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# Anaesthesiologica

# Pre-hospital emergency anaesthesia in trauma patients treated by anaesthesiologist and nurse anaesthetist staffed critical care teams

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Funding information None declared. Background: Pre-hospital tracheal intubation in trauma patients has recently been guestioned. However, not only the trauma and patient characteristics but also airway provider competence differ between systems making simplified statements difficult. Method: The study is a subgroup analysis of trauma patients included in the PHAST study. PHAST was a prospective, observational, multicentre study on pre-hospital advanced airway management by anaesthesiologist and nurse anaesthetist manned pre-hospital critical care teams in the Nordic countries May 2015-November 2016. Endpoints include intubation success rate, complication rate (airway-related complication according to Utstein Airway Template by Sollid et al), scene time (time from arrival of the critical care team to departure of the patient) and pre-hospital mortality. Result: The critical care teams intubated 385 trauma patients, of which 65 were in shock (SBP <90 mm Hg), during the study. Of the trauma patients, 93% suffered from blunt trauma, the mean GCS was 6 and 75% were intubated by an experienced provider who had performed >2500 tracheal intubations. The pre-hospital tracheal intubation overall success rate was 98.6% and the complication rate was 13.6%, with no difference between patients with or without shock. The mean scene time was significantly shorter in trauma patients with shock (21.4 min) compared to without shock (21.4 vs 25.1 min). Following pre-hospital tracheal intubation, 97% of trauma patients without shock and 91% of the patients in shock with measurable blood pressure were alive upon arrival to the ED.

**Conclusion:** Pre-hospital tracheal intubation success and complication rates in trauma patients were comparable with in-hospital rates in a system with very experienced airway providers. Whether the short scene times contributed to a low pre-hospital mortality needs further investigation in future studies.

#### KEYWORDS

airway management, emergency medical services, intubation

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#### 1 | INTRODUCTION

Trauma is a leading cause of premature mortality.<sup>1</sup> While pre-hospital trauma care has developed rapidly in the past decades, pre-hospital emergency anaesthesia remains controversial. There is substantial heterogeneity with regards to operating procedures of emergency medical services and the competencies of providers.<sup>2-4</sup> What interventions should be performed in the pre-hospital setting, and who should perform them is widely debated.<sup>5-7</sup> Minimizing the time from injury to definitive care is uncontroversial and is associated with decreased mortality and morbidity.<sup>8</sup> Airway compromise in severely injured patients is frequent and is a significant cause of poor outcome. Pre-hospital emergency anaesthesia and tracheal intubation (PHEA) is a critical but high-risk intervention with potential serious adverse events including hypoxia, hypotension, tracheal aspiration as well as difficult or unsuccessful intubation.<sup>9</sup> Recently, the benefit of pre-hospital emergency anaesthesia (PHEA) in trauma patients in haemorrhagic shock was disputed.<sup>10</sup> PHEA has been documented to increase in-hospital mortality in awake, hypotensive trauma patients and a delay of induction of anaesthesia until hospital arrival was proposed for that subset of patients.<sup>11</sup> Differences in airway provider competence may affect the performance and outcomes of the advanced airway management.<sup>12</sup> In the Nordic countries, with few exceptions, PHEA is performed by experienced anaesthesiologists. The objective of the present study is to describe PHEA outcomes in trauma patients with and without shock. Outcomes include intubation success rates, complication rates, scene time and pre-hospital mortality.

## 2 | METHODS

#### 2.1 | Context

In many regions in the Nordic countries, the emergency medical services are reinforced by rapid response car- and helicopter-based critical care teams.<sup>2</sup> Anesthesiologists staff the vast majority of these higher tier units. In the Nordic countries, anaesthesiologists are board certified in both anaesthesiology and intensive care medicine. Pre-hospital anaesthesiologists commonly rotate between pre-hospital duties and in-hospital theatre and intensive care work. These advanced pre-hospital providers routinely perform rapid sequence induction before tracheal intubation. This study encompasses pre-hospital critical care teams in both rural and urban areas, covering populations of more than 7 million inhabitants.

