Prediction of difficult mask ventilation using a systematic assessment of risk factors vs. existing practice – a cluster randomised clinical trial in 94,006 patients

A. K. Nørskov,1,2 J. Wetterslev,2 C. V. Rosenstock,1 A. Afshari,3 G. Astrup,4 J. C. Jakobsen,2,5 J. L. Thomsen,6 L. H. Lundstrøm1 and Collaborators*

1 Resident, Associate Professor, Consultant, Department of Anaesthesiology, Nordsjællands Hospital, Hillerød, Denmark
2 Resident, Chief Physician, Consultant, Copenhagen Trial Unit, 3 Consultant, Juliiane Marie Centre, Rigshospitalet, Copenhagen, Denmark
4 Consultant, Department of Anaesthesiology and Intensive Care, Aarhus University Hospital, Aarhus, Denmark
5 Consultant, Department of Cardiology, Holbæk Hospital, Holbæk, Denmark
6 Resident, Department of Anaesthesiology, Herlev Hospital, Herlev, Denmark

Summary

We compared implementation of systematic airway assessment with existing practice of airway assessment on prediction of difficult mask ventilation. Twenty-six departments were cluster-randomised to assess eleven risk factors for difficult airway management (intervention) or to continue with their existing airway assessment (control). In both groups, patients predicted as a difficult mask ventilation and/or difficult intubation were registered in the Danish Anaesthesia Database, with a notational summary of airway management. The trial’s primary outcome was the respective incidence of unpredicted difficult and easy mask ventilation in the two groups. Among 94,006 patients undergoing mask ventilation, the incidence of unpredicted difficult mask ventilation in the intervention group was 0.91% and 0.88% in the control group; (OR) 0.98 (95% CI 0.66–1.44), p = 0.90. The incidence of patients predicted difficult to mask ventilate, but in fact found to be easy (‘falsely predicted difficult’) was 0.64% vs. 0.35% (intervention vs. control); OR 1.56 (1.01–2.42), p = 0.045. In the intervention group, 86.3% of all difficult mask ventilations were not predicted, compared with a higher proportion 91.2% in the control group, OR 0.61 (0.41–0.91), p = 0.016. The systematic intervention did not alter the overall incidence of unpredicted difficult mask ventilations, but of the patients who were found to be difficult to mask ventilate, the proportion predicted was higher in the intervention group than in the control group. However, this was at a ‘cost’ of increasing the number of mask ventilations falsely predicted to be difficult.

Correspondence to: A. K. Nørskov

Email: anderskehlet@hotmail.com
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*See Appendix for list of collaborators

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Introduction
Facemask ventilation is an essential component of airway management. Predicting airway management difficulties remains a challenge [1]. Better prediction may reduce morbidity and mortality by adequate allocation of relevant personnel and the use of appropriate equipment [2].

The 4th National Audit Project (NAP4) and major national anaesthesia societies recommend a pre-operative assessment of every patient’s airway [1, 3–5]. However, it remains unclear how this airway assessment should be performed and how it might relate to risk of difficult mask ventilation [6]. The incidence of difficult mask ventilation is ~2–6 in 300 [7–10]. Difficult mask ventilation has been shown to be associated with difficult intubation, and the incidence of combined difficult mask ventilation and difficult intubation is ~1 in 300 [9, 11]. Although rarely occurring, the ‘cannot intubate – cannot ventilate’ situation accounts for > 25% of all anaesthesia-related deaths [1]. However, few studies have investigated risk/predictive factors [7, 8, 10, 11]. Moreover, it has not been established that systematic prediction of difficult mask ventilation is beneficial. Because it is not easy to perform trials on rare, adverse events, the impact of these tools are therefore seldom tested [12], but cluster randomisation offers an effective means of study [13, 14].

We have previously reported the diagnostic accuracy of difficult mask ventilation prediction to be poor, with 94% of all difficult mask ventilations being unpredicted [9]. We hypothesised that by introducing a hospital-wide protocol, we could better predict difficult mask ventilation (and indeed, combined difficult mask ventilation and difficult intubation). Our main aim was to compare the effect of this systematic assessment protocol vs. existing practice (i.e. no fixed protocol).

