the criteria for Intensive Care Unit admission or have a 'do not intubate'(DNI) order. The aim of this randomised, controlled trial was to assess the effectiveness of non-invasive mechanical ventilation (NIV) versus the standard medical therapy (SMT) in reducing the need of intubation, improving survival and reducing respiratory distress in very old patients with acute hypercapnic respiratory failure (AHRF).

**Participants and design:** eighty-two patients aged >75 years (mean age 81.3 ± 3.5 years) were randomised to receive NIV or SMT.

**Settings:** three respiratory units.

**Measurements:** the primary outcome was the rate of meeting the endotracheal intubation (ETI) criteria. Secondary outcomes were the mortality rate, the respiratory rate, dyspnoea score, arterial blood gases.

**Results:** the rate of meeting the ETI criteria was lower in the NIV group compared with the SMT group (7.3 versus 63.4%, respectively;  $P < 0.001$ ), as was the mortality rate [(odds ratios) OR = 0.40; 95% CI: 0.19–0.83;  $P = 0.014$ ]. Twenty-two of 41 SMT patients with DNI orders received NIV as a rescue therapy. The mortality rate in this subgroup was comparable with the NIV group and significantly lower compared with patients receiving ETI (OR = 0.60, 95% CI: 0.18–1.92 versus 4.03, 95% CI: 2.35–6.94, respectively;  $P = 0.009$ ). Arterial blood gases, respiratory rate and dyspnoea improved significantly faster with NIV than with SMT.

**Conclusions:** compared with SMT, NIV decreased the rate of meeting the ETI criteria and the mortality rate of very old patients with AHRF. NIV should be offered as an alternative to patients considered poor candidates for intubation and those with a DNI order.

**Keywords:** non-invasive ventilation, COPD, acute respiratory failure, intubation rate, survival rate, ICU admission, elderly

## Introduction

With increased life-expectancy, living to an advanced age is common [1]. Although it has been demonstrated that the

in-hospital mortality is similar in old and younger patients admitted to an Intensive Care Unit (ICU) [2], older patients usually receive less invasive and costly hospital care, even after adjustment for the severity of their illness [3]. Because

of the increasing prevalence of chronic respiratory disorders, the number of elderly patients meeting the criteria for mechanical ventilation is likely to increase [4, 5].

Given that the decision on whether to ventilate patients with chronic pulmonary diseases depends on the clinician's assessment and prognosis, [6] some patients, who might otherwise survive, are being denied mechanical ventilation because of unwarranted prognostic pessimism [7]. Another issue is that all the studies performed to assess the prognosis of older patients requiring mechanical ventilation excluded patients with a 'do-not-intubate' (DNI) order [8–10]. Non-invasive mechanical ventilation (NIV) is an alternative to intubation and ICU admission since it can be safely applied even outside a 'protected' environment provided that the patient's acidosis is not too severe. A small observational study suggested that NIV could be a successful treatment for acute respiratory failure in patients over 75 [11] in whom intubation was contra-indicated. However, this result was not confirmed by subsequent NIV trials because, on average, much younger patients were enrolled [12–22]. In the present, prospective, multicentre, randomised study, we compared the effect of NIV with that of the standard medical therapy (SMT) in reducing the rate of meeting the endotracheal intubation (ETI) criteria in old patients with acute hypercapnic respiratory failure (AHRF). Secondary outcomes were the mortality rates of the NIV and SMT groups, the proportion of patients in whom NIV was used as rescue therapy, the changes in some physiological parameters including dyspnoea, arterial blood gases (ABGs), respiratory rate and neurological status.

## Material and methods

A two-group, parallel, randomised, controlled trial was carried out in patients with known chronic pulmonary disease who developed AHRF. For the purpose of this study, admission criteria to the respiratory critical care unit (RCCU) were standardised. All patients aged over 75 who were admitted to any of three RCCUs (Pavia and Gaiato, Italy, Locarno and Bellinzona, Switzerland) because of an acute exacerbation of their respiratory disease were eligible for this study, regardless of whether they had a DNI order. In Switzerland, end-of-life decisions are part of clinical practice, rather, lacking a specific law, putting into practice DNI orders varies in Italy, but it was common practice in the centres participating in this study to ask the patients to sign a written consent about their willingness to be or not to be intubated or resuscitated when or if eventually required.

