

ORIGINAL



# Nurses versus physician-led interhospital critical care transport: a randomized non-inferiority trial

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## Abstract

**Purpose:** Regionalization and concentration of critical care increases the need for interhospital transport. However, optimal staffing of ground critical care transport has not been evaluated.

**Methods:** In this prospective, randomized, open-label, blinded-endpoint non-inferiority trial, critically ill patients on mechanical ventilation transported by interhospital ground critical care transport were randomized between transport staffed by a dedicated team comprising a critical care nurse and paramedic (nurses group) or a dedicated team including a critical care physician (nurses + physician group). The primary outcome was the number of patients with critical events, both clinical and technical, during transport. Clinical events included decrease in blood pressure, oxygen saturation, or temperature, blood loss, new cardiac arrhythmias, or death. Non-inferiority was assumed if the upper limit of the two-sided 90 % confidence interval (CI) for the between-group difference lies below the non-inferiority margin of 3 %.

**Results:** Of 618 eligible transported critically ill patients, 298 could be analyzed after randomization and allocation to the nurses group ( $n = 147$ ) or nurses + physician group ( $n = 151$ ). The percentages of patients with critical events were 16.3 % (24 incidents in 147 transports) in the nurses group and 15.2 % (23 incidents in 151 transports) in the nurses + physician group (difference 1.1 %, two-sided 90 % CI [−5.9 to 8.1]). Critical events occurred in both groups at a higher than the expected (0–1 %) rate. In the nurses group consultations for physician assistance were requested in 8.2 % (12 in 147 transports), all of which were performed prior to transport.

**Conclusions:** The number of patients with critical events did not markedly differ between critical care transports staffed by a critical care nurse and paramedic compared to a team including a critical care physician. However, as a result of an unexpected higher rate of critical events in both groups recorded by an electronic health record,

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**Take-home message:** In this randomized trial on nurses versus physician-led interhospital critical care transport, the number of critical events did not markedly differ between the two groups. However, as a result of an unexpected higher rate of critical events in both groups recorded by an electronic health record, non-inferiority of nurse-led interhospital critical transport could not be established.

non-inferiority of nurse-led interhospital critical transport could not be established (<http://www.controlled-trials.com/ISRCTN39701540>).

**Keywords:** Critical care transport, Interhospital, Patient transfer, Mobile intensive care unit

## Introduction

The need for interhospital critical care transport of adults is likely to increase with the continual regionalization of care [1–3]. Regionalization is supported by the association between volume and improved outcome in specialties such as trauma and critical care [4, 5]. Transport of a critically ill patient between hospitals bears the risk of clinical and technical events which should be outweighed by the individual benefit [6, 7]. The combination of a registered critical care nurse and a paramedic as the team in critical care transports is more common in the USA than in Europe where a team including a critical care physician is the generally adopted practice [8–10]. However, the added value of a critical care physician as part of the transport team has not been demonstrated [11–15]. We conducted a randomized non-inferiority trial which compared ground critical care transports staffed by a team comprising a paramedic and critical care nurse or a team including a critical care physician. The hypothesis of the study was that interhospital ground critical care transports staffed by a team comprising a critical care nurse and paramedic is non-inferior compared to a team including a critical care physician, as expressed by the number of patients with critical events during transport.

## Methods

### Design and randomization

The design of the study was a prospective, randomized, open-label, blinded-endpoint trial (PROBE design) to demonstrate non-inferiority of a critical care transport staffed by a dedicated team comprising a critical care nurse and paramedic (nurses group) or a dedicated team including a critical care physician (nurses + physician group). Patients were randomized between these two transport strategies. The randomization procedure was Web-based using permuted blocks with a variable block size and stratified by interhospital distance (within or greater than 40 km). Randomization was done immediately after the transport request by phone by the referring hospital. Referring hospitals were not informed about the result of randomization to prevent study-induced bias in the pretransport stabilization period.

The critical care nurse, registered in the Dutch Intensive Care Nurse Registry, had at least 2 years of additional clinical experience in an critical care unit of an academic medical center after registration. The paramedic was

licensed in advanced cardiac life support including rescue endotracheal intubation according to federal regulations with at least 5 years of prehospital experience and an active professional at the municipal Emergency Medical Service of Amsterdam. The critical care physician was a European board-certified intensivist, an anesthesiologist, or a senior resident in anesthesiology with at least half a year of full-time critical care training in an academic medical center. Both nurses and physicians completed the extended critical care transport training of the academic medical center including certification for the use of the trolley of the mobile intensive care unit.