## 2.2 | Data collection

This study is a subgroup analysis of trauma patients included in the Nordic PHAST (*Pre-hospital advanced airway management by anaesthetists and nurse anaesthetists critical care teams*) study.<sup>13</sup> PHAST was a prospective, observational, multicentre study on pre-hospital

#### **Editorial Comment**

For management of the severely injured at the accident scene, there is always a decision point to either administer advanced treatment at the site, which can take time to optimize, or rapidly transport the severely injured to the nearest advanced hospital. This study shows that prehospital emergency anaesthesia and airway management can be performed with very high success rates if done by experienced providers.

advanced airway management that included all patients who underwent attempted pre-hospital tracheal intubation between May 2015 and November 2016. Participating critical care units were six helicopter emergency medical services and six rapid response car units. Eight of 12 participating units were staffed by anaesthesiologists and four units were staffed by nurse anaesthetists. The caseload was varied and pre-hospital teams were dispatched to trauma as well as medical emergencies. All the services provided rapid sequence induction and carried anaesthetic agents, analgesics and neuromuscular blocking agents. The pre-hospital critical care units have equipment to facilitate advanced airway management including supraglottic airway devices, conventional laryngoscopes, video laryngoscopy (with the exception of Trondheim HEMS and Stavanger HEMS), bougies, surgical airway equipment and capnographs. The airway provider registered the study data in a case report form after each mission and data were later transferred to a database.

#### 2.3 | Endpoints and definitions

Tracheal intubation in trauma patients is described with focus on intubation success rate and airway complications as well as scene time and pre-hospital mortality. A tracheal intubation attempt was defined as laryngoscopy with the intent to intubate. Successful tracheal intubation was confirmed with lung auscultation and/or capnography. Tracheal intubation complications were defined in accordance with Sollid et al as dental trauma, vomiting, aspiration of gastric contents or blood, intubation of the oesophagus or right main stem bronchus, oxygen saturation <90%, systolic blood pressure (SBP) <90 mm Hg and pulse <60 beats/min.<sup>14</sup> Shock was defined as a systolic blood pressure <90 mm Hg. Scene time was defined as the time from the arrival of the critical care team on scene until the departure of the response vehicle carrying the patient.

#### 2.4 | Statistical analysis

Baseline characteristics were described as means and standard deviations for continuous variables and number and percentages for categorical variables. The association between shock (the exposure)

and scene time (the outcome) was analysed using linear regression. The difference in mean scene time in patients with shock compared to no shock was reported with 95% confidence intervals with and without multivariable adjustment. Linear regression was used to identify variables associated with scene time that might confound the association between shock and scene time. A P value of <.1 was chosen as a threshold for inclusion in the multivariable analysis. Variables eligible for inclusion were age, sex, estimated weight, intoxication, aggravated conditions; darkness, aggravated conditions; hostile environment, traumatic brain injury and provider total number of intubations (Table 1). Age and estimated weight were used as continuous variables, number of tracheal intubations as a categorical variable and the other variables were used as dichotomous variables. After selection, estimated weight and number of tracheal intubations were included in the final model. There was a nonlinear association between estimated weight and scene time and estimated weight was flexible modelled using restricted cubic splines with 3 knots. Variables from Table 1, not eligible for inclusion were those regarded as part of a causal pathway either to be causing

shock or to be secondary to shock: National Advisory Committee on Aeronautics' (NACA) severity score, multitrauma, blunt trauma, burns, penetrating trauma, cardiac arrest, seizure, intoxication, strangulation and first vital sign; Glascow Coma Scale, first vital sign; respiratory rate, first vital sign; oxygen saturation, first vital sign; and systolic blood pressure. Some data were missing in the dataset. The frequency of missing values in the variables was: total number of intubations 0.7%, age 12%, sex 2.0%, estimated weight 3.4%, NACA 20%, Glascow Coma Scale 1.0%, oxygen saturation 6.8%, respiratory rate 12%, heart rate 0.7% and number of endotracheal intubation attempts 0.3%. Data management and statistical analysis were performed using Stata version 15 (StataCorp).