Eighty-two patients diagnosed with chronic pulmonary disease on the basis of the clinical history, physical examination, chest X-ray and pulmonary function tests (if available) were included in the study.

The protocol was approved by each hospital's Ethics Committee. All the patients but 4, whose consent was given by the next of the kin, gave written informed consent to the study. This number is in keeping with most of the studies published in the field of AHRF [11–22].

## Clinical variables

Inclusion criteria were all of the following: pH < 7.35, PaCO<sub>2</sub> > 5.99 KPa, PaO<sub>2</sub> < 7.33 KPa, respiratory rate > 20 breaths/min, severe dyspnoea (Borg ≥ 5). Measurements were performed while patients were breathing room air to avoid any effect of oxygen supplementation on pH. All the patients tolerated the procedure well since their PaO<sub>2</sub>/FiO<sub>2</sub> ratio was, on average, above 200. Exclusion criteria were de-compensated cardiac disease and other serious co-morbidities. All the patients first underwent SMT lasting 94 ± 11 min before randomisation.

## Primary outcome

The primary outcome was the decrease in the rate of meeting the ETI criteria in patients receiving NIV. The presence of one major criterion or two minor criteria after 1 h from randomisation was considered indicative of the need for intubation.

The major criteria were [13]: no improvement in pH (i.e. < 0.01 at 1 and 3 h from randomisation in the presence of a pH ≤ 7.30) or worsening in pH after 1 h if pH ≤ 7.32; PaO<sub>2</sub> less than 5.99 KPa despite oxygen supplementation; deterioration of one or more points in the score of Kelly's neurological scale [23]; respiratory arrest; loss of consciousness; haemodynamic instability and loss of alertness.

Minor criteria were: dyspnoea > 5 on the Borg scale; respiratory rate > 35 breaths/min and the presence of a weak cough reflex with accumulation of secretions.

Criteria for starting NIV as a rescue therapy were the same as those needed for ETI, with the exclusion of respiratory arrest, loss of consciousness, haemodynamic instability and a pH < 7.20.

## Secondary outcomes

As secondary outcomes we considered the following: changes in ABGs at 1 and 3 h from randomisation, the neurological score, the dyspnoea score and the respiratory rate recorded at the time of measuring the ABGs. We also recorded the 6 and 12-month mortality rate both by checking the hospital records or by telephone interviews.

The presence of co-morbidities was assessed using the Charlson index [24], the consciousness level using the Kelly scale [23], while the McCabe score was used to estimate the probability of survival [25].

## Sample size and randomisation

Considering the primary outcome (ETI), we expected a 35% failure rate in the SMT group, based on the frequencies reported in previous randomised controlled trials performed in younger patients, and a 10% failure rate in the NIV group [26]. Thus, given a power of 80% with an  $\alpha$  error of 5%, to detect the expected difference of 25% between the two groups in the rate of meeting the ETI criteria, we had to enrol 40 patients per group [27].

The patients were randomly assigned to one of the two treatment groups using opaque, sealed, numbered envelopes. We first estimated the 'potential enrolment power' of each of the three RCCU, based on their records from the previous years. We estimated that 10–12 patients aged >75 and affected by AHRF would be enrolled each year in each recruiting hospital. Therefore, we prepared 36 envelopes per centre, using 2 blocks of 10, 2 blocks of 6, and 1 block of 4. The envelopes were kept in the Head Nurses' offices in every RCCU and the nurse on shift was allowed to open the envelope on request and to communicate the group assignment to the investigators. The Berger–Exner test [28], which correlates outcomes with positions on the randomisation block, was employed to rule out any possibility of a compromised allocation using the sealed envelope technique.