Methods
The Difficult Airway Management Trial (DIFFICAIR) was a cluster randomised trial in which 28 Danish anaesthesia departments (each expected to recruit > 200 patients whose tracheas were intubated) were randomly allocated (matched 1:1 in equal proportions) to an ‘intervention’ group using systematic prediction of difficult airway management or a ‘control’ group that continued existing practice. All patients ≥ 15 years of age who had undergone attempts at mask ventilation were included. The departments were randomly assigned (computer generated) based on the proportion of unpredicted difficult intubations in 2011 (Danish Anaesthesia Database data < 2% or ≥ 2%). All Heads of Department provided written informed consent to trial participation before randomisation of their centre.

We conducted the trial from 1 Oct 2012 to 31 Dec 2013. The Simplified Airway Risk Index (SARI) was implemented as a systematic screening tool for assessing intubation difficulties [15, 16]. Elements of the SARI (BMI, jaw protrusion and Mallampati) have also been shown to be predictive of difficult mask ventilation. Four additional and independent risk factors for difficult mask ventilation were assessed in intervention departments (see below). We have addressed the impact of implementing a screening tool for difficult intubation in a separate publication [17], this current paper exclusively addresses the issues of predicting difficult mask ventilation and combined difficulties with mask ventilation and intubation. The two publications include overlapping patients in regard to those being both mask ventilated and tracheally intubated. However, this population, and its related outcome measures, has not previously been described.

The trial was approved by The Danish Data Protection Agency and was exempted from the ethical committee system since it was labelled a quality assurance project [16].

A detailed statistical analysis plan for the intubation part was published before data extraction [16, 18]. The statistical analyses used in this paper adhere to the same principles outlined for the intubation paper [17, 18]. Trial reporting adheres to the ‘CONSORT’ statement: extension to cluster randomised trials’ [19].

In the intervention group, all patients were airway-assessed using the defined predictors for difficult airway management: (1) facial beard [7, 8, 10, 11]; (2) snoring [7, 10]; (3) history of sleep apnoea [7, 8, 11]; (4) neck radiation changes [8, 11]; (5) mouth opening [15, 20]; (6) thyromental distance [11, 17, 21]; (7) modified Mallampati classification [7, 8, 11, 17, 21]; (8) neck movement [11, 15]; (9) ability to extend lower jaw [7, 11, 15]; (10) weight [15]; and (11) history of difficult intubation [15, 21]. Repeated educational sessions (tutorial aids, videos, posters, cognitive aids etc.) reinforced compliance with the policy. All variables were recorded pre-operatively and entered into the Danish Anaesthesia
The control departments continued existing standards for pre-operative airway assessment, which was left broadly to the individual anaesthetist’s discretion. In a survey conducted before the start of the trial, all departments stated that they had no departmental standards for assessing the risk of difficult mask ventilation [23]. These departments had between one to six risk factors for difficult intubation pre-printed on the anaesthesia record, thus encouraging some kind of personal pre-operative airway assessment [23]. None of the departments had specific risk factors for difficult mask ventilation pre-printed on the anaesthesia record. The control departments were not able to record (or view) any risk factors in the Danish Anaesthesia Database (see above).

Outcome assessment was based on data recorded in the Danish Anaesthesia Database, a well-integrated quality insurance database containing quantifiable indicators, covering the peri-operative period. Regardless of trial group, all anaesthetists had to tick the Yes/No boxes to answer two mandatory questions before anaesthesia regarding prediction of difficult mask ventilation and difficult intubation. Furthermore, the anaesthetists recorded an airway management plan pre-operatively (Fig. 1).

Before the trial began, the database was programmed so the intervention departments could record the pre-operative airway assessment consisting of the aforementioned eleven risk factors for difficult airway management in addition to the anaesthetist’s anticipation of mask ventilation and intubation difficulties (Yes/No). No risk factors could be recorded into the database in control departments. Immediately following airway management, the anaesthetists recorded the actual circumstances regarding mask ventilation and intubation (Fig. 1).

The anaesthetists graded mask ventilation as easy, difficult or impossible, which is a simplification of the grading scale originally proposed by Han et al. [24] (Fig. 1). In the Danish Anaesthesia Database, grades 1 and 2 from Han’s original scale are merged into grade 1 (easy), whereas Han’s grades 3 and 4 are respectively identical with the Danish Anaesthesia Database’s grade 2 (difficult) and 3 (impossible). Since past cohort studies have focused on difficult and impossible mask ventilation (Han’s grade 3 and 4), the results from this trial may be comparable [7, 8, 11, 24].