In the nurses group, the critical care nurse, assisted by the paramedic, was allowed to adjust ventilator settings and titrate active medication dosage at their professional discretion excluding new drugs or other emergency therapy. In the nurses group, a critical care physician accompanied every transport for safety reasons but was not physically present in the patient compartment of the ambulance to avoid unsolicited medical advice or intervention. As the physician stayed in the driver compartment, the critical care nurses were able to request the physician's assistance at any time. After a request the transport was executed and completed by both physician and nurses.

In the nurses + physician group the physician was in charge and supervising patient care. The equipment used in both transport strategies was identical and included a mobile intensive care trolley with an IC-ventilator (model Raphael color, Hamilton Medical, Switzerland), six-channel vital signs monitor (model MP50, Philips Medical Systems, the Netherlands), eight syringe pumps, suction unit, defibrillator, medication, and disposables transported in a dedicated intensive care ambulance [8].

### Study setting

In this single-center trial the ground critical care transports were executed using a mobile intensive care unit based at the Academic Medical Center, University of Amsterdam, Netherlands. The interhospital transports were executed between all hospitals nationwide and not only those to and from the Academic Medical Center. The annual transport rate is approximately 350. Outside the setting of this trial a team comprising a critical care nurse and physician is used. All critical care nurses and physicians were members of the ICU staff in the Academic Medical Center.

## Patients

All consecutive critically ill patients (over 18 years of age) to be transported by the mobile critical care unit between January 2006 and March 2008 were eligible. Patients were excluded if they met one of the following criteria:

- (i)  $\text{PaO}_2$  (mmHg)/ $\text{FiO}_2$  (P/F ratio) <100 with positive end-expiratory pressure (PEEP) >15  $\text{cmH}_2\text{O}$ , or mean arterial pressure <60 mmHg despite adequate fluid therapy and vasoactive medication (noradrenaline > 0.35  $\mu\text{g}/\text{kg}/\text{min}$ , dopamine >15  $\mu\text{g}/\text{kg}/\text{min}$ ) or after cardiopulmonary resuscitation (chest compression or cardiac defibrillation) within 24 h prior to transport
- (ii) In need of immediate transport by local emergency medical services within 30 min, mandatory for emergency therapy in another facility according to federal rules and precluding study needs

## Data collection

Patient characteristics were collected by the transport coordinator over the phone at the time of the transport request including date and reason for admission, indication for transport, Acute Physiology and Chronic Health (APACHE) II score, actual intravenous medication, hemodynamics (invasive arterial blood pressures), and pulmonary status (e.g., ventilation mode, PEEP, P/F ratio) to evaluate eligibility for randomization by the transport coordinator.

Transport was defined as the time frame between the departure from the intensive care unit of the sending unit and arrival in the unit of the receiving hospital including intrahospital transport in corridors, elevators, and ambulance garage. At the start of transport an electronic health record (MetaVision®, iMDsoft, Israel) was initiated on a laptop connected to both patient monitor and IC-ventilator storing their parameters every minute for off-line analysis. The APACHE II scores of admissions in both sending and receiving hospital were calculated.

## Study outcomes

The primary outcome was the number of patients with critical events, both clinical and technical, during transport. Clinical events included decrease in transcutaneous arterial oxygen saturation of more than 10 % for more than 10 min, rise or fall in arterial blood pressure (systolic, diastolic, or mean, defined as more than 20 mmHg from baseline for more than 10 min), temperature fall below 36 °C, hemorrhage or blood loss estimated to be greater than 250 ml, new cardiac arrhythmias with associated hemodynamic deterioration (occasional premature cardiac complexes were not considered significant), or death. Technical events (defined as related to

technical aspects of critical care transport) included EKG lead disconnections, loss of battery power or any other technical equipment failure, airway loss requiring airway manipulation or reintubation, loss of any intravascular device, or dislodgment of any chest tube, Foley catheter, or surgical drain [16].

