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# **PREHOSPITAL ADVANCED AIRWAY MANAGEMENT IN THE NORDIC COUNTRIES**

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# PREHOSPITAL ADVANCED AIRWAY MANAGEMENT IN THE NORDIC COUNTRIES THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

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“Under pressure, you don't rise to the occasion, you sink to the level of your training”

- Archilochus

To Sofie, Carl and Eva



## ABSTRACT

Tracheal intubation (TI) is often the preferred technique to secure the airway of an unconscious patient in the prehospital setting. Prehospital TI is associated with several challenges, including limited assistance, few airway rescue devices and environmental difficulties. An example of the latter is the occasional need for TI inside the cabin of an ambulance helicopter. The Nordic countries consist of both rural and urban areas with typically cold subarctic climate. The region is characterized by almost exclusive use of airway experts, mainly anaesthetists, for prehospital TI. The overall aim was to investigate prehospital advanced airway management in Nordic countries with regard to success rates, times, providers and techniques.

Study I: A retrospective observational study of all patients intubated out-of-hospital with the device Airtraq<sup>®</sup> in Stockholm 2008-2012. A total number of 2453 patients were intubated during the study period and Airtraq<sup>®</sup> was used in 28 (1.1%) cases. Sixty-eight percent (19/28) of the Airtraq<sup>®</sup> intubation attempts were successful. When used due to an anticipated or unexpected difficult airway, the success rate was 61% (14/23).

Study II: An experimental prospective randomized crossover manikin study on anaesthetist TI was conducted in a military helicopter cabin in daylight or darkness with night vision goggles (NVG) or in a daylight emergency department (ED) setting. The TI success rate was 100% in all scenarios. The in-cabin helicopter TI time was shorter in daylight vs. darkness with NVG (16.5 s vs. 30.0 s;  $p=0.03$ ). There was no difference in TI time between the helicopter cabin daylight and ED setting (16.5 vs. 16.8 s;  $p=0.91$ ). There was no difference in either glottic visualization (CL 2.0 vs. 1.8;  $p=0.72$ ) or perceived intubation difficulty (VAS 3.0 vs. 2.8;  $p=0.24$ ) between the daylight helicopter and ED scenarios.

Study III: A prospective observational study of advanced airway management by twelve second-tier prehospital critical care teams in the Nordic countries was conducted from May 2015 to November 2016. Data were collected from six ambulance helicopters and six rapid response cars using the standardized Utstein-style airway template. During the study period, 2028 patients were intubated due to cardiac arrest (53.0%), other medical conditions (26.3%) and trauma (19.1%). The majority (67.0%) of the TIs were performed by providers who had intubated >2500 patients. The overall TI success rate was 98.7%, with a first pass success rate of 84.5% and overall complication rate of 10.9%. The median TI time was 25 s (IQR 15-30 s), and the time on scene was 25 min (IQR 18-33 min). The TI success rate was higher among physicians compared with nurses (99.0% vs. 97.6%;  $p=0.03$ ).

Study IV: An experimental prospective randomized crossover manikin study of in-cabin vs. outside helicopter cabin TI was conducted by 14 anaesthetists. The success rate was 100%, with all TIs being successful on the first attempt. There was no difference in glottic visualization (CL 1.0 vs. 1.0), but the participants perceived the in-cabin TI to be easier than intubating outside the helicopter cabin (VAS 1 vs. VAS 2;  $p=0.02$ ). The total on-scene time

was significantly shorter using the in-cabin TI strategy compared with the standard outside TI (266 vs. 320 s;  $p=0.04$ ).

In conclusion, prehospital TI is almost exclusively performed by very experienced airway providers in the Nordic countries. In this setting, the prehospital TI success rate is high and associated with few complications, comparable to in-hospital standards. The TI procedure is fast with a short on-scene time, which may benefit patients with time-critical emergencies, such as multitrauma and traumatic brain injuries. There may be potential to further decrease on-scene times with the in-cabin TI concept. The first-pass TI success rate was higher with video laryngoscopy compared with direct laryngoscopy, but the Airtraq<sup>®</sup> is not a suitable prehospital indirect laryngoscope. There is a need for large randomized studies to better investigate different aspects of the prehospital advanced airway management.



# LIST OF SCIENTIFIC PAPERS

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Gellerfors M, Larsson A, Svensén S, Gryth D.  
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Kornhall D, Gellerfors M, Näslund R, Lind F, Broms J, Helliksson F.  
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## LIST OF ABBREVIATIONS

CA	Cardiac arrest
CICO	Can't intubate can't oxygenate
CL	Cormack Lehane
COPD	Chronic obstructive pulmonary disease
ED	Emergency department
EMS	Emergency medical service
ERB	Ethical review board
HEMS	Helicopter emergency medical service
ICU	Intensive care unit
IQR	Interquartile range
NVG	Night vision goggles
NMBA	Neuromuscular blocking agent
OR	Odds ratio
SAD	Supraglottic airway device
SD	Standard deviation
RRC	Rapid response car
RSI	Rapid sequence induction
TI	Tracheal intubation
TBI	Traumatic brain injury
VAS	Visual analogue scale

# 1 INTRODUCTION

Some surgeons claim “The best prehospital fluid is gasoline”. Similar jokes have been made about prehospital advanced airway management. When trying to understand why an intervention that is well established in the emergency department (ED) is highly questioned in the prehospital setting, the literature provides several explanations. When the literature on prehospital advanced airway management is scrutinized, some interesting aspects unfold:

- The physiology of the patient is exactly the same whether he/she is roadside in a muddy ditch or in the intensive care unit of a university hospital.
- There is a substantial heterogeneity with regards to the advanced airway management competence, with highly limited provider experience in some countries.
- In general, the more times you have performed a procedure, the better and faster you become. This is true for anything from baking a cake to TI.
- It is probably beneficial with a short on-scene time for the patients with time-critical life-threatening conditions, like uncontrolled internal haemorrhage and traumatic brain injuries.

In the Nordic countries, prehospital TI is almost only performed by anaesthetists. Consequently, it is the same physicians performing the TI in the prehospital setting as in the intensive care unit. This is different from most emergency medical services (EMS) in the world. This thesis is an attempt to explore whether it is possible to achieve prehospital TI of in-hospital quality with regard to success rate, complications and speed. In addition, the potential for fast TI and shorter on-scene times through helicopter in-cabin TI is investigated.



## 2 BACKGROUND

### 2.1 ADVANCED AIRWAY MANAGEMENT

#### 2.1.1 Tracheal intubation

TI is a procedure when a tube is passed via the mouth or nose through the pharynx and through the vocal cords into the trachea. The tracheal tube is used to maintain the airway open, secure the airway from aspiration and support ventilation of the lungs. Direct TI is usually performed using a rigid laryngoscope inserted through the mouth. With the laryngoscope blade, the tongue and epiglottis are lifted out of the way, allowing direct visualization of the vocal cords such that a tracheal tube can be inserted into the trachea.

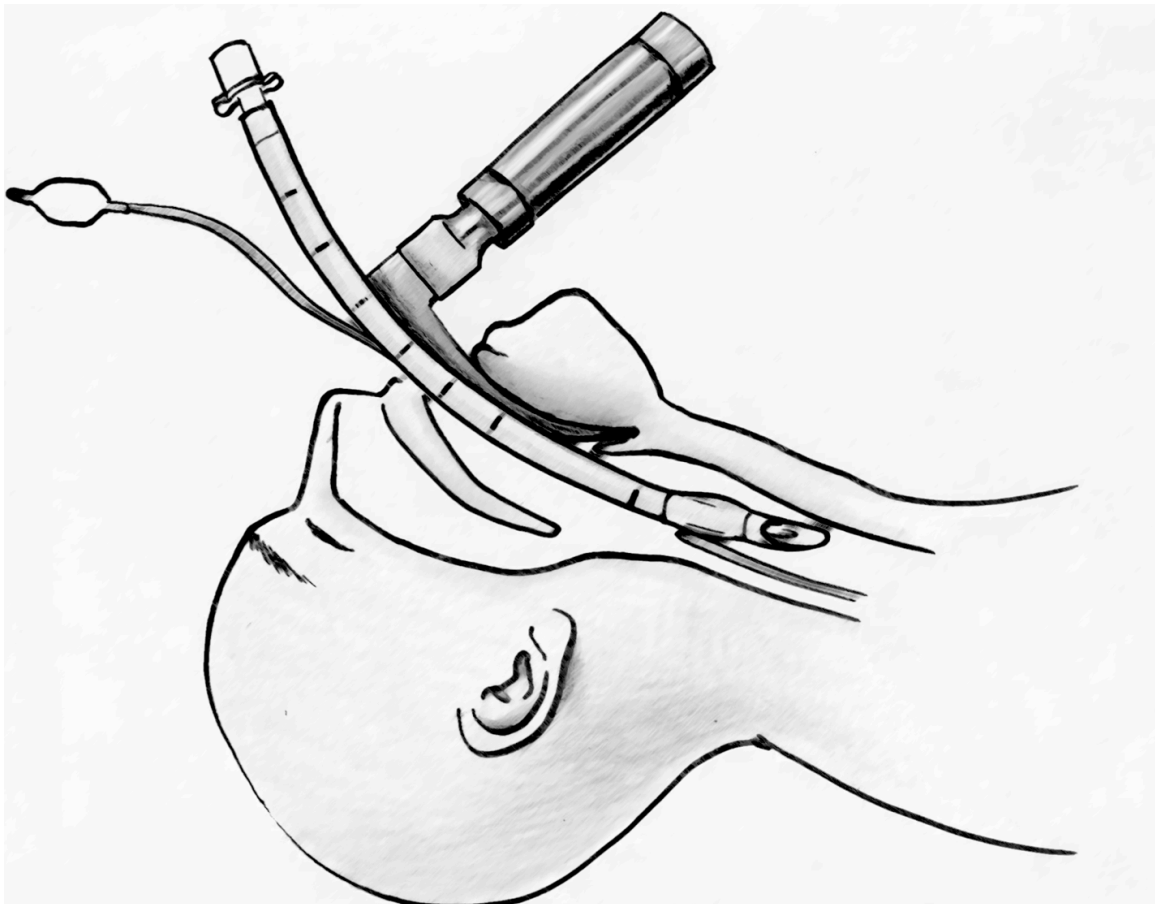


Fig 1. Tracheal intubation using direct laryngoscopy.