Patients were categorised as difficult to intubate in the case of three or more intubation attempts or failed intubation, regardless of technique; or, if a change in technique from direct laryngoscopy to an advanced technique, then difficulty was classed after two attempts (Fig. 1).

We regarded combined difficult mask ventilation and difficult intubation as ‘unpredicted’ if the anaesthetist had failed to predict either difficult mask ventilation or difficult tracheal intubation, or both.

The primary outcomes were: (1) the overall proportion of unpredicted difficult mask ventilation in intervention vs. control groups; (2) the overall proportion of easy mask ventilation, ‘false positives’ (these being patients predicted as difficult who turned out in fact to be easy; ‘false positives’).

The secondary outcomes were: (3) the proportion of all actual difficult mask ventilations that were unpredicted in the two groups; (4) for each of the intervention and control groups, the respective sensitivity; specificity; positive and negative predictive values; and positive and negative likelihood ratios.

Exploratory outcomes were: (5) the overall proportion of combined unpredicted difficult mask ventilation coupled with unpredicted difficult intubation; and (6) the overall proportion of combined unpredicted impossible mask ventilation coupled with unpredicted failed intubation.

The pre-trial sample size estimation was performed for the intubation part of the trial and based on the outcome ‘unpredicted difficult intubation’, as described in our previous papers [16–18]. After the
### Preoperative airway assessment

**- Control departments -**

A: The anaesthetist’s prediction of airway difficulties

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes or No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is facemask ventilation predicted to be difficult?</td>
<td></td>
</tr>
<tr>
<td>Is intubation by direct laryngoscopy predicted to be difficult?</td>
<td></td>
</tr>
</tbody>
</table>

**- Intervention departments -**

A: Predictors for difficult mask ventilation and difficult intubation

1. Facial beard  
2. Snoring  
3. History of sleep apnoea  
4. Neck radiation changes  
5. Mouth opening  
6. Thyromental distance  
7. Modified Mallampati class  
8. Neck movement  
9. Ability to protrude  
10. Body weight  
11. History of difficult intubation

B: The anaesthetist’s prediction of airway difficulties

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes or No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is facemask ventilation predicted to be difficult?</td>
<td></td>
</tr>
<tr>
<td>Is intubation by direct laryngoscopy predicted to be difficult?</td>
<td></td>
</tr>
</tbody>
</table>

### Scheduled airway management plan

In both groups one of the following options is chosen for each patient:

1. None / unknown
2. Spontaneous breathing
3. Mask ventilation
4. Laryngeal mask (any kind)
5. Intubation via direct laryngoscopy
6. Intubation via video laryngoscope
7. Intubation via flexible fiberoptic scope
8. Intubation via another method (e.g., Fastrach)
9. Tracheostomy under local anaesthesia
10. Already intubated or tracheotomised

### Actual airway conditions

In both groups actual airway management conditions were recorded for each patient

**Facemask ventilation**

Facemask ventilation is graded according to the following score. One of the below options is chosen in succession of the airway management procedure:

1. Easy facemask ventilation
2. Difficult facemask ventilation
3. Impossible facemask ventilation

Difficult facemask ventilation is defined as: inadequate, unstable or requiring two providers, with or without muscle relaxants. Impossible facemask ventilation is defined as: Unable to mask ventilate with or without muscle relaxant.

**Intubation**

Intubation is graded according to the following score. One of the below options is chosen in succession of the airway management procedure:

1. Minimum two intubation attempts - Only by direct laryngoscopy
2. Minimum two intubation attempts in which other intubation equipment (e.g., video laryngoscope) is used
3. These intubation attempts or more - Regardless of intubation method
4. Intubation failed despite attempting

Tracheal intubation by direct laryngoscopy is defined as unproblematic by a score = 1 and difficult at a score ≥ 2. Tracheal intubation by advanced intubation equipment (e.g., video laryngoscope) is defined as difficult at a score ≥ 3.