The a priori defined secondary outcome parameters were the separate numbers of clinical events and technical events, number and type of adjustments in ventilator settings, number and type of adjustments in rate of infusion and bolus medication (vasoactive medication and sedative medication), and amount of fluid therapy during transport. All outcome parameters were assessed offline blinded to their allocation group by use of the anonymized electronic medical records. In the nurses group, the incidence of consults for physician assistance was registered as a process variable.

## Statistical analysis

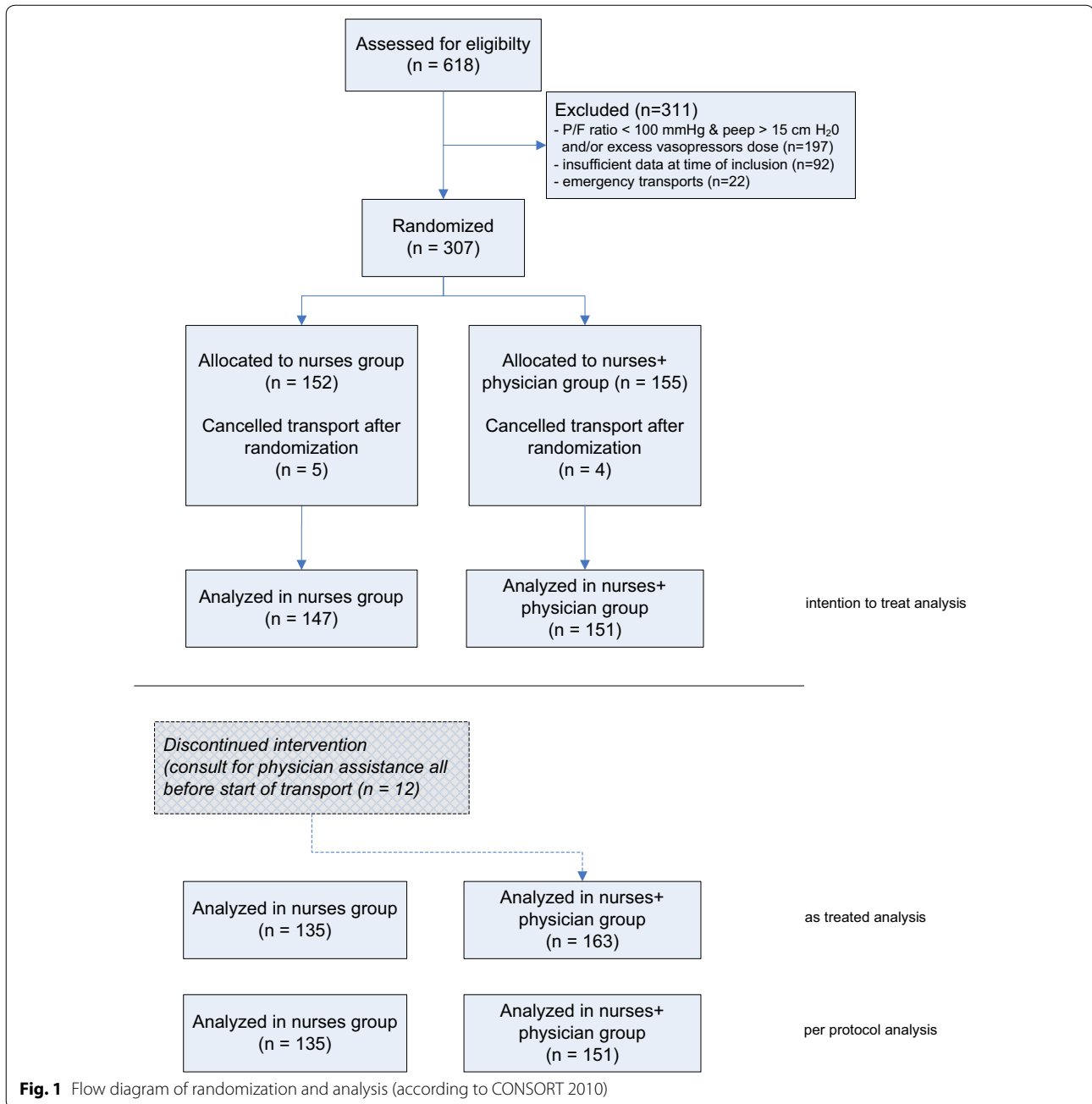
### Sample size

The incidence of critical events in ground critical care transport under supervision of both nurses and physician is around 0–1 % [11, 17, 18]. Hence, it was expected that in 1 % of the patients, critical events would occur in the nurses + physician group (control). The same incidence rate of critical events was expected in the nurses group (intervention) and a non-inferiority margin of 3 % was considered as clinically acceptable. A sample size of 137 patients in each group (274 in total) achieves 80 % power to detect a non-inferiority margin difference between the group proportions of 0.03. The nurses + physician (control) group proportion was assumed to be 0.01 and the nurses (intervention) group proportion 0.04 under the null hypothesis of inferiority. The power was computed for the case when the actual nurses (intervention) group proportion is 0.01. The test statistic used is the one-sided Z test (pooled) with a significance level targeted at 0.05. To anticipate for possible dropouts a total of 307 patients were randomized.

### Data analysis

Baseline characteristics of the transported patients were summarized using descriptive statistics. Continuous variables were expressed as medians with their 25th and 75th percentiles, whereas categorical variables were expressed as number and percentage of cases. Incidence of critical events (primary outcome) and the components of the critical events (clinical events and technical events: secondary outcome parameters) were statistically tested for non-inferiority.

Groups were compared on the other secondary outcomes under a common superiority hypothesis. All analyses were based on the intention-to-treat principle, whereas the primary outcome was additionally analyzed