Even though major airway complications are rare, they remain a cause of morbidity and mortality in surgical<sup>1 2 3 4</sup> and emergency settings.<sup>5</sup> TI problems are the major causes of anaesthesia-related death and disability in the UK<sup>6</sup> and according to the American Society of Anesthesiologists Closed Claims Database.<sup>4</sup>

TI may be difficult when direct visualization of the larynx is not possible due to an anatomic variation, trauma or a pathologic process. Several classification methods have been proposed to identify patients at risk of difficult intubation.<sup>7 8</sup> Difficult TI may occur in patients with, among others, morbid obesity, short neck, mandibular shortening, limited mouth opening,

prominent teeth, anterior larynx and neck pathology including cervical spine fixation. The actual difficulties surrounding TI may be determined by grading the exposure of the vocal cords by conventional direct laryngoscopy.<sup>9</sup> In patients with difficult airways, complications are more frequent. However, since difficult airways are less common, most TI complications occur in patients with an easy airway. For example, most laryngeal injuries occur during an easy TI.<sup>2</sup>

Challenges with TI have stimulated the development of indirect laryngoscopes. A key feature of the video laryngoscopes is good glottic visualization without the need to align the oral and tracheal axis. Frequently used indirect laryngoscopes are the video laryngoscopes, for example, GlideScope<sup>®</sup>, C-Mac<sup>®</sup> and McGrath<sup>®</sup>. The Airtraq<sup>®</sup> is another type of indirect laryngoscope without the video function.

The ‘can’t intubate can’t oxygenate’ (CICO) rate is <1/5000 in routine general anaesthesia and causes 25% of anaesthesia-related deaths.<sup>10 11</sup> However, airway management and complication definitions must be considered when interpreting the complication rate.<sup>12</sup> Additionally, the clinical setting is important when assessing airway complications. For example, failed TI occurred in ≈1 per 1500 in the elective surgery setting,<sup>12 13</sup> ≈1/300 in the obstetric setting,<sup>14</sup> and ≈1/50–100 in the prehospital,<sup>15</sup> emergency department (ED),<sup>16</sup> and intensive care unit (ICU)<sup>17</sup> settings. The incidence of CICO requiring a surgical airway is 1/200 in the ED.<sup>18 19</sup>

## **2.2 PREHOSPITAL ADVANCED AIRWAY MANAGEMENT**

Prehospital advanced airway management consists of TI, supraglottic airway and surgical airway. An international expert group have recently designated prehospital advanced airway management one of the five most important research fields in physician-provided prehospital critical care.<sup>20</sup>

### **2.2.1 Advanced airway management in the prehospital setting**

Prehospital TI is a potentially lifesaving procedure.<sup>21</sup> TI is often the preferred technique by prehospital critical care teams to secure an airway, while supraglottic airway and surgical airway are considered rescue techniques.<sup>22</sup> However, prehospital TI carries a risk of complications that may threaten the patient safety.<sup>23 24 25</sup> The incidence of complications related to prehospital TI is not negligible even in physician-staffed systems, and it is important that the prehospital care provider can identify patients most likely to benefit from tracheal intubation.<sup>26 27 28 29</sup>

Advanced airway management in the prehospital setting is challenging for several reasons. The incidence of difficult airway is higher in the prehospital compared with the in-hospital setting.<sup>30</sup> The prehospital availability of alternative airway devices is often limited,<sup>31 32</sup> and advanced airway management often must be performed by inadequately trained staff.<sup>33</sup> In



addition, the provider may be positioned on the floor, inside a small confined space like a car wreck or ambulance helicopter cabin. Helicopter emergency medical service (HEMS) TI is usually performed before loading the patient into the helicopter. Although EMS personnel are trained in laryngoscopy, the complication rate is still high, and TI is associated with a high mortality rate.<sup>34 35 36</sup>

Several studies have shown that prehospital TI prolongs the on-scene time.<sup>37</sup> In a recently published study from the Norwegian HEMS prehospital TI prolonged the on-scene time by approximately 10 min.<sup>38</sup> Prolonged on-scene times may increase mortality among some, but not all, trauma patients.<sup>39</sup>



Fig 2. Advanced airway management in the cabin of an Airbus H145 ambulance helicopter.

### **2.2.2 Prehospital advanced airway management in the military setting**

The care of the wounded soldiers is a high priority for military units around the world with medical providers working close to combat lines. The ability to anaesthetize patients safely is a keystone in military prehospital critical care.<sup>40</sup> However, the medical providers are often faced with a difficult environment when working in a forward-deployed unit. The challenges include hostile gunfire, extreme temperature, exposure to the elements and physical isolation without immediate medical backup. In the civilian setting, TI is usually performed before loading the patient into the helicopter. Nevertheless, in-flight TI may occasionally be

required. In military settings, it can also be the only option because of the hostile environment on the ground. Should an in-flight TI be necessary, direct laryngoscopy is challenging due to lack of space, inadequate light or other aggravating circumstances.<sup>41 42</sup>



Fig 3. Tracheal intubation in the cabin of a UH-60M Black Hawk helicopter.

Many military operations are carried out during the night, when adherence to light discipline may be important to avoid detection.<sup>43 44</sup> Darkness presents severe limitations because patient assessment and treatment are highly dependent on visual cues. The best way of securing an airway in a light-restricted environment is not known. Digital intubation and surgical airway have been suggested, but there is limited evidence for these methods.<sup>45 46</sup> Night vision goggles (NVG) are commonly used to achieve vision during darkness. Only one trial has investigated NVG TI of a training manikin and one trial NVG TI in an operating room.<sup>47 48</sup> Both NVG TI trials used monocular NVGs. In the manikin study, the intubators were emergency physicians who were not used to NVGs. In the clinical trial, only two providers (one nurse anaesthetist and one emergency medicine physician) performed all NVG TI in an operating room.

The best TI method in a light-restricted environment is not known. Much of the increased difficulty with NVG TI appears to be due to the lack of depth perception, which might be minimized by the use of binocular NVG. However, no studies have been conducted to assess TI with binocular NVG. Additionally, there are no data on NVG TI by military trained anaesthetists in a tactical environment.

### 2.2.3 Prehospital personnel

In the literature, it is generally reported that prehospital airway management of physician-staffed units<sup>27 42 49 50 51 52 53</sup> seems to have a higher standard compared with that of paramedic-staffed units. The incidence of failed prehospital TI by physician-staffed critical care teams has been reported to be 1-2% by several authors, including a recently published meta-analysis by Crewdson et al.<sup>51 54</sup> In the meta-analysis, prehospital TI was attempted in 125 177 patients: 23 738 by physicians and 101 439 by non-physicians. The median reported TI success rate was 0.97 (range 0.62-1.00). Physicians had a higher TI success rate compared with non-physicians (0.99 vs. 0.92;  $p < 0.01$ ). Following rapid sequence induction (RSI), physicians also had a higher TI success rate compared with paramedics (0.99 vs. 0.94;  $p < 0.01$ ).

A large retrospective observational trial analysed trauma patients undergoing prehospital advanced airway management by physicians at London HEMS between 1991 and 2012.<sup>55</sup> Of 28 939 patients, 7256 (25.1%) needed advanced airway management. TI was successful in 7158 patients (99.3%). Seven patients had supraglottic airway devices (SAD), and rescue surgical airways were done in 42 patients. Non-anaesthetists performed 4394 TIs and failed the intubation in 41 cases (0.9%), whereas anaesthetists performed 2587 TIs and failed in eleven cases (0.4%;  $p = 0.02$ ).

### 2.2.4 Advanced airway equipment

Several surveys have revealed deficits in the availability of prehospital advanced airway management equipment in Europe.<sup>56 57 58</sup> As a result, prehospital treatment of emergency patients according to current guidelines might not be possible. Although protocols detail medical equipment that should be carried by EMS and HEMS in Europe, they are not sufficiently comprehensive to list every device and may not be up to date with the current guidelines in this field. Furthermore, different organizations run the EMS, predisposing them to variations in equipment and guidelines.

The TI problems have stimulated the development of SADs and indirect video laryngoscopes that do not require alignment of the oral, pharyngeal, and tracheal axis. In a prospective German HEMS study on 228 prehospital TIs, glottic visualization was significantly better with the C-MAC<sup>®</sup> PM video laryngoscope compared with direct laryngoscopes.<sup>59</sup> The GlideScope Ranger<sup>®</sup> video laryngoscope showed a 97% success rate in 315 patients undergoing prehospital TI.<sup>60</sup> Prehospital TI with the C-MAC<sup>®</sup> video laryngoscope and Frova introducer in a Finnish anaesthetist-staffed HEMS resulted in a high first-pass success rate of 98.2%.<sup>61</sup> In contrast, a recent meta-analysis of TI in critically ill patients did not show an increase in the first-pass success rate with video laryngoscopy.<sup>62</sup> Furthermore, a subgroup analysis of experienced providers revealed that video laryngoscopy decreased the first-pass success rate (RR 0.57;  $p < 0.01$ ) as well as the overall success rate (RR 0.58). A randomized prehospital trial demonstrated a significantly lower TI success rate with the GlideScope Ranger<sup>®</sup> video laryngoscope compared with conventional laryngoscopy (61.9% vs. 96.2%,

p<0.001).<sup>63</sup> In addition, in another randomized trial, the indirect laryngoscope Airtraq<sup>®</sup> showed a very low prehospital TI success rate of 47%.<sup>64</sup> In summary, according to two recent Cochrane reviews, the benefit of video laryngoscopy in adult and children TI is unclear.<sup>65 66</sup>

SADs have several advantages when TI is not possible.<sup>67</sup> SADs, especially the i-gel<sup>®</sup>, may shorten the time to ventilation in the case of an entrapped road accident victim.<sup>68</sup> There are several other SADs for prehospital use including the Combitube<sup>®</sup> and King LT<sup>®</sup> tube.<sup>69</sup> A cross-sectional survey among non-physician EMS providers in Northern Finland showed that SADs are widely available but rarely used.<sup>70</sup>

There are several devices for transtracheal high-pressure oxygen delivery including the Ventrain<sup>®</sup>, the Enk Oxygen Flow Modulator<sup>®</sup> and the Rapid-O2<sup>®</sup>.<sup>71</sup> However, according to a meta-analysis of 10 172 patients surgical cricothyrotomy had a higher success rate compared with needle cricothyrotomy (90.5% vs. 65.8%).<sup>72</sup> In addition the Difficult Airway Society recommend scalpel cricothyroidotomy as the sole technique for emergency front-of-neck access.<sup>73</sup>