**Figure 1** Mandatory data registered in the Danish Anaesthesia Database. Registration of pre-operative airway assessment differed in the intervention and control departments.
trial, we performed power estimation for the mask ventilation part using ‘unpredicted difficult mask ventilation’ as the primary outcome. As we used cluster randomisation, further calculations were needed to account for the fact that within a cluster, observations tend to be correlated (i.e. non-independent). The sample size required thus depends on average cluster size and the degree of correlation within clusters, \( r \), also known as the intracluster correlation coefficient (ICC); we used a value of 0.002 [19].

Using the observed incidence of unpredicted difficult mask ventilation in the control group (0.9%), having 26 participating departments and an average cluster size of 3600 patients, we would be able to detect or reject

![Flow diagram of cluster and patient allocation](image-url)

**Figure 2** Flow diagram of cluster and patient allocation. DAD, Danish Anaesthesia Database.
a relative risk reduction of 33% with a power of 80%, accepting a risk of type-1 error of 5%. Therefore, the trial was powered to address what we considered a clinically relevant risk reduction. We expressed our main results in terms of an odds ratio, which is an index of the odds of experiencing the outcome (e.g. an unpredicted difficult mask ventilation) in the intervention group vs. the control group (with confidence intervals).

Similar to our previous paper, the analyses were carried out using generalised estimating equations in order to account for the design variables, such as the clustered nature of data and the stratification of departments into strata of high and low baseline incidence of unpredicted difficult intubation [25–27]. Using generalised estimating equations an adjusted odds ratio (OR) between the two groups were attained for relevant outcome measure. IBM SPSS Statistics, Version 22.0., Armonk, NY, USA were used for statistical analyses.

Results

Two control departments did not initiate the Danish Anaesthesia Database registration in time for the study and were excluded, giving a total number of 26 included clusters (15 intervention and 11 control departments) (Fig. 2).

Intervention departments included 46,804 patients, whereas the control departments included 47,202 patients. Baseline characteristics of clusters and patients are presented in Tables 1 and 2. In both groups we had complete data on all variables needed for all outcome measures. In intervention departments, the registration of all individual risk factors was complete in 69% of patients who underwent mask ventilation and 73% of patients who underwent both mask ventilation and tracheal intubation (only registered in intervention group).

The overall proportion of patients who were predicted difficult to mask ventilate was higher in the intervention group (n = 366; 0.78 (0.70–0.86)%) compared with the control group (n = 204; 0.43 (0.37–0.49)); OR was 1.51 (1.00–2.28), p = 0.049.

Concerning our primary outcome, difficult mask ventilation was unpredicted in 427 (0.91 (0.83–1.00)%) patients in the intervention group and 414 patients (0.88 (0.80–0.97)% in the control group (Fig. 3); OR 0.98 (0.66–1.44), p = 0.90 (Fig. 4).

The proportion of patients predicted being difficult to mask ventilate, but in fact found to be easy (‘falsely predicted difficult’) was 0.64 (0.57–0.72)% (n = 298) in the intervention group vs. 0.35 (0.30–