### Statistical analysis

Results are given as the mean  $\pm$  standard deviation. All statistical tests were two-sided, *P*-values of less than 0.05 were considered statistically significant, and intention-to-treat procedure was taken on in data analysis.

Groups were compared by means of one-way ANOVA when data were normally distributed, and the Mann–Whitney and the Wilcoxon tests were used when data was evenly distributed. Frequency distributions were compared with the Chi-square test.

Since most of the patients in the SMT group who met the criteria for ETI had a DNI order and NIV was used as a rescue treatment, two discrete-time survival analysis [29, 30] models were fitted to analyse mortality rate at 6 and 12 months:

- the mortality rate according to the randomised treatment (i.e. NIV and SMT);
- the mortality rate according to the use of NIV or ETI as rescue treatments, after adjustment for randomisation group. A logistical function to relate the discrete time

hazard probabilities to the explanatory (treatment) variables was used, and maximum likelihood estimates (MLE) of model parameters (=odds ratios, OR), 95% confidence intervals (95% CI) and *P*-values of the likelihood ratio test (LRT) from the output were reported.

Data analysis and discrete-time survival modelling were performed using the SPSS software (version 15.0), and the Mplus software (version 5.2), respectively.

## Results

Figure 1 illustrates the patients flow through the study. We found that our randomisation was successful since no relationship between outcomes and positions on the randomisation block was found, using the Berger–Exner test (*P* = 0.254).

### Patients' characteristics

The characteristics of the patients in the two groups are shown in Table 1.

NIV was delivered for an average of  $12.7 \pm 2.3$  h/day for  $5.7 \pm 3.2$  days in pressure support mode with a full face mask, using ventilators specifically designed for NIV. Patients received ventilation with a level of pressure support equal to  $16.3 \pm 2.2$  cm H<sub>2</sub>O and an external positive pressure of  $4.1 \pm 1.1$  cm H<sub>2</sub>O. Pressure support levels were set according to the patients' tolerance and to obtain target an expired tidal volume of 6–8 ml/kg, while the external positive pressure was always  $\leq 6$  cmH<sub>2</sub>O. In both groups, oxygen supplementation was provided to reach a  $90\% \leq \text{SaO}_2 \leq 94\%$  (FiO<sub>2</sub> range from 25 to 45%).

### Primary outcome

As shown in Table 2 upper part, in the NIV group 3 of 41 (7%) patients met the criteria for intubation, whereas 26 of 41 (63%) patients in the SMT group met these criteria (*P*

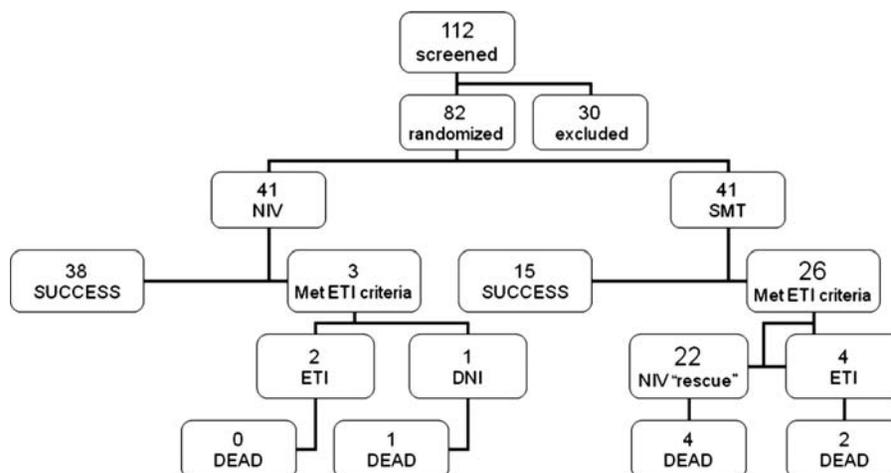


Figure 1. Trial profile.