### **2.2.5 Advanced airway drugs**

A recent Cochrane review confirmed that neuromuscular blocking agents (NMBA) provide good TI conditions.<sup>74</sup> In the hospital environment, it is standard to tracheal intubate a patient at risk of aspiration using RSI with a fast-acting NMBA, usually succinylcholine or rocuronium. As every patient in the prehospital setting must be considered at risk for aspiration, it has been argued that no lower standard should be applied. Furthermore, the prehospital TI success without relaxation is often poor.<sup>75</sup> Rognås and colleagues demonstrated that the incidence of difficult prehospital TI following RSI is considerably lower than in non-RSI cases.<sup>76</sup> In a survey from Central Europe, all ambulance helicopters carried succinylcholine. German ambulance helicopters have reported a similar availability of succinylcholine.<sup>77</sup>

### **2.2.6 Guidelines and training**

The Association of Anaesthetists of Great Britain and Ireland has early suggested a demand for guidelines on prehospital airway management.<sup>78</sup> A need for standardization of training and maintenance of critical skills has also been identified in other physician-manned prehospital systems.<sup>79</sup> The National Association of EMS Physicians have called for better training in airway management for prehospital personnel and a standardization of protocols.<sup>80</sup>

Several international guidelines on prehospital emergency anaesthesia now emphasize that prehospital advanced airway management should be performed with the same standards as in-hospital.<sup>81 82 83</sup> The prehospital providers should be able to perform unsupervised in-hospital emergency anaesthesia before conducting prehospital RSI.

### **2.2.7 Data reporting**

The number of published papers addressing prehospital airway management is substantial,

but the results have been difficult to interpret, both because of large variations in the EMS and HEMS systems and differences in data recording and reporting.

The development of an Utstein-style template for uniform reporting of data from prehospital advanced airway management studies has made it possible to compare data across EMS systems and between different professionals.<sup>84</sup> Several large prehospital advanced airway management studies have recently used the Utstein-style airway template.<sup>49 55 76</sup>

## **2.3 EMERGENCY MEDICAL SERVICES IN THE NORDIC COUNTRIES**

The Nordic countries are a mixed urban and rural area of approximately 1.369.000 km<sup>2</sup> with a population of 26.850.000 inhabitants. Thus, the overall population density (19.6 inhabitants/km<sup>2</sup>) is rather low. Many regions in the Nordic countries are mountainous wilderness areas with a subarctic climate. Snow and cold temperatures may force the prehospital provider to perform TI in the back of the road ambulances or inside the ambulance helicopter cabin. This prevents hypothermia of the patient, but it may affect the TI technique and success rate.

Although the EMS structure in Scandinavia is reasonably similar, there are some inter- and intra-national differences regarding staffing, the mission profile and systems for dispatch. Many Scandinavian regions utilize a two-tiered EMS system. The first tier consists of road ambulances staffed by a nurse with EMS training and a driver with basic emergency training. The second tier consists of prehospital critical care teams staffed with physicians, usually experienced anaesthetists.<sup>85 86</sup> In the Nordic countries, anaesthetists are specialized in both anaesthesiology and critical care. The vast majority of the prehospital anaesthetists work part-time in-hospital at an anaesthesiology and intensive care unit. They perform emergency anaesthesia and advanced airway management in the operating room, intensive care unit and emergency room as part of their daily work.

In a study of 16 Scandinavian anaesthetist-staffed prehospital services, there were 4236 alarm calls resulting in 2256 patient encounters, of which 23% had severely deranged vital functions.<sup>87</sup> The probability that the patient was physiologically deranged, received advanced drugs, or procedures was 34%. Medical aetiology was observed in 14.9 and trauma in 5.6 per 10 000 person-years. The authors concluded that the Scandinavian prehospital population incidence of critical illness and injury was 25–30/10 000 person-years (Denmark 74.9, Finland 14.6, Norway 11, and Sweden 5 missions per 10 000 person-years).

### **2.3.1 Prehospital tracheal intubation in the Nordic countries**

Prehospital TI by anaesthetists was investigated in a prospective Danish multicentre Utstein-style study.<sup>76</sup> The overall incidence of successful prehospital TI was 99.7%, with an overall complication rate of 7.9%. The 0.3% incidence of failed prehospital TIs was comparable to data reported from other physician-staffed HEMS / EMS in the UK<sup>50 53</sup>, Germany<sup>30 52</sup> and

France.<sup>88</sup> The 22.4% incidence of difficult TI is, however, surprisingly high. It is higher than the 8.9% incidence reported from a comparable system in Berlin.

A recent prospective observational international multicentre study investigated prehospital TI by physician-staffed HEMS. Of the 21 HEMS bases, three were from Finland and five from Norway. Airway management data were collected according to the Utstein-style airway template in 2327 critically ill or injured patients.<sup>84</sup> The airways were managed with TI (92%), SAD (5%), bag-valve-mask ventilation (2%) or continuous positive airway pressure (0.2%). TI failed during the first attempt in 14.5% and overall in 1.2% of patients. Cardiac arrest (CA) patients had a significantly higher risk of first-attempt intubation failure (OR 2.0; 95% CI: 1.5-2.6) compared with non-CA patients. Complications were observed in 13%, with oesophageal intubation being the most common complication.

Prehospital drug-assisted TI by non-physicians is practised by some units in Finland.<sup>70</sup> A retrospective analysis showed that after the implementation of a physician-staffed HEMS, the prehospital TI increased, whereas the incidence of prehospital hypoxia decreased.<sup>89</sup> In a univariate analysis of the physician-staffed HEMS, a lower patient age and prehospital TI were associated with a good neurological outcome.

## 2.4 SUMMARY

Prehospital TI is a potentially lifesaving procedure, but it carries risks of serious complications. The Nordic region is a large mixed urban and rural subarctic area with a mainly a two-tiered EMS structure. Many Nordic counties utilize second-tier anaesthetist-staffed critical care teams deployed with HEMS or RRC. Hence, prehospital advanced airway management is mainly performed by airway experts. Prehospital advanced airway management by anaesthetist-staffed prehospital critical care teams has not previously been investigated in a prospective large international multicentre trial.

Intubation problems have stimulated the development of indirect video laryngoscopes and SADs. One of the most commonly used prehospital indirect laryngoscopes, the Airtraq<sup>®</sup>, has recently shown a very low success rate in a prospective randomized trial. It is not known how the Airtraq<sup>®</sup> performs in a real-life prehospital setting.

HEMS TI is usually performed before loading the patient into the helicopter, which is associated with several disadvantages, including long scene times and the risk of patient hypothermia. In military settings, in-flight TI may be required because of a hostile environment on the ground. Should an in-flight TI be necessary, laryngoscopy is challenging due to the lack of space, inadequate light or other aggravating circumstances.<sup>41 42</sup> The literature on TI inside the helicopter cabin is highly limited, especially TIs done by very experienced anaesthetists.

### 3 AIMS

The overall aim was to investigate prehospital advanced airway management in the Nordic countries with regard to providers, airway devices and techniques. The Nordic region is characterized by the use of only airway experts, mainly anaesthetists, for prehospital TI. The specific aims were as follows.

1. Determine the prehospital TI success rate with the rescue device Airtraq<sup>®</sup>.
2. Compare the TI success rate in a simulated tactical ambulance helicopter environment under different light conditions.
3. Describe the prehospital TI success rate, complications and associated mortality in Nordic countries. Compare the TI success rate between different categories of providers and airway techniques.
4. Investigate if ambulance helicopter in-cabin TI (SPRINT) is safe and fast compared with standard outdoor TI with 360 degrees of access to the patient.





## 4 METHODS

### 4.1 ETHICAL CONSIDERATIONS

The involvement of humans in clinical research necessitates substantial ethical reflection. Critically ill and unconscious patients are more vulnerable compared with non-critically ill patients. Conducting research on such patients requires caution. In many countries, conducting randomized controlled trials with drugs and procedures is not permitted in unconscious patients, whereas a delayed consent approach may be acceptable under some conditions.

Study I was a retrospective study of the ambulance medical records of patients who had been tracheally intubated in the prehospital setting in Stockholm. As the study was retrospective, it did not affect the resuscitation and medical procedures for the patients. Studies II and IV were prospective experimental studies performed on manikins, limiting ethical issues. Study III was a prospective observational study. As a descriptive non-intervention trial, the treatment and care of the patients were not altered. The patients were given prehospital critical care treatment according to current guidelines and practices. However, it cannot be ruled out that actual participation in a trial affected the standard care of the patients.

The ethical review board (ERB) in Stockholm County had no objections to study I (2012/1668- 31/4). As study II was performed on manikins, it did not require ethical approval according to Stockholm ERB regulations (on-line accessed May 10, 2014) and ERB telephone consultation. Study III was registered with Clinicaltrials.gov (NCT02450071). ERB approvals were obtained from Norway (2015/545/REK vest), Sweden (2015/411-31, 2015/1519-32), Denmark (the Danish Health and Medicine Authority no. 3-3013-941/1/) and the Danish Data Protection Agency (no. 20087-58-0035, 15/16531). In Finland, the study did not require Ethical Review Board approval because it did not deviate from normal practices or documentation. Study IV was submitted to the ERB in Stockholm, but since it was conducted on manikins, it was exempted from ethical review (2017/858-31/1). Data handling and record keeping were performed in compliance with the regulatory requirements in Nordic countries. The clinical studies were conducted in accordance with the WMA Declaration of interests.<sup>90</sup>

## 4.2 OVERVIEW OF METHODS

The studies were conducted using quantitative methods. Study I was a retrospective cohort study. Studies II and IV were experimental prospective randomized crossover studies. Study III was a prospective observational study.