on both as-treated and per-protocol basis. The as-treated analysis included the transported patients who initially were randomized to the nurses group but were switched to the nurses + physician group after a formal request for assistance by the nurses. Hence, in the as-treated analysis the switched patients were analysed according to the treatment they received whereas in the per-protocol approach they were omitted from the analysis (Fig. 1). Multiple critical events per patient were

analyzed as a single event as the patient was considered the unit of measurement in the sample size calculation. An additional sensitivity analysis was performed pooling all events as they occurred in each group to analyze the effects of multiple events per patient.

Statistical uncertainty of the between-group difference between the primary (critical events) and secondary outcome (clinical and technical events) proportions was expressed as two-sided 90 % confidence intervals

**Table 1** Baseline characteristics of the transported patients

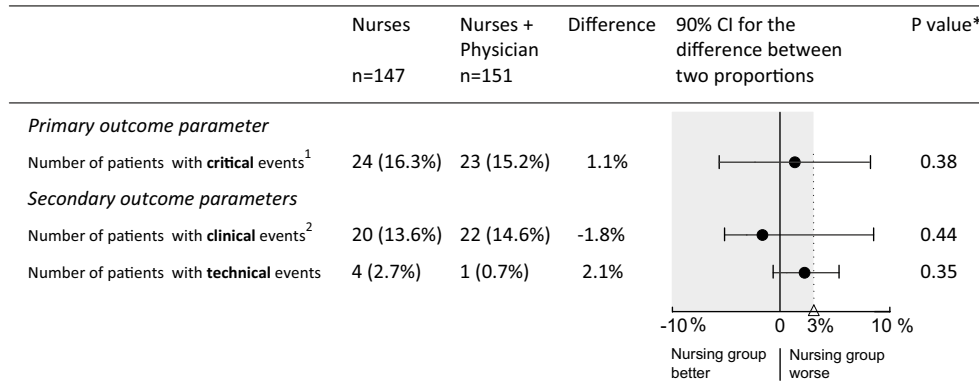
	Nurses group ( <i>n</i> = 147)	Nurses + physician group ( <i>n</i> = 151)
Age (years)	60 [46–74]	65 [52–74]
Women	62 (42 %)	66 (45 %)
APACHE II score in sending hospital	19 [14–24]	18 [14–23]
Length of stay in ICU before transport (days)	3 [1–66]	3 [1–41]
Patients		
<24 h in sending ICU	86 (59 %)	81 (54 %)
>24 h in sending ICU	61 (41 %)	70 (46 %)
Reason for admission		
Medical	81 (55 %)	90 (60 %)
Surgical	45 (31 %)	42 (28 %)
Neurological/neurosurgical	21 (14 %)	19 (12 %)
Indication for transport		
Lack of ICU beds	78 (53 %)	78 (52 %)
Expertise in referral center	56 (38 %)	61 (40 %)
Return to primary hospital	13 (9 %)	12 (8 %)
Interhospital transport distance (km)	30 [17–53]	30 [16–53]
Transport time (mins)	66 [55–81]	65 [50–85]
Transports ( <i>n</i> )		
≤40 km	90	97
>40 km	57	54
PaO <sub>2</sub> /FiO <sub>2</sub> ratio at inclusion (mmHg)	211 [150–286]	233 [158–301]
Inotropic/vasoactive medication ( <i>n</i> )		
Dopamine	32	37
Noradrenaline	78	70
Dobutamine	16	11
Nitroglycerine	12	11
Phosphodiesterase inhibitors	11	9
Others (i.e., alpha-adrenergic agonist, calcium channel blocker)	12	9
Mechanical ventilation modes ( <i>n</i> )		
Pressure controlled	99	102
Volume controlled	7	13
Assisted spontaneous breathing	41	36