**Table 1.** Patients' characteristics at enrolment

	SMT	NIV	P-value
Age (years)	81.3 ± 4.8	81.3 ± 4.8	0.98
BMI (kg/m <sup>2</sup> )	24.9 ± 5.7	26.6 ± 5.7	0.58
McCabe score	1.3 ± 0.6	1.1 ± 0.6	0.26
Kelly score	1.9 ± 0.9	1.6 ± 0.8	0.11
SAPS II	35.0 ± 13.2	32.0 ± 13.5	0.46
Sex (M/F)	26/15	28/13	0.66
pH	7.29 ± 0.05	7.30 ± 0.04	0.11
PaCO <sub>2</sub> (KPa)	9.16 ± 1.47	8.69 ± 1.57	0.17
PaO <sub>2</sub> /FiO <sub>2</sub>	238.9 ± 70.1	231.1 ± 54.4	0.59
Chronic respiratory disorder			
COPD	33	33	0.77
Kscoliosis	3	3	
Fibrothorax	4	5	
Other	1	0	
Number of co-morbidities (Charlson index)	0.98 ± 0.7	1.02 ± 0.8	0.78
Do-not-Resuscitate order	29/41	33/41	0.81

SAPS II, simplified acute physiological score.

**Table 2.** Differences for ETI (primary end-point), and the secondary end-points pH, PaCO<sub>2</sub>, respiratory rate and Borg dyspnoea score changes at 1 h after the enrolment, in the two-arm groups

	NIV	SMT	P-value
ETI	3/41 (7.3%)	26/41 (63.4%)	<0.001
pH	0.04 ± 0.05	-0.006 ± 0.03	<0.001
PaCO <sub>2</sub> (KPa)	-0.91 ± 1.11	0.29 ± 1.13	<0.001
Respiratory rate (b.p.m.)	-4.1 ± 6.4	-0.9 ± 4.1	0.01
Dyspnoea score	-1 ± 1.5	-0.4 ± 1.2	0.05

Data are shown as frequency (%) or mean ± standard deviation.

< 0.001). When patients who suffered from chronic respiratory disorders different from chronic obstructive pulmonary disease were excluded from the statistical analysis the level of significance did not change.

**Secondary outcomes**

*Clinical changes*

Table 2 also illustrates the changes in ABGs between enrolment and after 1 h of NIV. Both pH and PaCO<sub>2</sub> improved significantly faster in the NIV group (*P* < 0.001), while changes in the PaO<sub>2</sub>/FiO<sub>2</sub> ratio (not reported in the table) did not vary significantly between the two groups. Respiratory rate and dyspnoea score improved significantly faster in the NIV group (*P* < 0.01 and *P* < 0.05, respectively), while the neurological status was not influenced by the treatment used (data not shown).

Some side effects were recorded in the group treated with NIV: twenty patients had nasal skin irritation and 14 of them had nose abrasions, which, in two cases, was severe enough to require a switch from the full face mask to the helmet.

**Table 3.** Frequency distributions (number of death/number of alive) of death history (in hospital 6 m and 12 m) and maximum likelihood estimates (MLE) of odds ratios (95% confidence intervals) from discrete-time survival analysis modelling

	No. of death/no. of alive			OR (95% CI) <sup>b</sup>	P-value
	Inhospital	6 m	12 m		
<b>Randomised treatment</b>					
SMT	6/35	11/22 <sup>a</sup>	8/14	1 (reference)	0.014 <sup>c</sup>
NIV	1/40	4/34 <sup>a</sup>	11/23	0.40 (0.19–0.83)	
<b>Rescue treatment</b>					
SMT	1/15	2/11	5/6	1 (reference)	
NIV	3/57	13/42 <sup>a</sup>	12/30	0.60 (0.18–1.92)	0.009 <sup>c</sup>
ETI	3/3	0/3	2/1	4.03 (2.35–6.94)	

<sup>a</sup>Two missing patients at 6 months.

<sup>b</sup>The randomised treatment ORs are 'marginal' estimates without adjusting for rescue treatment; the rescue treatment ORs are 'conditional' estimates after adjusting for randomised treatment.

<sup>c</sup>Likelihood ratio test (LRT) evaluating the overall treatment effect.