Study	Design	Study population	Participants	Outcome	Statistical methods
I	Retrospective observational	Patients of all ages residing in Stockholm county 2008-2012	Patients intubated out-of-hospital with Airtraq <sup>®</sup> N=28	1° TI success rate  2° TI success rate in difficult airway	Descriptive statistics
II	Experimental, randomized crossover	Manikins intubated in daylight and darkness/NVG in a Black Hawk simulator and in an ED setting	Prehospital anaesthetists N=12	1° TI time  2° TI attempts, Cormack-Lehane, VAS	Descriptive statistics and Wilcoxon test
III	Prospective observational	Patients of all ages residing in the Nordic countries 2015-2016	Patients with attempted prehospital TI N=2028	1° TI success rate  2° TI complications, TI time and on-scene time, etc.	Descriptive statistics and X <sup>2</sup> test
IV	Experimental, randomized crossover	Manikins intubated in- and outside a H145 ambulance helicopter	Prehospital anaesthetists N=14	1° TI success  2° TI time and attempts, VAS, etc.	Descriptive statistics and Wilcoxon test

Table 1. Overview of the study methods. TI, tracheal intubation

## 4.3 STUDY SETTINGS AND DESCRIPTIONS

**Study I** was conducted in Stockholm County, an urban area of 6519 km<sup>2</sup> with 2.14 M inhabitants (328 inhabitants/km<sup>2</sup>). In 2010, Stockholm had a two-tiered EMS with 55 road ambulances staffed with nurses with additional EMS training and basic emergency medical technicians (EMTs). The nurses were not allowed to perform RSI, but some of them intubated patients with cardiac arrest. No ambulances carried Airtraq<sup>®</sup>, for which reason they were not included in the study. The second tier consisted of prehospital critical care teams, one staffed with anaesthetists and the remaining three with nurse anaesthetists and a basic EMT. The prehospital critical care teams intubated patients with cardiac arrest and performed

RSI. The majority of the personnel in the prehospital critical care teams worked part-time in-hospital at an anaesthesiology department. All four prehospital critical care teams carried Airtraq<sup>®</sup> and were allowed to use it at the discretion of the intubating professional.

Study I was a retrospective medical chart review of the patients in Stockholm county 2008-2012 who had been intubated with Airtraq<sup>®</sup>. No patients with at least one Airtraq<sup>®</sup> intubation attempt were excluded.

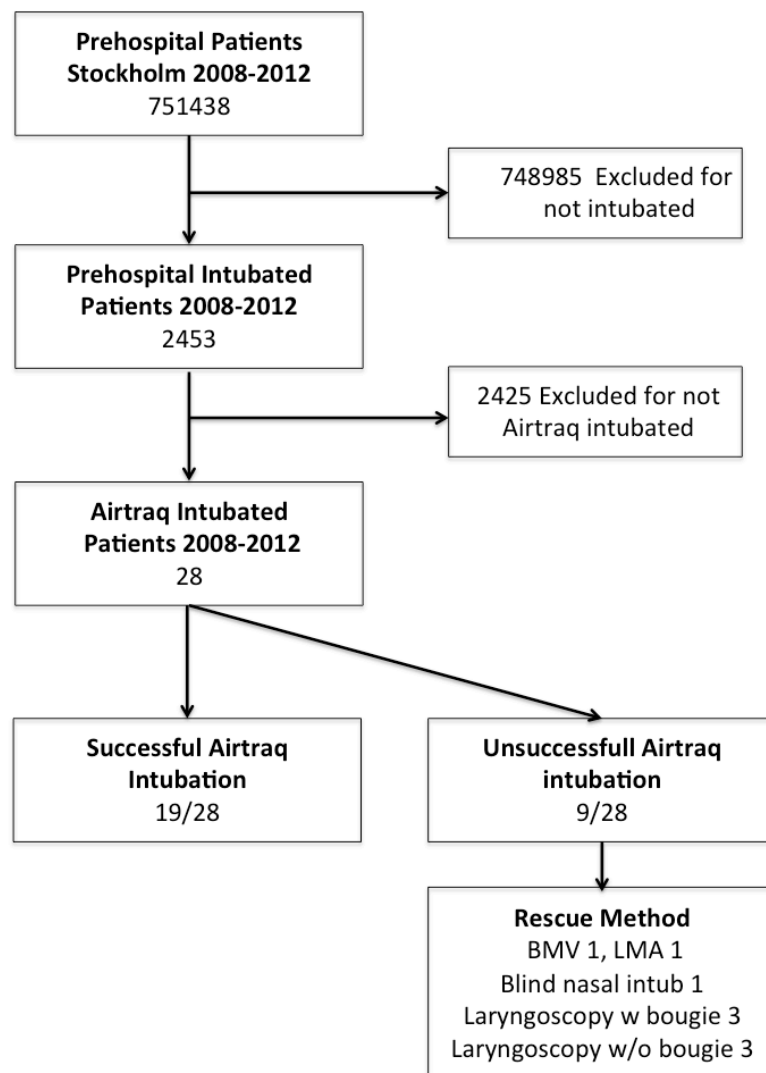


Fig 4. Airtraq<sup>®</sup> tracheal intubation flowchart.

**Study II** was an experimental prospective randomized crossover study performed using an intubation manikin. Twelve anaesthetists intubated the manikin in an ED setting. The ED TI was then followed by manikin TI in a simulated UH-60M Black Hawk helicopter cabin in either first ambient daylight and then in total darkness using NVG, or vice versa, in a 1:1 randomized crossover fashion. Finally, the manikin was again intubated in a daylight ED setting. The study was performed at the Swedish Armed Forces Defence Medicine Center (FörmedC) on a Laerdahl SimMan<sup>®</sup> Manikin. Into the manikin's lungs was instilled 8 g CO<sub>2</sub>

to allow capnographic (EMMA™ Capnograph, Massimo Sweden AB, Sweden) tube position verification. The manikin was intubated with a Macintosh size 3 blade laryngoscope (light bulb covered with black tape in the NVG scenario) and a 7-mm endotracheal tube.

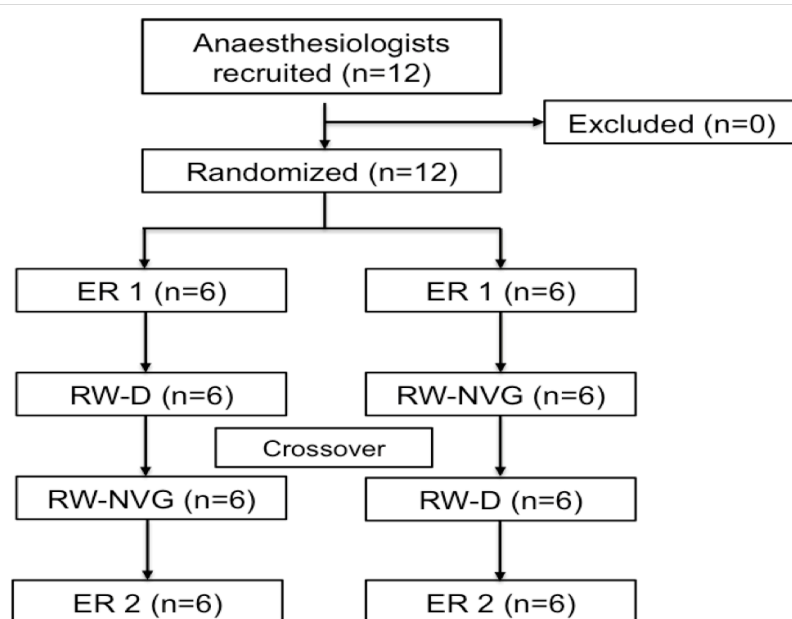


Fig 5. Flowchart of the experimental tracheal intubation study in emergency room (ER) and rotor wing (RW) settings. ER intubation scenario 1 and 2; RW-D, daylight helicopter setting; RW-NVG, helicopter setting in the dark with NVG.

**Study III** was performed in twelve second-tier prehospital critical care teams in Nordic countries, covering both rural and urban areas of 147 000 km<sup>2</sup> with 7.1 million inhabitants (48.4 inhabitants/km<sup>2</sup>). Eight of twelve units were staffed by anaesthetists, whereas four units were staffed by nurse anaesthetists (HEMS Stockholm, HEMS Östersund, RRC Sollentuna Stockholm, RRC Huddinge Stockholm). The second tier units were deployed by six helicopters in Sweden (Stockholm, Gothenburg, Östersund), Finland (Helsinki) and Norway (Stavanger, Trondheim) and six rapid response cars in Sweden (Stockholm 1-3, Gothenburg) and Denmark (Aarhus, Odense). In the Nordic countries, anaesthetists are specialized in both anaesthesiology and critical care. The vast majority of the prehospital providers in the study work part-time in-hospital at an anaesthesiology and intensive care unit. They perform emergency anaesthesia and advanced airway management in the operating room, intensive care unit and emergency room as part of their daily work. The prehospital critical care teams attend both trauma and medical cases. All second-tier units carry anaesthetics agents, analgesics, NMBA and perform RSI. The units have advanced airway management equipment including conventional laryngoscopes, video laryngoscopes (not Norway), stylets, gum-elastic bougies, SADs and surgical airway equipment.

The study was a prospective observational multicentre study. All patients who had undergone an attempted TI by the twelve units listed above from May 2015 to November 2016 were included in the study. The only exclusion criterion was TI during inter-hospital missions.

**Study IV** was an experimental prospective randomized crossover study on manikin TI inside an ambulance helicopter cabin compared with outside the ambulance helicopter. TI inside the ambulance helicopter is a new concept called SPRINT. The manikin (Laerdal, product no. 170-00150, Stavanger, Norway) simulated an unconscious patient with TBI requiring TI. At the start of the scenario, the prehospital critical care team, with an anaesthetist and a flight paramedic, approach the manikin situated 30 m from the ambulance helicopter (H145, Airbus helicopters, Toulouse, France). The anaesthetist performed the primary survey, and the timing was started when the physician declared the intention to intubate. The prehospital critical care team was randomized to start with a scenario transporting and then intubating the manikin inside the H145 ambulance helicopter (SPRINT), followed by a scenario with TI outside the ambulance helicopter, or vice versa, in a 1:1 crossover fashion. A Mac 4 laryngoscope (Short handle, Heine, Germany), 7-mm tracheal tube with a mounted stylet (Super Safety Clear Flexiset™, Athlone, Ireland) and capnograph (EMMA™ Capnograph, Massimo Sweden AB, Sweden) were used for the TI. Only the RSI and advanced airway management by the anaesthetists were examined in the study.