Table 1 Cluster-level summaries. Values are median (IQR [range]) or number (proportion).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention departments</th>
<th>Control departments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients attempted mask ventilated</td>
<td>2961 (1216–3653 [475–8994])</td>
<td>3620 (1491–6077 [305–10,472])</td>
</tr>
<tr>
<td>Number of patients attempted intubated and mask ventilated</td>
<td>1165 (303–1962 [53–5895])</td>
<td>2004 (162–2971 [74–4914])</td>
</tr>
<tr>
<td>Fraction of unpredicted difficult mask ventilation in patients attempted mask ventilated</td>
<td>0.8 (0.2–1.0 [0.0–1.4])</td>
<td>0.8 (0.1–0.9 [0.0–1.6])</td>
</tr>
<tr>
<td>Fraction of unpredicted easy mask ventilation in patients attempted mask ventilated</td>
<td>0.4 (0.2–0.7 [0.0–1.0])</td>
<td>0.3 (0.2–0.4 [0.0–0.6])</td>
</tr>
<tr>
<td>Fraction of combined unpredicted difficult mask ventilation and difficult intubation in patients attempted mask ventilated and intubated</td>
<td>0.2 (0.0–0.3 [0.0–0.5])</td>
<td>0.2 (0.0–0.3 [0.0–0.5])</td>
</tr>
<tr>
<td>Age; years</td>
<td>52 (47–55 [42–58])</td>
<td>52 (48–61 [41–65])</td>
</tr>
<tr>
<td>BMI; kg.m(^{-2})</td>
<td>25.3 (24.8–25.7 [23.8–25.9])</td>
<td>25.5 (25.1–25.7 [24.6–26.2])</td>
</tr>
<tr>
<td>ASA physical status</td>
<td>2 (1–2 [1–2])</td>
<td>2 (1–2 [1–3])</td>
</tr>
<tr>
<td>Private hospitals</td>
<td>4 (27%)</td>
<td>2 (18%)</td>
</tr>
<tr>
<td>Stratum ‘high’ (≥ 2% unpredicted difficult intubations at baseline, 2011)</td>
<td>6 (40%)</td>
<td>5 (45%)</td>
</tr>
<tr>
<td>Departments with Ear-Nose-Throat surgery</td>
<td>7 (47%)</td>
<td>6 (55%)</td>
</tr>
</tbody>
</table>
Of the patients who were found to be difficult to mask ventilate in the intervention group, 495 (1.06 (0.97–1.16)%) the proportion not predicted was 86.3 (83.0–89.0)% n = 427. The control group registered 454 (0.96 (0.88–1.05)%) difficult mask ventilations of which 414 (91.2 (88.2–93.5)%) were unpredicted; OR 0.61 (0.41–0.91), p = 0.016 (Fig. 4).

The sensitivity of the ability to correctly predict difficult mask ventilation was significantly higher in the intervention group (13.7%) vs. the control group.
Figure 3 Flow chart in patients in whom mask ventilation was attempted.
However, no statistically significant differences were detected for specificity, positive and negative predictive values, or positive and negative likelihood ratios between the two trial groups (Table 3).

In the intervention group, 22 patients (0.05 (0.03–0.07)% vs. 10 (0.02 (0.01–0.04)% in the control group had impossible mask ventilation and 18 of 22 vs. 9 of 10 were not predicted to be impossible in the intervention and control group, respectively.

We identified 44,337 patients who in whom tracheal intubation was attempted as who were also ventilated with a facemask; 22,380 in the intervention group and 21,957 controls. The proportion of patients who were difficult to intubate were 3.2 (2.9–3.4)% in the intervention group vs. 3.4 (3.2–3.7)% in the control group, and failed intubation occurred in 0.1% in both groups.

The proportion of patients who were difficult to mask ventilate among intubated patients was 1.6 (1.5–1.8)% vs. 1.5 (1.3–1.6)% in the intervention and control group, respectively. Thus, a higher proportion was difficult to mask ventilate in both groups, when identifying the patients who were also intubated. In the intervention group, 71 of 365 (19.5 (15.7–23.8)% who were difficult to mask ventilate were also difficult to intubate vs. 65 of 318 (20.4 (16.4–25.2)% in the control group (Fig. 5). Three of 365 (0.8%) vs. 4 of 318 (1.3%) also had a failed intubation, underlining an association between difficult mask ventilation and difficult/failed intubation in both groups. The incidence of combined difficult mask ventilation and difficult intubation was 0.3% in both groups. Of patients with combined difficulties 78.9 (68.0–86.8)% were unpredicted in the intervention group compared with 81.5 (70.5–89.1)% in the control group (Fig. 3), the OR between the groups was 0.76 (0.41–1.41), p = 0.39 (Fig. 6).

Discussion
Although implementation of a systematic predictive tool led to a higher rate for predicting difficult mask ventilation, there remained an equal proportion of unpredicted difficult mask ventilation in the intervention and control groups. Perhaps as a consequence of the higher prediction rate, the proportion of ‘falsely predicted difficult’ mask ventilations increased in the intervention group. However, of the patients who were found to be difficult to mask ventilate, the proportion predicted in the intervention group was higher than in the control group. This result is arguably the most important for airway management. Although the results for the intervention do not reach conventional thresholds for specificity, positive and negative predictive
values, safety rests on the avoidance of unpredicted difficult situations, as it is these that can lead to harm.