Among the patients who met the criteria for intubation, 21 of 25 in the SMT group and 1 of 3 in the NIV group had a DNI order, so that NIV was used as rescue therapy in 21 patients in whom SMT failed and was successful in 17 of these cases.

**Mortality rate**

The duration of hospital stay was similar in the two groups (19.2 ± 18.4 days for the NIV group versus 22.1 ± 33 days for the SMT group). The causes of in hospital-death in the SMT group were cardiac arrest (*n* = 2), ventilator associated pneumonia (*n* = 1), severe arrhythmia (*n* = 1), myocardial infarction (*n* = 1) and refractory respiratory failure (*n* = 1). One patient died in the NIV group of myocardial infarction.

Table 3 lower part shows that the mortality rate was overall significantly lower in the NIV versus SMT group (OR = 0.40, 95% CI: 0.19–0.83, *P* = 0.014) and, in particular, it was lower at hospital admission and at 6 months (*P* = 0.04 and 0.0026, respectively).

Analysing the effect of the use of NIV or ETI as rescue treatments, after adjustment for group randomisation (i.e. *ceteris paribus* the randomised treatment), we found that ETI was associated with the highest risk, while no differences were observed between NIV and SMT, this latter group consisting of those patients not reaching ETI criteria (OR = 0.60, 95% CI: 0.18–1.92 versus OR = 4.03, 95% CI: 2.35–6.94, respectively; *P* = 0.009). Equivalent ORs were obtained after adjusting for the presence of co-morbidities.

**Discussion**

There is still no agreement about the best treatment and outcomes for elderly patients admitted to an ICU for an episode of acute respiratory failure [31] and prospective studies are needed to obtain information on these two important issues.

This randomised, controlled study shows that the use of NIV to treat AHRF in old patients reduces the need for intubation, improves survival (in-hospital, 6 and 12 months) and, simultaneously, induces a faster resolution of respiratory distress compared with SMT.

Acute respiratory failure is often the final event in patients with chronic respiratory disorders and will represent the second or third cause of death in the future [5]. ICU admission and mechanical ventilation are not necessarily associated with a poor prognosis in the elderly [2], however, most of the studies that demonstrate this were performed on patients without pre-existing pulmonary diseases, despite the fact that individuals with chronic respiratory disorders represent a large proportion of patients over 70–75 years admitted to an ICU [4]. Old patients with hypercapnia (i.e. PaCO<sub>2</sub> >45 mmHg) were shown to have a poor survival rate after an episode of AHRF [32]. This may explain why a recent observational study performed in France found that up to 50% of octogenarians were not admitted to an ICU [33], despite needing intensive medical or ventilatory treatment.

Our study demonstrates that most of these patients could be successfully treated with NIV and, therefore, they could also be treated in a medical ward, if the pH level is not dangerously low (i.e. >7.28) [34].

Surprisingly, in our study, the SMT success rate was lower than in other randomised controlled trials (40% versus 55%, respectively). The reasons for these results are not clear, but may be related to different inclusion criteria of the patients, different environments and by the lack of prompt correction of the respiratory distress, which may have triggered sudden cardiac arrest in patients with a pre-existing cardiac co-morbidity (4 of 6 deaths in the SMT group were caused by acute cardiac problems).

The rescue therapy with NIV was very successful (75%) and this is in keeping with the results of two other randomised, controlled trials in which this technique was used after SMT had failed, albeit in different clinical situations [35, 36]. The use of NIV as a rescue therapy in the SMT group patients who met the intubation criteria represents the most likely explanation for the low mortality rate. This highlights the importance of using NIV not only as a palliative measure but, also, as a preferential treatment when intubation is either not wanted by the patient or questionable for the physician.

NIV not only improved the survival rate, but also accelerated the process of reducing tachypnoea and dyspnoea, which are the major symptoms of respiratory distress. The application of inspiratory and expiratory aid is important to reduce the inspiratory burden, both in acute and chronic settings [37, 38]. It has been shown that the sensation of dyspnoea correlates strongly with the inspiratory load [39], so that it is likely that NIV could also be useful to relieve the sense of breathlessness that is particularly high in chronically ill old patients.