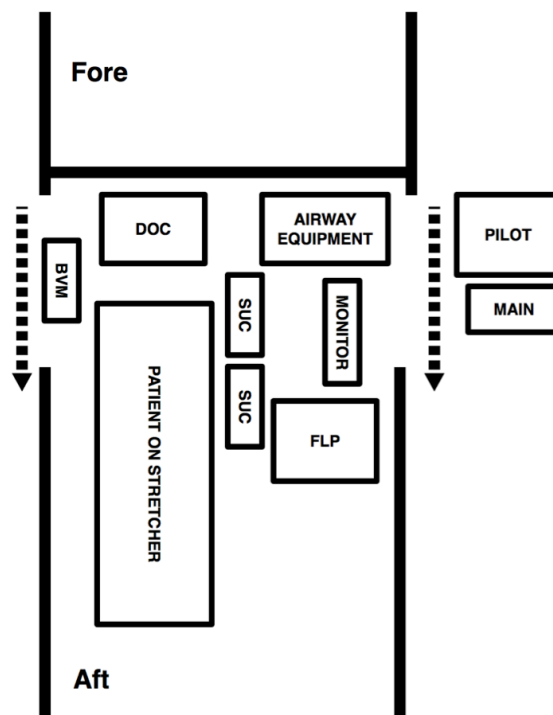


Fig 6. The H145 ambulance helicopter setup for SPRINT in-cabin tracheal intubation. The airway kit dump, including the anaesthetic drugs, is positioned on the intubating anaesthetist's (DOC) left, in front of the paramedic's (FLP) seat, where all equipment is easily accessible to both operators.

#### 4.4 MEASUREMENTS AND DATA COLLECTION

In **Study I**, the primary endpoint was the TI success rate. Successful TI was defined as satisfactory results from capnography and/or lung auscultation after Airtraq<sup>®</sup> TI. The TI was also considered successful if no medical record information contradicted a successful TI, such as further laryngoscopy attempts and/or mask or SAD ventilation mentioned after the TI. Secondary endpoints included Airtraq<sup>®</sup> TI success in unexpected or anticipated difficult airways. The ambulance medical record system, CAK-net, was used to collect the study data. All prehospital medical records were sought for tracheal intubation, laryngoscopy and Airtraq<sup>®</sup> with different spellings.

In **study II**, the primary endpoint was TI time. The TI time was defined as the time from passing the front teeth with the laryngoscope until capnographic tube confirmation. Secondary endpoints included the number of TI attempts, Cormack-Lehane (CL) glottic visualization and intubation difficulty according to the visual analogue scale (VAS). The investigators recorded the endpoints, times and anaesthetists' self-assessments on a paper case report form. The data was later transferred to an IBM SPSS database for statistical calculations.

In **study III**, the prehospital advanced airway management data were defined and selected according to the consensus-based Utstein-style airway template by Sollid et al.<sup>84</sup> Descriptive variables included patient characteristics, demographic data and indication for TI. Exposure variables describing the airway management were registered. The primary endpoint was overall TI success rate. Other outcome variables, such as the success rate on each TI attempt, complications, TI time and on-scene time, among others, were recorded. The provider performing the advanced airway management registered the data on a paper case report form. The study nurse subsequently transferred the data on the paper case report form to an IBM SPSS Statistics database.

In **study IV**, the primary endpoint was the TI success rate. In addition, the number of TI attempts, CL glottic visualization, perceived difficulty according to VAS and intubation times were registered. The time to secure the airway (TSA) was defined as the time from the start of the scenario until the tracheal tube was cuffed. The duration of TI was defined as the time from when the laryngoscope passed the front teeth to when the tracheal tube was cuffed. Partial scene time (PST) was defined as the time from TI decision until the patient was in the helicopter connected to the ventilator. The investigators recorded the endpoints, times and provider self-assessments on a paper case report form. The data were then transferred to an IBM SPSS Statistics database for statistical calculations.

## 4.5 STATISTICAL METHODS

In **study I**, descriptive statistics were used.

In **study II and IV**, descriptive statistics and the Wilcoxon test was used. Statistical significance was set at  $p < 0.05$ . With a difference in TI time of 25 s between study groups, an SD of 20,  $\alpha = 0.05$  and 90% power a sample size of nine subjects per group were required.

In **study III**, descriptive statistics were generated. The  $X^2$  test was used to calculate differences between groups, and  $p < 0.05$  was considered significant.

In **study I**, Excel (Excel, version 2010, Microsoft Corp, Washington, USA) and in **study II-IV** IBM SPSS Statistics (SPSS Statistics, version 21 and 23, IBM Corporation, NY, USA) were used.





## 5 RESULTS

The major findings are summarized in the Results section. For details on the results, the articles and manuscripts are available at the end of this book.

### 5.1 STUDY I

From 2008-2012, 751 438 patients were assessed and/or treated by EMS in Stockholm County. Of these patients, 2453 were intubated. Airtraq<sup>®</sup> was only used in 28 of the TIs. The majority (23/28) of patients were intubated due to cardiac arrest, five patients due to trauma and one following respiratory insufficiency. Among the patients intubated with Airtraq<sup>®</sup>, the average age was 52 years, 75% were male and 39% had undergone a previous failed conventional laryngoscopy attempt.

Demographic data	Patients, N (%)
Average age (years)	52,4
Children <16 (n)	2
Gender (Female/Male)	7/21 (25/75)
Year 2008-2012	28
Indication for intubation	
Cardiac arrest	23/28 (82,1)
Foreign Body	3/28 (10,7)
Hanging	2/28 (7,1)
Drowning	1/28 (3,6)
Trauma	5/28 (17,9)
Respiratory Insufficiency	1/28 (3,6)
Drug facilitated intubation with suxamethonium.	5/28 (17,9)
Anticipated or unexpected difficult airway	23/28 (82,1)
Failed conventional laryngoscopy intubation	11/28 (39,3)
Failed laryngeal mask	2/28 (7,1%)
Intubated by Doctor/Nurse	14/14 (50/50)
Air/Ground rescue	3/25 (10,7/89,3)

Table 1. Demographic data and indications for prehospital Airtraq<sup>®</sup> tracheal intubation. Data are presented as years, number and ratios.

Of the 28 Airtraq<sup>®</sup> TI attempts, 68% (19/28) were successful. In 23 of the 28 patients, Airtraq<sup>®</sup> was used due to an anticipated or unexpected difficult airway, with a success rate of 61% (14/23). The Airtraq<sup>®</sup> TI success rate was 46% (6/13) among the patients with a previously failed conventional TI attempt or SAD. Following RSI, the Airtraq<sup>®</sup> TI success rate was 80% (4/5). The Airtraq<sup>®</sup> TI success rate was 100% among the five patients suffering

from severe trauma who required manual in-line stabilization. Failed Airtraq<sup>®</sup> airway management caused no fatalities.

<b>Airtraq<sup>®</sup> efficacy</b>	<b>Success rate, N (%)</b>
Children <16 (n)	1/2 (50)
Overall successrate	19/28 (67,9)
Cardiac arrest	15/23 (65,2)
Foreign Body	2/3 (66,7)
Hanging	0/2 (0)
Drowning	1/1 (100)
Trauma	5/5 (100)
Drug facilitated intubation with suxamethonium	4/5 (80)
Anticipated or unexpected difficult airway	14/23 (60,8)
Prior failed conventional laryngoscopy intubation	4/11 (36,4)
Failed laryngeal mask (LMA)	2/2 (100)
Failed convent. laryngoscopy intubation or LMA	6/13 (46,2)

Table 2. Subgroup analysis of the Airtraq<sup>®</sup> tracheal intubation success rate.

## 5.2 STUDY II

Twelve physicians were enrolled in the experimental study on manikin TI. The setting was a Black Hawk helicopter cabin in daylight versus in darkness with NVG and ED. The participants had on average been working as physicians for 15 years, 11,3 years within anaesthesiology and 2,8 years within EMS. The participating physicians had 5,4 years of military experience, including 7,5 hours of NVG use.

<b>Intubator characteristics</b>	<b>Years +/- SD</b>
Age	45.6 +/- 8.1
Physician experience	15.2 +/- 8.1
Anaesthesiology experience	11.3 +/- 7.4
Consultants : Registrars (n)	9 : 3
Years as anaesthetist	7.4 +/- 7.2
EMS experience	2.8 +/- 4.3
HEMS experience	2.5 +/- 4.2
Military experience	5.4 +/- 9.7
NVG experience (hours)	7.5 +/- 13.1

Table 3. Characteristics of the intubating physician. Data are presented as years, ratios, and hours.

When conducted by the anaesthetists in the study, the TI success rate was 100%. There was no difference in time between TI in the helicopter cabin in daylight and in the ED setting (16.5 vs. 16.8 s;  $p=0.91$ ). There was no significant difference in either glottic visualization (CL 2.0 vs. 1.8;  $p=0.72$ ) or perceived TI difficulty (VAS 3.0 vs. 2.8;  $p=0.24$ ) between the daylight helicopter and ED scenarios.

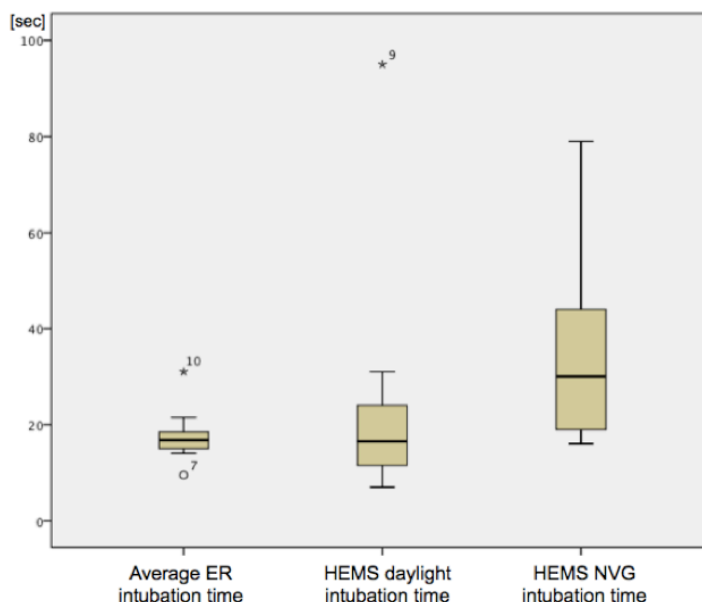


Fig 7. Box plot analysis of median tracheal intubation time in the three different scenarios. Data are presented in seconds.