Data are presented as median [25th–75th percentile] or *n* (%) unless indicated otherwise

(CIs). If the upper limit of the CI crosses the 3 % margin, non-inferiority of the nurse group is not established. We also applied one-sided significance testing using a method based on a Chi-square analysis [19]. A one-sided *p* value less than 0.05 indicates non-inferiority of the nurses group. With regard to the remaining secondary outcomes, between-group difference of the proportions was expressed as two-sided 95 % CIs and analyzed using the  $\chi^2$  test (two-sided *p* value less than 0.05 was considered statistically significant). Analyses were performed in SPSS (version 22.0) and R (version 3.2.1).

## Results

Patient assignment is shown in Fig. 1. Of a total of 618 eligible patients, 311 were excluded on the basis of exclusion criteria (*n* = 197), insufficient data at time of inclusion (*n* = 92, i.e., missing P/F ratio), or emergency transport (*n* = 22). Finally, 307 patients were randomized; 152 were allocated to the nurses group and 155 to the nurses + physician group. In the nurses group 147 patients could be analyzed versus 151 in the nurses + physician group because of nine transports cancelled after randomization.



**Fig. 2** Comparisons of primary (critical events) and secondary outcome parameters (clinical and technical events) by non-inferiority between nurses (intervention) and nurses + physician (control) group

The baseline characteristics of the randomized patients are summarized in Table 1. The groups were well matched. The median [25th–75th] APACHE II score in the sending hospital was 19 [14–24] in the nurses group versus 18 [14–23] in the nurses + physician group. Lack of an ICU bed as indication for transport occurred in 78 patients in both groups (53 % vs. 52 %). Median [25th–75th] transport distance was 30 km [17–53 vs. 16–53] and median [25th–75th] transport time was 66 min [55–81] vs. 65 min [50–85].

The primary outcome parameter is depicted in Fig. 2, indicating that non-inferiority of the nurses group was not established. The percentages of patients with critical events were 16.3 % (24 incidents in 147 patients) in the nurses group and 15.2 % (23 incidents in 151 patients) in the nurses + physician group (difference 1.1 %, 90 % CI [–5.9 to 8.1],  $p = 0.38$ ).

The percentages of patients with clinical events as secondary outcome parameter were 13.6 % (20/147 patients) in the nurses group and 14.6 % (22/151 patients) in the nurses + physician group (difference –1.0 %, 90 % CI [–5.2 to 8.7],  $p = 0.44$ ). Of note, there were no hemorrhages, arrhythmias, or deaths in both groups. The percentages of patients with technical events were 2.7 % (4/147 patients) in the nurses group and 0.7 % (1/151 patients) in the physician group (difference 2.1 %, 90 % CI [–0.7 to 5.3],  $p = 0.35$ ). In the nurses + physician group, five transports were identified with two critical events per patient.

In the nurse group 8.2 % (12 in 147 patients) of consultations for physician's assistance were requested and all occurred before the start of the transports in the unit of the sending hospital without any involvement of the sending ICU staff. All 12 consults were related to hemodynamic and/or respiratory instability beyond the perceived skills of the nurse in charge. Analyzing these

switched patients according to their actual received treatment revealed an incidence of critical events of 17.8 % (24 events in 135 patients) in the nurses group vs. 14.1 % (23 events in 163 patients) in the nurses + physician group (difference 3.7 %, 90 % CI [–3.3 to 10.9],  $p = 0.49$ ), also indicating absence of non-inferiority of the nurses group. This absence was also demonstrated in the per-protocol analysis, where the switchovers were omitted from the nurses group: 17.8 % (24 events in 135 patients) in the nurses group vs. 15.2 % (23 events in 151 patients) in the nurses + physician group (difference 2.6 %, 90 % CI [–4.7 to 9.9],  $p = 0.48$ ).