### 2.5 | Ethics

The study is a pre-specified subgroup analysis of the PHAST study with Ethical Review Board approvals obtained from Sweden (2015/411-31, 2015/1519-32), Denmark (Danish Data Protection

TABLE 1Patient, environment andprovider characteristics of the studypopulation in relation to no shock andshock

	All patients (n = 294)	Trauma, no shock (n = 229)	Trauma, shock (n = 65)			
Airway provider intubation experience						
200-2500 tracheal intubations	75 (26%)	49 (22%)	26 (41%)			
2500-10 000 tracheal intubations	200 (69%)	165 (72%)	35 (55%)			
>10 000 tracheal intubations	17 (5.8%)	14 (6.1%)	3 (4.7%)			
Patient age, years, mean (SD)	45.4 (22.7)	45.6 (22.7)	44.8 (23.0)			
Male sex, n (%)	212 (73.6%)	163 (72.1%)	49 (79.0%)			
Estimated weight, kg, mean (SD)	77.8 (18.4)	78.2 (18.3)	76.5 (18.5)			
NACA, mean (SD)	5.1 (0.5)	5.0 (0.5)	5.6 (0.6)			
Blunt trauma	274 (93.2%)	219 (95.6%)	55 (84.6%)			
Traumatic brain injury, n (%)	182 (61.9%)	161 (70.3%)	21 (32.3%)			
Multi trauma, n (%)	107 (36.4%)	74 (32.3%)	33 (50.8%)			
Other blunt trauma, n (%)	29 (9.9%)	15 (6.6%)	14 (21.5%)			
Burns, n (%)	7 (2.4%)	4 (1.7%)	3 (4.6%)			
Penetrating trauma, n (%)	22 (7.5%)	10 (4.4%)	12 (18.5%)			
Gun shot	8 (2.7%)	4 (1.7%)	4 (6.2%)			
Knife	11 (3.7%)	4 (1.7%)	7 (10.8%)			
Other penetrating	3 (1.0%)	2 (0.9%)	1 (1.5%)			
Cardiac arrest, n (%)	14 (4.8%)	2 (0.9%)	12 (18.5%)			
First vital sign; GCS, mean (SD) <sup>a</sup>	6 (3.2)	6 (3.2)	4 (2.5)			
First systolic blood pressure, mean (SD) <sup>a</sup>						
Unmeasurable	42 (14.3%)	0 (0.0%)	42 (64.6%)			
≤89 mm Hg	23 (7.8%)	0 (0.0%)	23 (35.4%)			
≥90 mm Hg	229 (77.9%)	229 (100.0%)	0 (0.0%)			
First saturation >90% <sup>a</sup>	187 (68.2%)	178 (80.9%)	9 (16.7%)			

Abbreviations: EMS, emergency medical services; GCS, Glasgow coma scale; NACA, National Advisory Committee on Aeronautics' severity score; SD, standard deviation. <sup>a</sup>All first vital signs are measurements before induction of anaesthesia. Anaesthesiologica

Agency no. 20087-58-0035, 15/16531 and the Danish Health and Medicine Authority no. 3-3013-941/ 1/) and Norway (2015/545/ REK vest). In Finland, the PHAST study did not deviate from normal practice or documentation and consequently did not require Ethical Review Board approval.

# 3 | RESULTS

Among the 2028 patients who underwent attempted pre-hospital tracheal intubation in the PHAST study, 385 were trauma patients (Figure 1). Records that had missing information on systolic blood pressure (n = 66), missing information on scene time (n = 17) and



FIGURE 1 Flowchart describing study inclusion and exclusion

those who were trapped on scene (n = 5) were excluded. One patient was regarded as an outlier and possibly incorrectly registered with a scene time of 330 min. Two patients had a scene time of 0 min, these were regarded as incorrect values and were excluded. After exclusion, we identified 294 trauma patients who underwent attempted pre-hospital tracheal intubation.

The mean patient age was 45 years and 74% were male (Table 1). The mean NACA score was 5.1. Of the trauma patients, 7.5% suffered from penetrating trauma and 93% from blunt trauma. Traumatic brain injury (TBI) was present in 62% of the trauma patients. The mean GCS was 6. Of the trauma patients, 78% (229/294) were not in shock and 22% (65/294) were in shock with systolic blood pressure below 90 mm Hg. Saturation >90% was present in 81% of the trauma patients without shock and 17% of the trauma patients in shock. Seventy-five per cent of patients were intubated by an experienced provider who had performed >2500 tracheal intubations.

#### 3.1 | Tracheal intubation outcomes

The overall success rate of pre-hospital tracheal intubation was 98.6% (290/294) with a first pass success rate of 88.4% (Table 2). There was no difference in tracheal intubation overall success rate in patients with shock vs no shock (100% vs 98%; P = .28).