The in-cabin helicopter TI time was shorter in daylight vs. in darkness with NVG (16.5 s vs. 30.0 s;  $p=0.03$ ). In the helicopter, glottic visualization was better (CL 2.0 vs. 3.0;  $p < 0.01$ ) and TI was easier (VAS 3.0 vs. 6.5;  $p < 0.01$ ) in daylight compared with darkness with NVG. In addition, the intubation time was shorter in the ED setting vs. in darkness with NVG (16.8 s vs. 30.0 s;  $p=0.01$ ).

Scenario	TI success (Yes/No)	TI Time (s) Median (IQR)	No attempts Median (IQR)	CL score Median (IQR)	TI difficulty Median (IQR)
ER 1	Yes	17.0 (7)	1.0 (0)	2.0 (1)	3.0 (4)
ER 2	Yes	16.0 (7)	1.0 (0)	2.0 (1)	2.0 (2)
ER (average)	Yes	16.8 (3.5)	1.0 (0)	1.8 (0.5)	2.8 (1.9)
RW-D	Yes	16.5 (14)	1.0 (0)	2.0 (1)	3.0 (3)
RW-NVG	Yes	30.0 (29)	1.0 (0)	3.0 (2)	6.5 (4)

Table 4. Tracheal intubation results. Median data are presented as yes/no, second(s), number of TI attempts, CL score, TI difficulty according to VAS, and corresponding interquartile range (IQR).

Comparison	Intubation time	CL score	VAS
	Difference median (IQR)	Difference median (IQR)	Difference median (IQR)
RW-D vs. RW-NVG	9 (20.8), p = 0.03	1.0 (0.8), p < 0.01	3.0 (1.8), p < 0.01
RW-D vs. ER	- 1.5 (10.3), p = 0.91	0.0 (0.9), p = 0.72	0.3 (2.5), p = 0.24
RW-NVG vs. ER	12.3 (14.8), p < 0.01	0.8 (1.9), p < 0.01	4.0 (1.9), p < 0.01
ER 1 vs. ER 2	0.5 (7.8), p = 0.21	0.0 (0.8), p = 0.48	0.0 (3.0), p = 0.33

Table 5. Median differences in tracheal intubation time, CL score, and intubator VAS difficulty assessment. Data are presented as seconds, CL score difference, and VAS with corresponding interquartile range (IQR) and p-value.

### 5.3 STUDY III

From May 2015 to November 2016, 32 007 patients were attended to by the participating second-tier units. Of these patients, 2028 were intubated due to cardiac arrests (53.0%), other medical conditions (26.3%) and trauma (19.1%). Sixty-six percent of the patients were male, and the median age was 62 years (IQR 45-74). The TIs were performed by anaesthetists (67.1%), nurse anaesthetists (25.2%), anaesthetist registrars (5.7%) and emergency medicine physicians (1.5%). The majority (67.0%) of the TIs were performed by a provider who had intubated >2500 patients.

The overall TI success rate in the study was 98.7%, with a first pass success rate of 84.5%. After the second and third attempts, 95.9% and 98.2% of the TIs were successful. The median TI time was 25 s (IQR 15-30 s). Conventional laryngoscopy was compared to video laryngoscopy more frequently used on the first (58.4% vs. 41.6%), second (62.9% vs. 31.6%) and third (42.6% vs. 41.1%) attempts. The first pass success rate was higher with video laryngoscopy compared with direct laryngoscopy (92.9% vs. 78.6%; p<0.01), whereas the intubation time was longer with video laryngoscopy (25 s vs. 20 s; p<0.01). Surgical front of neck access was conducted in ten patients (0.5%). Among the 27 patients with failed TIs, their airways were further managed with SADs (n=14), bag-valve-mask (n=7) and surgical airway (n=6). The overall rate of complications related to TI was 10.9%, with hypotension (4.4%) and hypoxia (2.2%) being the most common.

<b>Demographic data</b>	<b>Patients, N (%)</b>
<b>Provider data</b>	2005
Anaesthetist	1345 (67.1%)
Anaesthetist registrar	115 (5.7%)
Emergency medicine physician	30 (1.5%)
Internal medicine	9 (0.4%)
Nurse anaesthetist	506 (25.2%)
<b>Experience of tracheal intubations</b>	2002
50-200	14 (0.7%)
200-2500	647 (32.3%)
2500-10 000	1233 (61.6%)
>10 000	108 (5.4%)
<b>Patient data</b>	2028
Age (median)	62 y (IQR 45-74)
Male	1319/1972(66.9%)
ASA (median)	2
Ischemic heart disease	262/991 (26.4%)
COPD	134/974 (13.8%)
<b>Patient categories</b>	2028
Trauma total	387 (19.1%)
Traumatic brain injuries	215 (10.6%)
Penetrating trauma	31 (1.5%)
Cardiac arrest	1075 (53.0%)
Medical other	533 (26.3%)
Cardiac disease (not CA)	41 (2%)
Stroke/intracranial haemorrhage	182 (9%)
Seizure	61 (3%)
Asthma/COPD	99 (4.9%)
Intoxication	150 (7.4%)
Ear-nose-throat disease	12 (0.6%)
Other	210 (10.4%)

Table 6. Demographic data for the providers and patients. IQR, interquartile range; COPD, chronic obstructive pulmonary disease.

	<b>Cardiac arrest</b>	<b>Trauma</b>	<b>RSI</b>	<b>Total</b>
	N (%)	N (%)	N (%)	N (%)
<b>TI success total</b>	1056/1075 (98.2%)	381/387 (98.4%)	929/935 (99.4%)	2001/2028 (98.7%)
TI success 1 attempt	843/1075 (78.4%)	339/387 (87.6%)	856/935 (91.6%)	1713/2028 (84.5%)
TI success ≤ 2 attempts	1014/1075 (94.3%)	375/387 (96.9%)	916/935 (98.0%)	1945/2028 (95.9%)
TI success ≤ 3 attempts	1049/1075 (97.6%)	380/387 (98.2%)	926/935 (99.0%)	1992/2028 (98.2%)
<b>TI time</b>				25 s (IQR 15-30)
Diff. airway TI success	678/694 (97.7%)	259/265 (97.7%)	522/528 (98.9%)	1215/1239 (98.1%)
<b>Complications (total)</b>	76/1075 (7.1%)	54/387 (14.0%)	147/935 (15.7%)	222/2028 (10.9%)
Hypoxia	6/1075 (0.6%)	17/387 (4.4%)	38/935 (4.1%)	44/2028 (2.2%)
Hypotension	3/1075 (0.3%)	19/387 (4.9%)	85/935 (9.1%)	90/2028 (4.4%)
Bradycardia	3/1075 (0.3%)	2/387 (0.5%)	9/935 (1.0%)	11/2028 (0.5%)
Cardiac arrest	14/1075 (1.3%)	4/387 (1.0%)	9/935 (1.0%)	21/2028 (1.0%)
Bronchial intubation	2/1075 (0.2%)	0/387 (0.0%)	2/935 (0.2%)	3/2028 (0.1%)
Oesophageal intubation	26/1075 (2.4%)	5/387 (1.3%)	6/935 (0.6%)	34/2028 (1.7%)
Aspiration	2/1075 (0.2%)	6/387 (1.6%)	10/935 (1.1%)	14/2028 (0.7%)
Dental injury	2/1075 (0.2%)	0/387 (0.0%)	1/935 (0.1%)	3/2028 (0.1%)
Surgical airway	9/1075 (0.8%)	4/387 (1.0%)	5/935 (0.5%)	14/2028 (0.7%)
Other complications	21/1075 (2.0%)	12/387 (3.1%)	22/935 (2.4%)	39/2028 (1.9%)
<b>Ongoing CPR at ED</b>	228/1060 (21.5%)	29/382 (7.6%)	16/924 (1.7%)	266/2028 (13.1%)
Prehospital death	384/1060 (36.2%)	32/382 (8.4%)	19/924 (2.1%)	441/2028 (21.7%)
<b>On-scene time</b>				25.0 min (IQR 18-33)

Table 7. Prehospital tracheal intubation success and complication outcomes in cardiac arrest, trauma, rapid sequence induction, and total patients. RSI, rapid sequence induction; TI, tracheal intubation; CPR, cardiopulmonary resuscitation; ED, emergency department; IQR, interquartile range.

The TI success rate was higher following RSI compared with patients intubated without RSI (99.4 vs. 98.1%;  $p=0.02$ ). The TI success rate was 98.2% in patients with cardiac arrest compared with 99.1% in patients without cardiac arrest ( $p=0.08$ ). Among the patients with a difficult airway, the TI success rate was lower compared with patients without a difficult airway (98.1% vs. 99.6%;  $p>0.01$ ). The TI success rate was higher among physicians compared with nurses (99.0% vs. 97.6%;  $p=0.03$ ). The time on the scene in patients requiring TI was 25 min (IQR 18-33 min). When arriving at the ED, 65.2% of the patients in the study were alive, whereas another 13.1% were receiving CPR. Death was pronounced before arrival to the ED in 21.7% of patients.

Subgroup	TI success, n	%	P-value
Cardiac arrest	1056/1075	98.2%	
Non-cardiac arrest	942/950	99.1%	0.08
Rapid sequence induction	929/935	99.4%	
No rapid sequence induction	1071/1092	98.1%	0.02
Easy airway	786/789	99.6%	
Difficult airway	1215/1239	98.1%	<0.01
Rapid response car	881/899	98.0%	
HEMS	1120/1129	99.2%	0.03
Nurse	495/507	97.6%	
Physician	1503/1518	99.0%	0.03

Table 8. Subgroup analysis. TI, tracheal intubation; HEMS, helicopter emergency medical service.

## 5.4 STUDY IV

Fourteen anaesthetists were enrolled in the experimental study on manikin TI inside an ambulance helicopter compared with outside the ambulance helicopter. The participants had, on average, 9.4 years of experience in anaesthesia, of which 2.9 years were from HEMS. The anaesthetists had intubated, on average, 2923 patients before participating in the study.

Intubator characteristics	Years +/- SD
Age	42.5 +/- 4.9
Physician experience	12.6 +/- 2.9
Anaesthesiology experience	9.4 +/- 2.4
Consultants : Registrars (n)	14 : 0
Years as anaesthetist	4.4 +/- 2.4
HEMS experience	2.9 +/- 2.0
Total no. tracheal intubations	2923 +/- 1205

Table 9. Intubator characteristics (n=14). Data are presented as the mean ± standard deviation years, ratio and numbers.