Moreover, our data revealed a 20% risk of difficult intubation in both groups when already faced with difficult mask ventilation, reconfirming the association found in earlier observational studies [9, 11].

This is probably the first randomised clinical trial addressing the effects of using systematic assessment of risk factors for difficult mask ventilation.

Even though all departments stated that they registered no risk factors for mask ventilation difficulties, it is important to emphasise that practice in the control group was not ‘no airway assessment at all’. If clinical practice for individual anaesthetists in the control group was of high quality then it may have approximated practice in the intervention centres by default, contributing to a dilution of the intervention effect.

Our trial has a number of other potential limitations. First, in the intervention group, it is possible practitioners were ‘sensitised’ to the possibility of difficult mask ventilation, so reporting of this was higher as a consequence. Second, our sample size estimation was based on a previous paper, which used the incidence of unpredicted difficult intubation, and not difficult mask ventilation. However, considerably more patients were mask ventilated than intubated during the trial period, hereby increasing the number of patients included and the statistical power for this part of the trial. Power estimation suggested that the trial had a power of 80% to detect or reject a 33% relative risk difference in the numbers of unpredicted difficult mask ventilations between the groups. Even though the number of patients in each trial group was almost perfectly balanced, the case-mix was slightly uneven. However, our use of generalised estimating equation modelling took this into account.

We adjusted our results for use of neuromuscular blocking agents (NMB). However, the mask ventilation

Table 3 Accuracy of predicting difficult mask ventilation and combined difficult mask ventilation and intubation. Values are number (proportion).

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 46,804 95% CI</td>
<td>n = 47,202 95% CI</td>
</tr>
<tr>
<td>Prediction of difficult mask ventilation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total patients</td>
<td>46,804</td>
<td>47,202</td>
</tr>
<tr>
<td>Predicted difficult (positive)</td>
<td>366 (204)</td>
<td></td>
</tr>
<tr>
<td>True positive (predicted and actually difficult)</td>
<td>68 (40)</td>
<td></td>
</tr>
<tr>
<td>False positive (predicted difficult, but actually easy)</td>
<td>298 (164)</td>
<td></td>
</tr>
<tr>
<td>Predicted easy (negative)</td>
<td>46,438</td>
<td>46,998</td>
</tr>
<tr>
<td>True negative (predicted easy and actually easy)</td>
<td>46,011 (46,584)</td>
<td></td>
</tr>
<tr>
<td>False negative (predicted easy and actually difficult)</td>
<td>427 (414)</td>
<td></td>
</tr>
<tr>
<td>Sensitivity</td>
<td>13.7% (10.9–17.2)</td>
<td>8.8% (6.4–11.9)</td>
</tr>
<tr>
<td>Specificity</td>
<td>99.4% (99.3–99.4)</td>
<td>99.6% (99.6–99.9)</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>18.6% (14.8–23.0)</td>
<td>19.6% (14.5–25.9)</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>99.1% (99.0–99.2)</td>
<td>99.1% (99.0–99.2)</td>
</tr>
<tr>
<td>Positive likelihood ratio</td>
<td>21.3 (16.7–27.4)</td>
<td>25.1 (18.0–35.0)</td>
</tr>
<tr>
<td>Negative likelihood ratio</td>
<td>0.9 (0.8–0.9)</td>
<td>0.9 (0.9–0.9)</td>
</tr>
<tr>
<td>Prediction of difficult mask ventilation and intubation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total patients</td>
<td>22,380</td>
<td>21,957</td>
</tr>
<tr>
<td>Predicted DMV and/or DTI (positive)</td>
<td>956 (646)</td>
<td></td>
</tr>
<tr>
<td>True positive (predicted and actually difficult)</td>
<td>15 (12)</td>
<td></td>
</tr>
<tr>
<td>False positive (predicted difficult, but actually easy)</td>
<td>941 (634)</td>
<td></td>
</tr>
<tr>
<td>Predicted easy MV and TI (negative)</td>
<td>21,424 (21,311)</td>
<td></td>
</tr>
<tr>
<td>True negative (predicted easy and actually easy)</td>
<td>21,368 (21,258)</td>
<td></td>
</tr>
<tr>
<td>False negative (predicted easy and actually difficult)</td>
<td>56 (53)</td>
<td></td>
</tr>
<tr>
<td>Sensitivity</td>
<td>21.1% (12.7–32.7)</td>
<td>18.5% (10.3–30.4)</td>
</tr>
<tr>
<td>Specificity</td>
<td>95.8% (95.5–96.0)</td>
<td>97.1% (96.8–97.3)</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>1.6% (0.9–2.6)</td>
<td>1.9% (1.0–3.3)</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>99.7% (99.7–99.8)</td>
<td>99.7% (99.7–99.8)</td>
</tr>
<tr>
<td>Positive likelihood ratio</td>
<td>5.0 (3.2–7.9)</td>
<td>6.4 (3.8–10.7)</td>
</tr>
<tr>
<td>Negative likelihood ratio</td>
<td>0.8 (0.7–0.9)</td>
<td>0.8 (0.7–0.9)</td>
</tr>
</tbody>
</table>