Tracheal intubation complications were registered in 13.6% of the patients, with no difference between patients with shock and without shock (12% vs 14%; P = .73). The reported complications are presented in Table 3. Pre-intubation checklists were less frequently used in patients in shock compared to in patients without shock (15% vs 63%; P < .01).

Following attempted pre-hospital tracheal intubation, 97% of the trauma patients not in shock were alive at the arrival to the emergency department (ED). Of the trauma patients in shock (SBP <90 mm Hg) with measurable blood pressure, 91% were alive at the arrival to ED (Table 4).

who have undergone attempted pre- hospital tracheal intubation during a
hospital tracheal intubation during a
primary mission in relation to no shock
and shock

	Trauma, no shock (n = 229)	Trauma, shock (n = 65)	P value
Successful intubation, n (%)	225 (98%)	65 (100%)	0.28 <sup>a</sup>
Number of attempts, n (%)			
1	208 (91%)	52 (80%)	0.017 <sup>a</sup>
2	15 (6.6%)	13 (20%)	
3	3 (1.3%)	0 (0.0%)	
4	2 (0.9%)	0 (0.0%)	
5	1 (0.4%)	0 (0.0%)	
Intubation complication <sup>a</sup>	32 (14%)	8 (12%)	0.73 <sup>b</sup>
Use of checklist, n (%)	141 (63%)	9 (15%)	<0.001 <sup>b</sup>

<sup>a</sup>Intubation complication was defined as surgical airway, oesophageal intubation, bronchus intubation, cardiac arrest, hypoxia, bradycardia, hypotension, aspiration, dental trauma or other complication.

<sup>b</sup>Pearson's chi-squared.

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TABLE 3 Complications among trauma patients who underwent attempted pre-hospital tracheal intubation during a primary mission in relation to no shock and shock

			Candinavica	
	All patients (n = 294)	Trauma, no shock (n = 229)	Trauma, shock (n = 65)	
Surgical airway, n (%)	2 (0.7%)	2 (0.9%)	0 (0.0%)	
Oesophageal intubation, n (%)	3 (1.0%)	3 (1.3%)	0 (0.0%)	
Bronchus intubation, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Post-intubation cardiac arrest, n (%)	2 (0.7%)	0 (0.0%)	2 (3.1%)	
Hypoxia (SpO2 <90%), n (%)	14 (4.8%)	13 (5.7%)	1 (1.5%)	
Bradycardia (heart rate <60 beats/min), n (%)	2 (0.7%)	1 (0.4%)	1 (1.5%)	
Hypotension (Systolic blood pressure <90), n (%)	17 (5.8%)	13 (5.7%)	4 (6.2%)	
Aspiration, n (%)	4 (1.4%)	4 (1.7%)	0 (0.0%)	
Dental trauma, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	

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TABLE 4 Survival outcomes in the study population according to no shock and shock after exclusion of patients with cardiac arrest or unmeasurable blood pressure (n = 45) at arrival to trauma scene

Label	No shock	Shock with measurable SBP < 90
Total, n (%)	228 (100)	21 (100)
Alive at ED, n (%)	222 (97)	19 (91) <sup>a</sup>
Ongoing CPR at arrival to ED, n (%)	2 (0.9)	1 (4.8)
Pre-hospital death, n (%)	2 (0.9)	0 (0.0)
Missing, n (%)	2 (0.9)	1(4.8)

*Note*: Abbreviations: CPR, cardiopulmonary resuscitation; ED, emergency department; SBP, systolic blood pressure.

<sup>a</sup>P value .10 (Pearson's chi-squared). Further testing on the outcomes in this table is not meaningful due to few patients in each category.

#### 3.2 | Scene time

Scene times and distribution of values according to shock or no shock are presented in Figure 2. The mean scene time for all trauma patients undergoing pre-hospital tracheal intubation was 24.3 min (standard deviation [SD] 11.1). The mean scene time for patients with shock was 21.4 min (SD 11.0) compared to 25.1 min (SD 11.1) in patients in no shock resulting in a mean difference of -3.7 min (95% CI -6.74 to -0.63). In the multivariable analysis, after adjustment for estimated weight and provider total number of tracheal intubations, the mean difference was -4.02 min (95% CI -7.13 to -0.92) in patients in shock compared to patients in no shock.

### 4 | DISCUSSION

This study documents successful pre-hospital tracheal intubation among trauma patients by experienced pre-hospital anaesthesiologists and nurse anaesthetists. Furthermore, the study documents short scene times following pre-hospital tracheal intubation, with even shorter scene times for patients in shock.