### Limitations

The data from the present multicentre study may not be generalised since all the Centres involved in the trial have

long-term experience in using NIV and this may have influenced the success rate of this technique, as reported [34]. Indeed, two of the four hospitals are referral centres for the treatment of chronic respiratory failure and home mechanical ventilation, so that most of the patients enrolled in the study were already familiar with the personnel and a few of them were already accustomed to the use of NIV. Patients were consecutively enrolled in the study and, as illustrated in Figure 1, our non-enrolment rate was really low, suggesting that our group represents the general population of elderly patients. Therefore, further studies are warranted to confirm our data on a larger population, keeping in mind that the quality-of-life and prolonged improvement in dyspnoea may be important outcomes to assess.

In our study, we used NIV ventilators or ICU ventilators with NIV module, specifically designed to detect any form of patient/ventilator asynchrony (i.e. they have a sophisticated monitoring system) and to provide higher FiO<sub>2</sub>, if needed. Perhaps, our results cannot be generalised in units where less sophisticated respirators are used.

### Conclusions

In conclusion, we have shown that, during an episode of AHRF in old patients with a pre-existing chronic respiratory disorder, the use of NIV is associated with a lower proportion of patients meeting the ETI criteria, a higher survival rate and faster resolution of respiratory distress when compared with SMT. The use of NIV as a rescue therapy is associated with a lower mortality rate compared with ETI. NIV seems appropriate to use in elderly patients when intubation may be considered a questionable option or when the patient has signed a DNI order.

### Key points

- NIV has been shown to improve the clinical outcomes, compared with the standard medical treatment, during an episode of hypercapnic acute respiratory failure. The present randomised study is the first one to confirm the efficacy of this method of ventilation also in patients aged >75 years.
- The rate of meeting the criteria for ETI was lower in the NIV group versus standard medical treatment (control group).
- NIV was used as a 'rescue' therapy for those patients meeting the intubation criteria in the control group and refusing intubation.
- The mortality rate was lower in the NIV group versus the standard medical treatment, using the intention-to-treat analysis.
- Arterial blood gases, respiratory rate and dyspnoea improved significantly faster with NIV than with the standard medical treatment.

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## Conflicts of interest

All the authors declare no conflict of interest.