No between-group differences were observed concerning the other secondary outcomes parameter, although the nurses + physician group tended to give more fluid therapy in excess of 1000 ml during transport (Table 2). The sensitivity analysis of the primary outcome with pooled events per group, resulting in 28 critical events in the nurses + physician group, confirmed the absence of non-inferiority: percentages of critical events were 16.3 % (24 events in 147 patients) in the nurses group and 18.5 % (28 events in 151 patients) in the nurses + physician group (difference –2.2 %, 90 % CI [–9.5 to 5.1],  $p = 0.15$ ). The same applies to the as-treated (difference 0.6 %, 90 % CI [–6.6 to 8.04],  $p = 0.35$ ) and per-protocol analysis (difference –0.7 %, 90 % CI [–8.3 to 6.9],  $p = 0.25$ ).

## Discussion

The present trial failed to establish non-inferiority in interhospital ground critical care transports staffed by a dedicated team comprising a critical care nurse and paramedic compared to a dedicated team including a critical care physician as expressed by the number of critical events during transport.

Results of the intention-to-treat analysis were confirmed in the per-protocol, as-treated, and sensitivity



**Table 2 Comparisons of secondary outcome parameters between nurses (intervention) group and nurses + physician (control) group**

	Nurses group (n = 147)	Nurses + physician group (n = 151)	% difference* [95 % CI]	p*
Adjustments in ventilator settings				0.92
Zero adjustments	90 (61.2 %)	95 (62.9 %)	-1.7 [-12.6 to 9.3]	
1 adjustment	29 (19.7 %)	27 (17.9 %)	1.8 [-7.1 to 10.8]	
>1 adjustments	28 (19.0 %)	29 (19.2 %)	-0.2 [-9.2 to 8.9]	
Type of ventilator adjustments				
PEEP	14 (9.5 %)	15 (9.9 %)	-0.4 [-7.4 to 6.6]	1.00
FiO <sub>2</sub>	18 (12.2 %)	24 (15.9 %)	-3.7 [-11.7 to 4.4]	0.46
Pressure (Pmax or Psupport)	29 (19.7 %)	29 (19.2 %)	0.5 [-8.5 to 9.6]	1.00
Respiratory rate	30 (20.4 %)	22 (14.6 %)	5.8 [-2.8 to 14.6]	0.24
Adjustments in vasoactive medication				0.86
Zero adjustments	113 (76.9 %)	120 (79.5 %)	-2.6 [-12.1 to 6.8]	
1 adjustment	23 (15.6 %)	21 (13.9 %)	1.7 [-6.4 to 10.0]	
>1 adjustments	11 (7.5 %)	10 (6.6 %)	0.9 [-5.3 to 7.1]	
Adjustments in sedative medication				0.92
Zero adjustments	111 (75.5 %)	125 (82.8 %)	1.6 [-7.0 to 10.1]	
1 adjustment	19 (12.9 %)	21 (13.9 %)	-1.0 [-8.9 to 6.9]	
>1 adjustments	4 (2.7 %)	5 (3.3 %)	-0.6 [-5.2 to 3.9]	
Use of bolus medication	13 (8.8 %)	7 (4.6 %)	4.2 [-1.6 to 10.5]	0.22
Fluid therapy during transport				0.06
<500 ml	72 (49 %)	82 (54.3 %)	-5.3 [-16.5 to 6.0]	
500–1000 ml	67 (45.6 %)	52 (34.4 %)	11.2 [0.0 to 22.0]	
>1000 ml	8 (5.4 %)	17 (11.3 %)	-5.9 [-12.5 to 0.5]	

\* Between-group differences of the proportions were expressed as two-sided 95 % CIs and using the  $\chi^2$  test, two-sided  $p < 0.05$  was considered statistically significant

analyses. The risks associated with critical care transport, either between or within hospitals, have been widely recognized [15, 20–22]. In previous studies of interhospital transports with comparable cohorts of critical care patients, rates of critical events were high as 40–50 % if a regular ambulance transport system was used and were thought to be as low as 0–10 % with a dedicated critical care transport system [15, 16, 23–25].