**FIGURE 2** Box and dot plots describing scene time in patients according to shock. Dot plots: Each dot represents a patient distributed according to scene time. Boxplots: The median is represented by the central line inside the box. Upper and lower quartiles are shown at the ends of the boxes. Whiskers show 5th and 95th percentiles

The 98.6% overall tracheal intubation success rate was comparable to previously published studies from physician-staffed prehospital critical care units.<sup>12,15,16</sup> The overall intubation success rate in the trauma subgroup was also similar to the 98.7% intubation success rate in entire mixed patient PHAST cohort.<sup>13</sup> Ninety-eight per cent of the trauma patients were intubated within 2 attempts. The first pass success rate of 88.4% was somewhat higher than in a previously published international prospective multicentre study.<sup>15</sup> Despite the high overall success rate in the study population, we found a significantly lower first attempt success rate in patients in shock, although all patients in this group were intubated within 2 attempts. A number of environmental factors such as impaired patient access, suboptimal patient and provider positioning, limited equipment as well as difficult or hazardous operating environment can challenge the pre-hospital tracheal intubation and influence success rates.<sup>17-19</sup> Tracheal intubation during ongoing resuscitation efforts can pose an even greater challenge as there may be less opportunity to prepare and optimize for advanced airway management. In these situations, there may also be competing priorities that could contribute to the lower first pass success rate in shocked patients.

To ensure uniform data, tracheal intubation complications were defined in accordance to a consensus-based template.<sup>14</sup> The complication rate of 13.6% is comparable to previously published results of a prospective, international multicentre helicopter emergency medical service (HEMS) trial (13%) as well as a prospective, national multicentre study of anaesthesiologist staffed pre-hospital critical care teams in Denmark (14.1%).<sup>15,20</sup>

In the present study, we demonstrate a relatively short scene time for the whole study population of 24 min (SD 11.1). The scene time is by indirect comparison shorter than previously reported scene times for physician-staffed pre-hospital critical care teams in United Kingdom (40 min) and Hungary (49 min).<sup>21,22</sup> Reasons for the shorter scene times are unclear but may partly be explained by differences in patient characteristics as well as provider competence. In the Nordic countries, only anaesthesiologists, senior anaesthesiology registrars and experienced nurse anaesthetists perform unsupervised pre-hospital emergency anaesthesia and tracheal intubations. Physician-staffed pre-hospital critical care teams are mainly staffed by anaesthesiologists. Our data suggest that the pre-hospital care providers were experienced in advanced airway management, since 75% of the providers reported a total number of intubations of >2500. Furthermore, some aspects of present pre-hospital practice in the Nordic countries such as less devotion to 360° patient access, not restricting primary tracheal intubation manoeuvre to over-bougie as well as short challengeresponse checklists, may promote shorter on scene times, without compromising safety and affecting the high tracheal intubation success rates in severely injured patients.<sup>13</sup> Interestingly, patients in shock have significantly shorter mean scene times than patients who were not in shock (21.4 vs 25.1 min). The patients in the shock group seem to have more deranged physiology parameters and higher NACA score. The shorter scene time for this subset of patients may partly be explained by the physician-led pre-hospital critical care team recognizing the critical condition of the patients and expediting the scene management with greater urgency. The variable of physician-led pre-hospital critical care team's patient assessment of injury severity and its relation to the rapidity with which they provide care and expedite scene time are difficult to quantify but may have a substantial influence on scene times and which interventions are deemed necessary in patients with timecritical conditions. Of interest, the use of pre-intubation checklists was substantially lower in trauma patients in shock compared to those without shock (15% vs 63%). This may favour shorter scene times, although it is unlikely to be solely due to omitting checklist reading. Shorter scene times for patients where pre-intubation checklists were not used have previously been reported in another subgroup analysis.<sup>23</sup>