## References

- Day JC. Population projections of the United States by age, sex, race, and Hispanic origin: 1995 to 2050. Current population reports. Washington, DC: US Bureau of Census, 1996; 25–1130.
- Wood KA, Ely W. What does it mean to be critically ill and elderly? *Current Opinion in Critical Care* 2003; 9: 316–20.
- Hamel MB, Phillips RS, Teno J *et al* Seriously ill hospitalized adults: do we spend less on older patients? *J Am Geriatr Soc* 1996; 44: 1043–8.
- Boumendil A, Aegerter P, Guidet B and the CUB-Rea network treatment intensity and outcome of patients aged 80 and older in intensive care units: a multicenter matched-cohort study. *JAGS* 2005; 53: 88–93.
- Yach D, Hawkes C, Gould CL, Hofman KJ. The global burden of chronic diseases. Overcoming impediments to prevention and control. *JAMA* 2004; 291: 2616–22.
- Escher M, Pemeger TV, Chevrolet JC. National questionnaire survey on what influences doctors' decisions about admission to intensive care. *BMJ* 2004; 329: 452–8.
- Wildman MJ, Sanderson C, Groves J *et al* Implications of prognostic pessimism in patients with chronic obstructive pulmonary disease or asthma admitted to intensive care in the UK within the COPD and asthma outcome study: multicentre observational cohort study. *BMJ* 2007; 335: 1132–5.
- Ely WE, Evans GW, Haponik EF. Mechanical ventilation in a cohort of elderly patients admitted to an intensive care unit. *Ann Intern Med* 1999; 131: 96–104.
- Ely WE, Wheeler AP, Thompson T, Ancukiewicz M, Steinberg KP, Bernard GR. Recovery rate and prognosis in older persons who develop acute lung injury and the acute respiratory distress syndrome. *Ann Intern Med* 2002; 136: 26–36.
- Esteban A, Anzueto A, Frutos-Vivar F *et al* Outcome of older patients receiving mechanical ventilation. *Intensive Care Med* 2004; 30: 639–46.
- Benhamou D, Girault C, Faure C, Portier F, Muir JF. Nasal mask ventilation in Acute Respiratory failure: experience in elderly patients. *Chest* 1992; 102: 912–7.
- Bott J, Carrol MP, Conway JH *et al* Randomised controlled trial of nasal ventilation in acute ventilatory failure due to chronic obstructive airways disease. *Lancet* 1993; 341: 1555–7.
- Brochard L, Mancebo J, Wysocki M *et al* Noninvasive ventilation for acute exacerbation of chronic obstructive pulmonary disease. *N Engl J Med* 1995; 333: 817–22.
- Kramer N, Meyer TJ, Meharg J, Cece RD, Hill NS. Randomized, prospective trial of noninvasive positive pressure ventilation in acute respiratory failure. *Am J Respir Crit Care Med* 1995; 151: 1799–806.
- Barbè F, Togoires B, Rubi M, Pons S, Maimo A, Agusti AG. Noninvasive ventilatory support does not facilitate recovery from acute respiratory failure in chronic obstructive pulmonary disease. *Eur Respir J* 1996; 9: 1240–5.
- Plant PK, Owen JL, Elliot MW. A multicentre randomised controlled trial of the early use of non-invasive ventilation in acute exacerbation of chronic obstructive pulmonary disease on general respiratory wards. *Lancet* 2000; 335: 1931–5.
- Nava S, Ambrosino N, Clini E *et al* Noninvasive mechanical ventilation in the weaning of patients with respiratory failure due to chronic obstructive pulmonary disease. A randomized, controlled trial. *Ann Intern Med* 1998; 128: 721–8.
- Girault C, Daudenthun I, Chevron V, Tamion F, Leroy J, Bonmarchand G. Noninvasive ventilation as a systematic extubation and weaning technique in acute-on-chronic respiratory failure. A prospective, randomized controlled study. *Am J Respir Crit Care Med* 1999; 160: 86–92.
- Ferrer M, Esquinas A, Arancibia F *et al* Noninvasive ventilation during persistent weaning failure: a randomized controlled trial. *Am J Respir Crit Care Med* 2003; 168: 70–6.
- Confalonieri M, Della Porta R, Potena A *et al* Acute respiratory failure in patients with severe community-acquired pneumonia: a prospective randomized evaluation of noninvasive ventilation. *Am J Respir Crit Care Med* 1999; 160: 1585–91.
- Martin TJ, Hovis JD, Costantino JP *et al* A randomized, prospective evaluation of noninvasive ventilation for acute respiratory failure. *Am J Respir Crit Care Med* 2000; 161: 807–13.
- Conti G, Antonelli M, Navalesi P, Rocco M, Bufi M, Spadetta G. Noninvasive vs. conventional mechanical ventilation in patients with chronic obstructive pulmonary disease after failure of medical treatment in the ward: a randomized trial. *Intensive Care Med* 2002; 28: 1701–7.
- Kelly BJ, Matthay MA. Prevalence and severity of neurologic dysfunction in critically ill patients. *Chest* 1993; 104: 1818–24.
- Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chron Dis* 1987; 40: 373–83.
- McCabe WR, Jackson GG. Gram negative bacteremia: I. Etiology and ecology. *Arch Intern Med* 1962; 110: 845–7.
- Lightowler JV, Wedzicha JA, Elliott MW, Ram FS. Non-invasive pressure ventilation to treat respiratory failure resulting from exacerbations of chronic obstructive pulmonary disease: Cochrane systematic review and meta-analysis. *BMJ* 2003; 326: 185–90.
- Donner A. Approaches to sample size estimation in the design of clinical trials: a review. *Statistic Med* 1984; 3: 199–214.
- Berger VW, Exner DV. Detecting selection bias in randomized clinical trials. *Control Clin Trials* 1999; 20: L319–27.
- Singer JD, Willett JB. It's about time: using discrete-time analysis to study duration and the timing of events. *J Educ Stat* 1993; 18: 155–95.
- Singer JD, Willett JB. *Applied Longitudinal Data Analysis. Modeling Change and Event Occurrence*. New York: Oxford University Press, 2003.
- Hennessy D, Juzwishin K, Yergens D, Noseworthy T, Doig C. Outcomes of elderly survivors of intensive care. A review of the literature. *Chest* 2005; 127: 1764–74.
- Ray P, Birolleau S, Lefort Y *et al* Acute respiratory failure in the elderly: etiology, emergency, diagnosis and prognosis. *Crit Care* 2006; 10: R82 (doi:10.1186/cc4926).