CI, confidence intervals; DMV, difficult mask ventilation; DTI, difficult tracheal intubation.
Figure 5  Flow chart of results of patients in whom mask ventilation and tracheal intubation was attempted.
The overall proportion of unpredicted difficult mask ventilation was not reduced in the intervention group; the proportion of unpredicted difficulties remained very high (86% and 91% in the two groups). There remains a challenge to improve the diagnostic accuracy of airway prediction.

Acknowledgements
The authors would like to thank the Danish Anaesthesia Database and the participating departments.

Competing interests
Before the trial began, a peer-reviewed protocol was published and made available on http://www.clinicaltrials.gov (NCT01718561) [16]. No authors declare any financial relationships with any organisations that might have an interest in the submitted work or other relationships or activities that could appear to have influenced the submitted work. AN received research grants from the TRYG foundation as part of his PhD study for the submitted work. The trial was funded by independent grants from the TRYG foundation; Nordsjællands Hospitals research council; the National Research Council of Denmark; the Capital Regions funds for research; and the DASAIMs fund. The funding entities had no influence on the trial design, conduct or reporting. The research group is independent from the funders.

References

### Appendix

#### List of collaborators

M. Böttger, Centre of Head and Orthopaedics, Rigshospitalet, Copenhagen, Denmark; M. Ellekivi, Juliane Marie Centre, Rigshospitalet, Copenhagen, Denmark; B. M. B. Schousboe, Neuroscience Centre, Rigshospitalet, Copenhagen, Denmark; A. Horn, Consultant, Department of Anaesthesiology, Frederiksborg Hospital, Frederiksborg, Denmark; K. Lorentzen, Department of Anaesthesiology, Glostrup Hospital, Glostrup, Denmark; M. H. Madsen, Department of Anaesthesiology, Nordsjællands Hospital, Hillerød, Denmark; J. S. Knudsen, Department of Anaesthesiology, Kolding Hospital, Kolding, Denmark; B. K. Thisted, Department of Anaesthesiology, Copenhagen Private Hospital, Lyngby, Denmark; S. Estrup, Department of Anaesthesiology, Nykøbing Falster Hospital, Nykøbing Falster, Denmark; H. B. Mieritz, Department of Anaesthesiology, Aabenraa Hospital, Aabenraa, Denmark; T. Klesse, Department of Anaesthesiology, Sonderborg Hospital, Sonderborg, Denmark; H. J. Martinussen, Department of Anaesthesiology, Private Hospital Kollund, Kollund, Denmark; A. G. Vedel, Heart Centre, Rigshospitalet, Copenhagen, Denmark; R. Maaløe, Department of Anaesthesiology, Bispebjerg Hospital, Copenhagen, Denmark; K. B. Bosling, Department of Anaesthesiology, Roskilde Hospital, Roskilde, Denmark; P. R. C. Kirkegaard, Department of Anaesthesiology, Næstved Hospital, Næstved, Denmark; C. R. Ibáñez, Department of Anaesthesiology, Haderslev Hospital, Haderslev, Denmark; G. Aleksandroviciute, Department of Anaesthesiology, Thy-Mors Hospital, Thisted, Denmark; L. S. Hansen, Department of Anaesthesiology, Lillebælt Hospital, Vejle, Denmark; T. Mantoni, Abdominal Centre, Rigshospitalet, Copenhagen, Denmark