Globally, trauma systems and emergency medical services have been designed to minimize time from injury to definitive care at hospital.<sup>24</sup> In the context of the Nordic countries, physician-based prehospital critical care teams are expected to safely perform advanced pre-hospital interventions, including tracheal intubation, without unnecessarily delaying definitive care. As response time and transport time are mostly determined by the distance to scene and from scene to hospital as well as by the means of transport, and further decrements of these time intervals may be difficult, the scene time is of special interest since it depends on the performance and competence of the pre-hospital care provider. However, evidence for the relationship between pre-hospital time and its impact on outcome for trauma patients is conflicting. The impact of pre-hospital time intervals on outcome has not been consistently demonstrated, potentially secondary to heterogeneous populations and difference in context and conditions.<sup>25-30</sup> A review article from 2015 concluded that although shorter response time and transport time might favour positive outcome for the undifferentiated trauma patient, a shorter scene time did not. In fact, the authors stated that there seemed to be an association between longer scene time and decreased mortality.<sup>30</sup> In contrast, McCoy et al observed increased odds of mortality among patients with penetrating injury with scene times exceeding 20 min. However, they did not observe the same association in patients with blunt trauma, even in patients with injury severity score >15.27 Brown et al showed that prolonged scene time relative to other pre-hospital time intervals was associated with increased mortality. In the study, extrication and pre-hospital tracheal intubation were found to mediate the effect of prolonged scene time on mortality but the authors elegantly show that increased proficiency and competence of the emergency medical service provider seemed to attenuate the effect.<sup>31</sup> Several studies show, unsurprisingly, that pre-hospital tracheal intubation prolongs scene times.<sup>32,33</sup> When performed by experienced pre-hospital critical care teams trained in advanced airway management and in specific patient categories, the benefits may outweigh the detrimental effects of prolonged scene times.<sup>31,34,35</sup> Minutes spent on intubation in the pre-hospital setting may even reduce time in the emergency department.<sup>36</sup> Even though the optimal scene time has not been defined for the severely injured and the evidence is conflicting of which patients

will benefit from short scene time, the need for definitive care at a trauma centre is obvious. Thus, the proper approach is presumably to strive for short scene time in all severely injured patients. This may be particularly important in the context of hypovolemic shock and penetrating injuries. For the pre-hospitally intubated patients in shock (SBP <90 mm Hg), the survival to hospital was 91% after excluding patients with unmeasurable blood pressure, which may be contributed to the short scene times demonstrated in present study. The relatively low level of evidence of the existing literature highlights the need for well-designed randomized studies to fully address whether or not trauma patients in hypovolemic shock should be intubated in the pre-hospital setting. Furthermore, external validity is very important for future studies to be performed in the prehospital context to which the conclusion is to refer.

## 5 | LIMITATIONS

The study has several limitations and should be interpreted with caution. The study is a subgroup analysis with its inherent limitations. While anonymous, the self-reporting nature of the PHAST database by the clinicians poses a risk of registration or recall bias. Furthermore, there is a risk of underreporting of adverse events or complications. For some variables, the data sample is small. The exclusion of 66 patients due to missing information on systolic blood pressure and 17 patients where information on scene was not recorded can skew the results. The results may not be generalizable for emergency medical services in which providers have less airway expertise. The dataset focuses on advanced airway management and does not account for other procedures that may impact scene time and survival.

#### 6 | CONCLUSION

Following pre-hospital tracheal intubation in trauma patients by anaesthesiologist and nurse anaesthetist manned pre-hospital critical care teams, the success and complication rate was comparable with in-hospital rates. The overall scene times were short, and even shorter among patients with shock. This may contribute to the low pre-hospital mortality rate observed in trauma patients in shock with measurable SBP <90 mm Hg. However, future well-designed studies are needed to investigate this hypothesis.

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#### CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

#### AUTHORS CONTRIBUTIONS

MGe conceived and initiated the study. BA, DH and MGe contributed to the design of the study. BA, DH and MGe gathered and structured the dataset and performed the analysis. BA drafted the manuscript. MGe, DH, DK and MGu critically revised the manuscript and approved the manuscript to be submitted. BA affirms that the manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted.

#### ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study is a pre-specified subgroup analysis of the PHAST study with Ethical Review Board approvals obtained from Sweden (2015/411-31, 2015/1519-32), Denmark (Danish Data Protection Agency no. 20087-58-0035, 15/16531 and the Danish Health and Medicine Authority no. 3-3013-941/ 1/) and Norway (2015/545/ REK vest). In Finland, the PHAST study did not deviate from normal practice or documentation and consequently did not require Ethical Review Board approval.

#### CONSENT FOR PUBLICATION

Not applicable.

#### DATA AVAILABILITY STATEMENT

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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