33. Garrouste-Orgeas M, Timsit JF, Montuclard L *et al* Decision-making process, outcome, and 1-year quality of life of octogenarians referred for intensive care unit admission. *Intensive Care Med* 2006; 32: 1045–51.
34. Carlucci A, Delmastro M, Rubini F, Fracchia C, Nava S. Changes in the practice of non-invasive ventilation in treating COPD patients over 8 years. *Intensive Care Med* 2003; 29: 419–25.
35. Ferrer M, Valencia M, Nicolas JM, Bernadich O, Badia JR, Torres A. Early non-invasive ventilation averts extubation failure in patients at risk. A Randomized Trial. *Am J Respir Crit Care Med* 2006; 173: 164–70.
36. Esteban A, Frutos-Vivar F, Ferguson ND *et al* Non-invasive positive pressure ventilation for respiratory failure after extubation. *New Engl J Med* 2004; 350: 2452–60.
37. Appendini L, Patessio A, Zanaboni S, Carone M, Gukov B, Donner CF, Rossi Physiologic effects of positive end-expiratory pressure and mask pressure support during exacerbations of chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1994; 149: 1069–76.
38. Nava S, Ambrosino N, Rubini F *et al* Effect of nasal pressure support ventilation and external PEEP on diaphragmatic function in severe stable COPD patients. *Chest* 1993; 103: 143–50.
39. Killian KJ, Bucens DD, Campbell EJM. The effect of breathing patterns on the perceived magnitude of added loads to breathing. *J Appl Physiol* 1982; 52: 578–84.

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## Geriatricians' views of advance decisions and their use in clinical care in England: qualitative study

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### Abstract

**Background:** an anticipatory decision document records a person's wishes regarding medical treatment at a time when they have capacity to make choices, to be enacted when this capacity is lost. In England and Wales an advance decision to refuse treatment (ADRT, or advance decision), a legally binding document, is currently rarely used. A disparity is suggested to exist between physicians' support for anticipatory decisions in principle and their lack of impact on decision-making in practice.

**Objective:** to elicit geriatricians' views on advance decisions and their use in decision-making in England.

**Design:** a qualitative approach was taken. Semi-structured interviews were conducted with 10 geriatricians. An inductive approach was used for data analysis.

**Results:** geriatricians held positive views on anticipatory decisions in principle. In practice, they reported being highly likely to follow a decision which was in line with their clinical view. They would also favour an ADRT which was prescriptive in terms of the situation and treatment to which it applied. However, geriatricians expressed concerns in relation to patient understanding of the role and limits of these documents. Participants expressed discomfort in following an ADRT which, in their professional opinion, did not represent the patient's best interests, despite it being a legally binding document. A conflict between doctors' beneficence and patients' autonomy was apparent, with geriatricians differing in their views on how ADRTs should fit into medical decision-making; particularly how far anticipatory decisions can represent ongoing patient autonomy.

**Conclusion:** despite their status in law, an ADRT which conflicts with a geriatrician's clinical opinion may not be implemented, in breach of the Mental Capacity Act. To avoid this, they must be seated within wider advance care planning.

**Keywords:** advanced care planning, geriatrician, qualitative, advanced decision to refuse treatment, elderly