When performed by the anaesthetists in the study the TI success rate was 100%, with all TIs being successful on the first attempt. There was no difference in glottic visualization (CL 1.0 vs. 1.0), but the participants perceived the in-cabin TI to be easier than intubation outside the

helicopter cabin (VAS 1 vs. VAS 2;  $p=0.02$ ). There was no difference in TI time between intubation inside versus outside the helicopter cabin (13 vs. 15.5 s;  $p=0.30$ ). However, the total on-scene time was significantly shorter with the in-cabin TI strategy compared with the standard outside TI (266 vs. 320 s;  $p=0.04$ ).

<b>Scenario</b>	<b>TI success (%)</b>	<b>DOI (s) Median (IQR)</b>	<b>TSA (s) Median (IQR)</b>	<b>PST (s) Median (IQR)</b>	<b>VAS Median (IQR)</b>
STANDARD	100%	15.5 (6.8)	138 (62.5)	320 (109.5)	2 (1)
SPRINT	100%	13.0 (4.5)	201 (46.5)	266.5 (72)	1 (0)
Difference (p)	0	2.5 ( $p=0.30$ )	- 63 ( $p=0.01$ )	53.5 ( $p=0.04$ )	1 ( $p=0.02$ )

Table 10. Ratio of successful tracheal intubation (TI) on the first attempt expressed as percentages. Airway management times; duration of intubation (DOI), time to secure airway (TSA) and partial scene time (PST) are presented as median seconds (s) and interquartile ranges (IQR). The laryngoscopy view is expressed using the Cormack-Lehane score (CL) with the IQR. Overall perceived intubating conditions were recorded using a visual analogue scale (VAS) ranging from 1 to 10, representing increasing difficulty.

Qualitative aspects: No anaesthetist or flight paramedic experienced problems or had concerns about the in-cabin SPRINT intubation method. The participants appreciated how the monitoring and equipment were accessible in the helicopter cabin, within arm's reach in a well-known environment. The participants spontaneously emphasized that in-cabin TI may reduce the risk of accidental extubation because it eliminates the need to move a tracheally intubated patient over difficult terrain.



## **6 DISCUSSION**

### **6.1 PREHOSPITAL ADVANCED AIRWAY MANAGEMENT IN NORDIC COUNTRIES**

The Nordic countries comprise a mixed urban and rural area of approximately 1.369.000 km<sup>2</sup> with a population of 26.850.000 inhabitants. The population density (19.6 inhabitants/km<sup>2</sup>) is rather low.<sup>91</sup> In this setting, prehospital TI by prehospital critical care teams is most commonly performed because of cardiac arrest (53%), followed by trauma (19%), TBI (11%), stroke (9%) and intoxication (7%). The high proportion of intubated male (67%) patients has also been reported by other services such as the Swiss HEMS Rega (74%).<sup>92</sup> The high proportion of male patients is probably caused by the over-representation by men in cardiac arrests and trauma. The median age of the intubated patients in the Nordic countries was 62 years (IQR 45-74), which is also similar to the median age of 56 years reported by Rega in Switzerland.

Many regions in the Nordic countries are mountainous wilderness areas with a subarctic climate. Snow and cold temperatures frequently force the prehospital critical care teams to perform TI in the road ambulances or inside the ambulance helicopter cabin, which may avoid hypothermia in the patient. However, some authors suggest that in-cabin TI may be inappropriate and more difficult.<sup>93 94</sup> Furthermore, the literature on in-cabin TI is limited. Nevertheless, study IV indicates that when in-cabin TI is performed by anaesthetists, neither the success rate nor glottic visualization is impaired compared with TI outside the helicopter cabin. In fact, anaesthetists perceive in-cabin TI to be easier. The safe use of in-cabin TI, without an increase in the failure rate and complications, has also been proposed by other authors.<sup>95 96</sup>

### **6.2 PREHOSPITAL ADVANCED AIRWAY PROVIDERS IN THE NORDIC COUNTRIES**

Anaesthetists are in-hospital airway experts. In the Nordic countries, they are additionally specialists in critical care and on the emergency medicine critical care response team of the hospitals. In many countries, prehospital TI is performed by a wide range of providers with limited experience in advanced airway management and critical care. In Europe, anaesthetists and emergency medicine physicians mainly perform in-hospital emergency anaesthesia and TI. With increasing knowledge about the risks of TI, some EMS systems have decided that only providers that are capable of unsupervised in-hospital TI may perform the procedure. In Nordic countries, only anaesthetists perform unsupervised in-hospital TI, for which reason only anaesthetists meet the requirements for prehospital RSI. Hence, the Nordic region is distinguished from a prehospital perspective by the almost exclusive use of airway experts, anaesthetists, on the prehospital critical care teams.

Study III demonstrated exceptional airway experience of the critical care teams in Nordic countries. More than 67% of the patients were intubated by a provider who had performed >2500 TIs. This airway experience is even more extensive than that reported in the international multicentre HEMS-study AIRPORT, in which 52% of the physicians had intubated >1000 patients.<sup>49</sup> A retrospective study in the UK on 7256 TIs suggested that anaesthetists have a higher prehospital TI success rate compared with emergency medicine physicians.<sup>55</sup> The effect of continuous TI exposure was also demonstrated in a study by Breckwold and coworkers.<sup>52</sup> Not surprisingly, proficient intubators (18 TI/year) had a higher incidence of difficult TIs compared with expert intubators (304 TI/year). According to a study on prehospital RSI, anaesthetists were the physician category with the highest TI success rate.<sup>53</sup> This finding was later supported by a meta-analysis demonstrating the highest prehospital TI success rate among anaesthetists (99.4%).<sup>51</sup>

When the prehospital TI in study III was performed with the anaesthesia competence previously described, it was associated with a high overall success rate (98.7%) and few complications (10.9%). The 84.5% first-pass success rate compared favourably to the 77.8% reported in a recent meta-analysis of prehospital TI.<sup>51</sup> Following RSI, the first-pass TI success rate was, by an indirect comparison, higher in study III compared with the physician-HEMS trial AIRPORT (91.6% vs. 89%).<sup>49</sup> The variations in first-pass success may be partly explained by differences in patient characteristics and TI indications. Nevertheless, differences in provider competence may also have affected the success and complication rates, a finding that is consistent with a Cochrane review emphasizing competence as a key factor in emergency TI.<sup>97</sup>

The 10.9% complication rate of prehospital TI in the Nordic countries was somewhat lower than that reported in a physician-HEMS study (12%) and a Danish rapid response car study (14.2%).<sup>49 76</sup> In addition, the 4.1% rate of post-RSI hypoxia in study III was lower than in other physician staffed prehospital critical teams in the UK (10.2%), Denmark (5.3%), Germany (13.3%) and Hungary (8.1%).<sup>27 76 98 99</sup> The development of new airway equipment and apnoeic oxygenation, as well as provider experience, may explain the low rate of hypoxia following RSI. Some of these factors may also have contributed to the low incidence (9.1%) of post-RSI hypotension in study III compared with other prehospital and in-hospital studies.<sup>27 100</sup>

The low risk of hypotension and hypoxia following RSI may have been beneficial for patients with traumatic brain injury, with 93% of these patients being alive at arrival to the ED. In a study from Finland, there was less hypoxia and hypotension when the patients were intubated by physicians compared to paramedics, translating into a higher 1-year survival rate (57% vs. 42%).<sup>101</sup> This finding is also in agreement with a meta-analysis showing an increase in mortality among TBI patients intubated by providers with limited experience.<sup>102</sup>

The prehospital challenges include environmental difficulties, unpredictable situations, limited equipment and assistance.<sup>78</sup> Despite these challenges in study III, the prehospital TI was associated with a high success rate and low complication rate comparable to in-hospital

rates.<sup>103</sup> A number of factors may have contributed to the high quality of the emergency TI in the demanding Nordic prehospital setting. In an editorial published in the British Journal of Anaesthesia, Crewdson and co-authors proposed explanations such as the prehospital critical care being delivered by experienced consultants in Scandinavia, with a high level of training, standardized equipment and adherence to airway algorithms.

### **6.3 PREHOSPITAL ADVANCED AIRWAY RESCUE EQUIPMENT**

Prehospital TI is usually performed with a conventional laryngoscope. Challenges with TI have stimulated the development of indirect laryngoscopes. A key feature of video laryngoscopy is good glottic visualization without the need to align the oral and tracheal axis.<sup>104</sup> According to the Difficult Airway Society, video laryngoscopy offers an improved laryngeal view compared with direct laryngoscopy and is now established as a first choice or rescue technique for some anaesthetists.<sup>73</sup> In addition, all anaesthetists should have immediate access to a video laryngoscope and be trained how to use it.

Study III demonstrated that in the Nordic prehospital setting, the use of video laryngoscopes was common (41.6%) for the first attempt, even by experienced airway providers. The first pass success rate was better with video laryngoscopy compared with direct laryngoscopy (92.9% vs. 78.6%;  $0 < 0.01$ ). This finding is consistent with a recent meta-analysis investigating the use of video laryngoscopy by experienced anaesthetists.<sup>105</sup> However, study III showed that TI with video laryngoscopy was slower than conventional laryngoscopy (25 s vs. 20 s;  $p < 0.001$ ).

A frequently used prehospital rescue device is the optical indirect laryngoscope Airtraq<sup>®</sup>. In a difficult airway model manikin study, the Airtraq<sup>®</sup> showed a good first attempt success rate (84%) when used by experienced laryngoscopists. However, the corresponding real-life results from study I revealed a considerably lower (61%) TI success rate in difficult airways. Furthermore, study I showed that when Airtraq<sup>®</sup> was used by anaesthetists and nurse anaesthetists in the Nordic prehospital setting, the overall success rate was low (68%). Even though the Airtraq<sup>®</sup> TI success rate in study I was numerically higher than in a prehospital randomized Austrian trial (47%),<sup>64</sup> it was still unacceptably low for use as a prehospital rescue device.

In the case of failed TI, especially in a 'can't oxygenate' situation, scalpel cricothyroidotomy is the preferred rescue technique.<sup>73</sup> The need for prehospital surgical cricothyroidotomy was low (0.7%) in a UK physician-HEMS, and even lower for the anaesthetists in the study. This finding is supported by data from study III, in which the rate of surgical cricothyroidotomy was 0.3%.