Here, we found an overall critical events rate of about 16–17 %. In previous studies event rates were either based on self-reported events or on pre- and post-transport cardiovascular and respiratory point measurements from the written chart. The use of an electronic health record instead of self-reported critical events is conceivably more accurate compared to self-reporting events by the staff or pre- and post-transport point measurements only. Those undetected or unreported deteriorations during transport are not taken into account in previous studies which might explain our higher than expected critical event rate [11, 16, 17, 26, 27]. Our composite primary endpoint was the combination of both clinical (14 % in the nurses vs 17 % in the nurses + physician

group) and technical events (3 % vs 2 %). The latter is self-reported and is indeed comparable to previous studies. An alternative explanation for the high event rates in the transported patients might be the absence of a validated checklist for the pretransport stabilization period [10, 28]. However, no studies have evaluated the effect of a pretransport checklist on safety in interhospital transports, either nurses- or physician-led [15, 28, 29]. In our study the staff in both groups was trained and experienced in interhospital transport including pretransport stabilization. In line with this, there were 12 requests for physician's assistance in the nurses group prior to transport. These requests were based on the nurses' opinion that the complexity and/or instability of these patients exceeded the professional limits of critical care nursing and indicative for their careful pretransport evaluation [30–32].

Undoubtedly our trial turned out to be too small to unequivocally establish non-inferiority of nurses-staffed transport because of this higher than expected critical events rate in the transported patients. At the same time, in order to tailor staffing to individual patient needs while avoiding

overstaffing, future research should focus on definitions and factors influencing hemodynamic and respiratory stability prior to transport and subsequent transport-related observed outcome [10, 15, 29, 33]. The additional role of telemedicine or validated pretransport scoring systems to indicate physician attendance in limited cases of transport should be part of this research [34, 35].

In the PROBE design of our trial the electronic medical record during IC-transport enabled blinded assessment of outcome parameters and is indubitably more accurate in documenting clinical deteriorations otherwise undetected or unreported. The applicability of our results might depend on regional differences in critical transport programs including the level of critical care nursing. The level of their education, additional transport programs, and professional performance including self-reliance guided by nurse-driven protocols undoubtedly influence their critical events rates. Nevertheless, our trial suffers from several limitations. Firstly, the surrogate endpoint critical events in this study might not necessarily reflect clinical relevant outcome [27]. The relationship between critical event rates during transport and multifactorial determined morbidity or mortality in critical care medicine has not been established yet. Definitions of critical events used in this trial reflect expert opinion on what might be harmful for a transported critically ill patient.

The resolution of a critical event during transport might better reflect competence of the escorting team rather than the incidence of events. But to our knowledge there is no validated and standardized way to score the quality of the team's response to an event. It is conceivable that this competence is already partially measured by the absence of critical events because many events are either preventable (i.e., technical by proper use of a device's checklist) or treatable (i.e., clinical by anticipating a fall in blood pressure before it exceeds the clinical event definition's limit of 10 min). Secondly, for safety reasons the most severe critically ill patients were excluded and the critical care physician, although not participating actively, was present and might have affected nurses' behavior. Nevertheless, scores of severity of illness in our trial were still high in both groups and comparable to other studies [7, 11, 20, 23]. Thirdly, the study was limited to patients admitted to the ICU and excluded emergency transports for immediate advanced care (e.g., from peripheral hospital emergency rooms to a tertiary cardiac catheterization laboratory). The response time of a regional specialized retrieval team is usually longer compared to emergency medical services, which excludes its availability in emergency transports if immediate advanced treatment is warranted.

In conclusion, the number of patients with critical events during ground critical care transport staffed by a critical care nurse and paramedic does not markedly differ from a team including a critical care physician. However, non-inferiority of nurse-led interhospital critical care transport could not be established. A definitive answer on the appropriate patient selection and team composition might arise from larger multicenter trials or meta-analysis. Until then, the results might not change the present policy of physicians escorting critical care transports in Western Europe and could fuel the discussion on critical care paramedics in the USA [36].

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#### Compliance with ethical standards

#### Ethical approval and informed consent

Approval was obtained from the local medical ethics committee that waived the need for informed consent according to the Dutch Act on Research Involving Human Subjects.

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#### Conflicts of interest

All authors have no potential conflicts of interest to disclose.

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