## 6.4 ON-SCENE TIME DURING PREHOSPITAL ADVANCED AIRWAY

A systematic review of the influence of prehospital time on trauma patient outcomes demonstrated a benefit of fast transport for patients suffering from neurotrauma and haemodynamic instability following penetrating injuries. When TI was performed by the experienced airway providers in study III, the on-scene time was shorter (25 min) than reported in the UK (40 min), Australia (42 min) and Hungary (49 min).<sup>50 106 99</sup> These differences may be explained by both variations in patient characteristics and provider skills. In addition, the Nordic country practice of not using long challenge-response checklists, not using bougie on all TIs and no mandatory 360-degree patient access may have contributed to the short scene times without affecting the TI success rate. Short (22 min) on-scene times following RSI have been reported previously in the Norwegian anaesthetist-staffed HEMS.<sup>107</sup> The short on-scene times in study III may have benefited patients with time-critical conditions such as TBIs and uncontrolled internal haemorrhage.

Performing the prehospital TI inside the helicopter cabin decreased the on-scene time by 53.5 s ( $p=0.04$ ) compared with TI outside the helicopter in study IV. Some of gained time was due to a parallel instead of sequential workflow by the flight paramedic and HEMS physician, i.e., some TI preparations were performed during the time the patient was moved from the scene to the helicopter. In addition, the need to carry TI equipment back and forth to the scene was reduced. When performed by prehospital anaesthetists in study II and IV, the helicopter in-cabin TI success rate was high (100%), with good glottic visualization (CL 2 and 1) and subjective easy intubation (VAS 3 and 1). This might be explained by the interior of the helicopter representing a controlled and familiar environment, thus eliminating some of the complicating factors outside the helicopter.

The data describing in-cabin TI are limited and difficult to compare due to differences in provider background, training, cabin interiors and standards of care. Some authors suggest that in-cabin TI may be inappropriate, whereas others advocate that in-cabin RSI is safe without increases in failure or complication rates.<sup>93 95</sup> In a study of 102 inflight tracheal intubations, there was no decrease in success rate (98%) compared with 186 pre-flight tracheal intubations (96%).<sup>96</sup> However, clinical randomized studies are needed before recommending the concept of in-cabin TI.

## 6.5 LIMITATIONS

The major limitation of studies I and III is the non-randomized study design, for which reason the results should be interpreted with caution. Another limitation of studies I and III is the self-reporting design, which carries a risk of registration and recall bias. In addition, the studies were not designed to investigate either long-term complications or mortality related to tracheal intubation. The major limitation of studies II and IV is the experimental manikin

design. In all four studies I-IV, the competence and role of the important airway assistant are not sufficiently described.



## 7 CONCLUSION

Scientific support for prehospital TI is mainly derived from studies with observational methodologies, limiting the quality of the evidence. In addition, prehospital TI studies are characterized by substantial heterogeneity with regard to systems, provider background and methods. More research is needed to investigate how an optimal secured airway can be achieved. In the Nordic countries, prehospital TI is performed by very experienced airway providers, mainly anaesthetists. In this unique setting,

- The prehospital TI is performed with a high success rate and few complications, comparable to in-hospital standards. Compared with nurses, physicians have a higher TI success rate.
- The first-pass TI success rate may be higher with video laryngoscopy in comparison to direct laryngoscopy. However, Airtraq is not a suitable prehospital rescue device since it is associated with a low success rate.
- Prehospital TIs are performed rapidly with an associated short on-scene time, which may benefit patients with time-critical emergencies such as multitrauma and traumatic brain injuries.
- Binocular NVG in-cabin TI may be feasible. Based on experimental manikin studies, in-cabin TI can be rapidly and easily performed with a high success rate, both in the civilian Nordic and military setting. Further clinical studies are needed before recommending this approach.





## 8 FUTURE PERSPECTIVES

Even though RSI and prehospital TI are generally accepted for securing the airway of an unconscious patient, most prehospital TI studies have an observational approach, and the evidence for the procedure is limited. Hence, there is a need for large prospective randomized trials to thoroughly investigate the procedure. However, as prehospital TI is a complex intervention, performed in a variety of patient categories, by different providers, and in different systems, the effect of prehospital TI will likely be difficult to assess.

In prehospital advanced airway studies, there is substantial heterogeneity with regard to EMS system, provider competence and methods used. Several different European prehospital guidelines now state that prehospital emergency anaesthesia and TI should meet the same standards as in-hospital.<sup>81 82</sup> However, the advanced airway experience needed to perform unsupervised emergency anaesthesia differs among countries. In the Nordic countries, only anaesthetists and anaesthetist registrars perform unsupervised emergency anaesthesia. To better compare prehospital advanced airway management between different systems, an Utstein-style advanced airway template for uniform data reporting was developed.<sup>84</sup> Nevertheless, this template could not quantitatively differentiate between systems with intermediate and expert airway providers. A revision of the Utstein-style advanced airway template is now being developed, after which it will likely be possible to better compare systems with intermediate and expert airway providers.

The majority of prehospital advanced airway studies focus mainly on the TI success rate. Unfortunately, many studies omit aspects such as whether the TI has taken a very long time, shifted the focus from important circulatory resuscitation or results in an unacceptably long on-scene time. It is reasonable to believe that a long scene time per se is not beneficial for a highly unstable patient with major internal haemorrhaging or traumatic brain injury. Future prehospital TI studies should focus on the entire TI process, including the preparation time, on-scene time and post-TI ventilation. In addition, hard clinical endpoints should be analysed.



## 9 SUMMARY IN SWEDISH

Den rekommenderade metoden att åstadkomma fri och säker luftväg hos en medvetslös patient utanför sjukhus är genom en s.k. prehospital intubation. Vid intubationsproceduren förs en luftrörstub ner i luftstrupen så att en fri luftväg åstadkoms och avancerad konstgjord andning möjliggörs. Den prehospital miljön medför flera försvårande omständigheter, inklusive begränsad tillgång till luftvägshjälpmiddel och assistans samt miljömässiga utmaningar. Ett exempel på det senare är vid behov av intubation inuti en ambulanshelikopters trånga kabin. De nordiska länderna utgörs av både tät- och glesbefolkade områden med vanligtvis kallt subarktiskt klimat. I Norden utförs prehospital intubation nästan uteslutande av luftvägsexperter, tillika anestesi- och intensivvårdsläkare. Avhandlingens övergripande syfte var att undersöka prehospital intubation i Norden avseende utförare, lyckandefrekvens, intubationstid och luftvägstekniker.

Studie I: En retrospektiv studie av ambulansjournaler i Stockholm 2008-2012, där användningen av intubationshjälpmedlet Airtraq<sup>®</sup> undersöktes. 2453 patienter intuberades under studieperioden varav Airtraq<sup>®</sup> användes i 28 (1,1%) av fallen. Sextioåtta procent (19/28) av Airtraq<sup>®</sup> intubationsförsöken lyckades. När Airtraq<sup>®</sup> användes i samband med förväntat eller oväntat svår luftväg lyckades intubationen i 61 % (14/23) av fallen.

Studie II: En experimentell randomiserad crossover simulatorstudie på anestesi- och intensivvårdsläkare utförd i intubation inuti militärhelikopter-kabin i ljus eller mörker med mörkerkikare samt i akutrumsmiljö. Andelen lyckade intubationer var 100% i samtliga scenarier. Intubationstiden i helikopter-kabinen var kortare i ljus jämfört med i mörker med mörkerkikare (16,5 s jämfört 30,0 s;  $p=0,03$ ). Det var ingen tidsskillnad mellan intubation i ljus helikopter-kabin och akutrum (16,5 s jämfört 16,8 s;  $p=0,091$ ). Det förelåg ingen skillnad mellan stämbandsvisualisering (CL 2,0 jämfört 1,8;  $p=0,72$ ) eller upplevd intubationssvårighet (VAS 3,0 jämfört 2,8;  $p=0,24$ ) mellan ljus helikopter- och akutrumsmiljö.

Studie III: En prospektiv observationsstudie av prehospital intubation vid sex ambulanshelikoptrar och sex akutbilar i Norden mellan maj 2015 och november 2016. Data registrerades enligt det standardiserade Utstein-luftvägsforuläret. Under studieperioden intuberades 2028 patienter på grund av hjärtstopp (53,0%), andra medicinska orsaker (26,3%) och trauma (19,1%). Majoriteten (67,0%) av intubationerna utfördes av mycket erfarna personer som tidigare hade intuberat >2500 patienter. Andelen lyckade intubationer var 98,7% med 84,5% lyckade intubationer på första försöket och 10,9% komplikationsfrekvens. Medianintubationstiden var 25 s (interkvartilavstånd 15-30 s) och skadeplatstiden var 25 min (interkvartilavstånd 18-33 min). Andelen lyckade intubationer var högre bland läkare jämfört med sjuksköterskor (99,0% jämfört 97,6%;  $p=0,03$ ).

Studie IV: En experimentell randomiserad crossover simulatorstudie på intubation inuti eller utanför en helikopter-kabin. 14 anestesi- och intensivvårdsläkare utförde intubationerna. Andelen lyckade intubationer var 100% med samtliga intubationer lyckade på första försöket. Det förelåg ingen skillnad mellan stämbandsvisualisering (CL 1,0 jämfört 1,0;  $p=0,72$ ) men intubation

inuti helikopterkabinen upplevdes som lättare (VAS 1,0 jämfört VAS 2;  $p=0,02$ ). Skadeplatstiden blev kortare genom intubation i helikopterkabinen (266 s jämfört med 320 s;  $p=0,04$ ).

Sammanfattning: I Norden utförs prehospital intubation nästan uteslutande av mycket erfarna anesthesi- och intensivvårdsläkare. Med denna förutsättning sker de prehospitala intubationerna av sjukhuskvalité med en hög andel lyckade intubationer och få komplikationer. De prehospitala intubationerna sker snabbt med en kort skadeplatstid, vilket kan gynna patienter med tidskritiska tillstånd som okontrollerad inre blödning och traumatisk skallskada. Möjligen kan ännu kortare skadeplatstid uppnås genom konceptet med intubation i helikopterkabin. Andelen lyckade intubationer på första försöket är högre med videolaryngoskop jämfört med vanliga laryngoskop, men Airtraq är inte ett lämpligt indirekt laryngoskop. Fler randomiserade studier behövs för att med hög vetenskaplig kvalité kartlägga centrala aspekter på den prehospital avancerade luftvägshanteringen.

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