

# Prediction of difficult airway management. The Simplified Airway Risk Index vs. standard clinical airway assessment on the incidence of unanticipated difficult airway management

## Design and rationale for: The prediction of Difficult Airway management trial: The DIFFICAIR trial - a cluster randomized trial on 70.000 patients

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### Background and aims

Unanticipated difficult airways are dreaded amongst anaesthesiologists. Better prediction of unanticipated difficult airways can reduce its morbidity and mortality, and better prediction might be obtainable.

Pre-operative airway assessment (AA) in Denmark is based on a non-specific clinical assessment. Systematic, evidence-based and consistent airway assessment may reduce the incidence of unanticipated difficult airway management (AM).

By assessing multiple predictors for difficult AM, the predictive value of the assessment increases. The Simplified Airway Risk Index (SARI) is a multivariate risk score for predicting difficult intubation (DI).

Aims: To compare the use of the SARI with a non-specified clinical AA on predicting DI and to identify predictors for difficult mask ventilation in order to design a risk score for difficult mask ventilation (DMV).

### Material and Methods

We cluster randomized<sup>1</sup> 28 Danish departments of anaesthesia to AA either by the SARI (intervention) or by usual non-specific AA (controls). Data from patients' pre-operative AA are registered in the Danish Anaesthesia Database (DAD). Objective scores for intubation and mask ventilation grade the severity of AM. The accuracy of predicting DI and DMV is measured for each group.

Primary outcome measure: The fraction of unanticipated DI.

Sample size: The fraction of unanticipated DI in Denmark is 1.87%. With a stratified randomization, type 1 error risk of 5% and a power of 80%, 30 departments are required to detect or reject a 30% relative risk reduction equalling an NNT of 180.

Sample size estimation is adjusted for the study design and based on standards for randomization on cluster-level<sup>2</sup>. With an average cluster size of 2.500 intubated patients, 70.000 patients will be enrolled over a 1-year trial period.

DAD is programmed so that registration of the SARI and predictors of DMV are mandatory for the intervention group but invisible to controls.

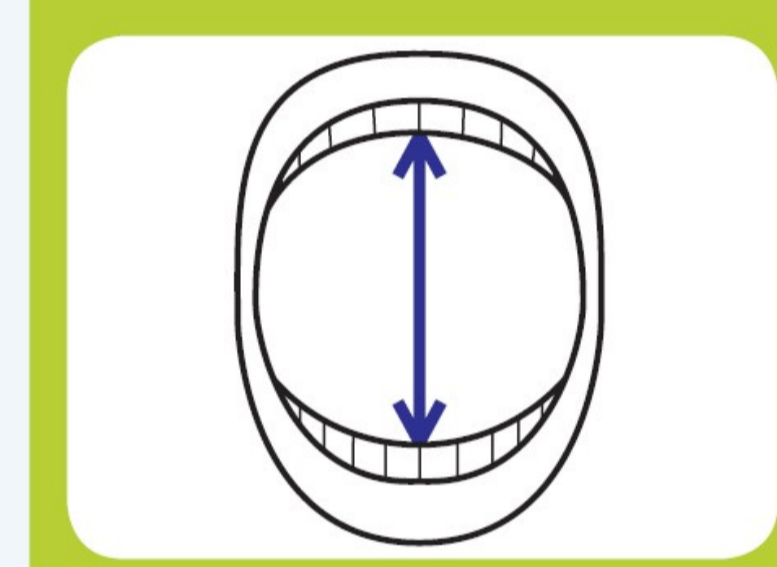
Investigators are appointed in all departments. A tutorial film, printed material for physicians in the intervention group and repeated teaching of AA and DAD registration are in place to ensure high and uniform registration standards.

### Discussion

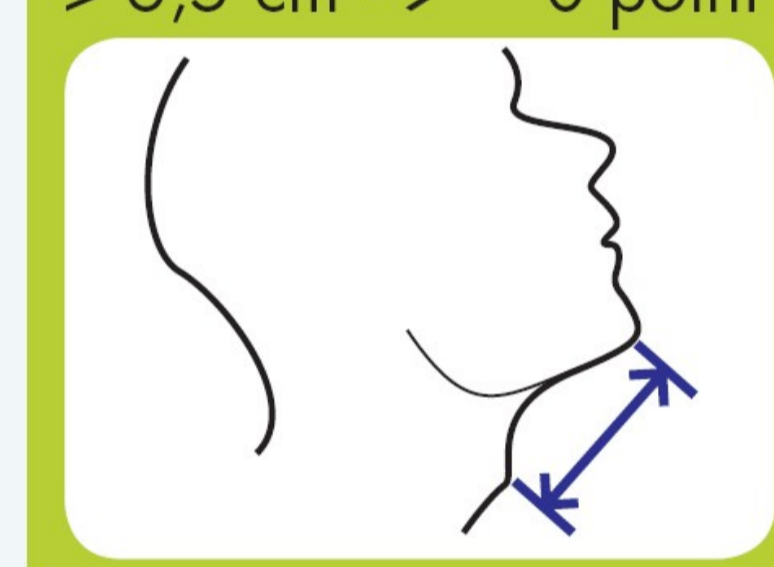
It is innovative to use a national clinical database as the basis for a randomized clinical trial. The method can serve as a precedent for implementation of evidence-based recommendations and database registration.

### Modificeret Simplified Airway Risk Index SARI

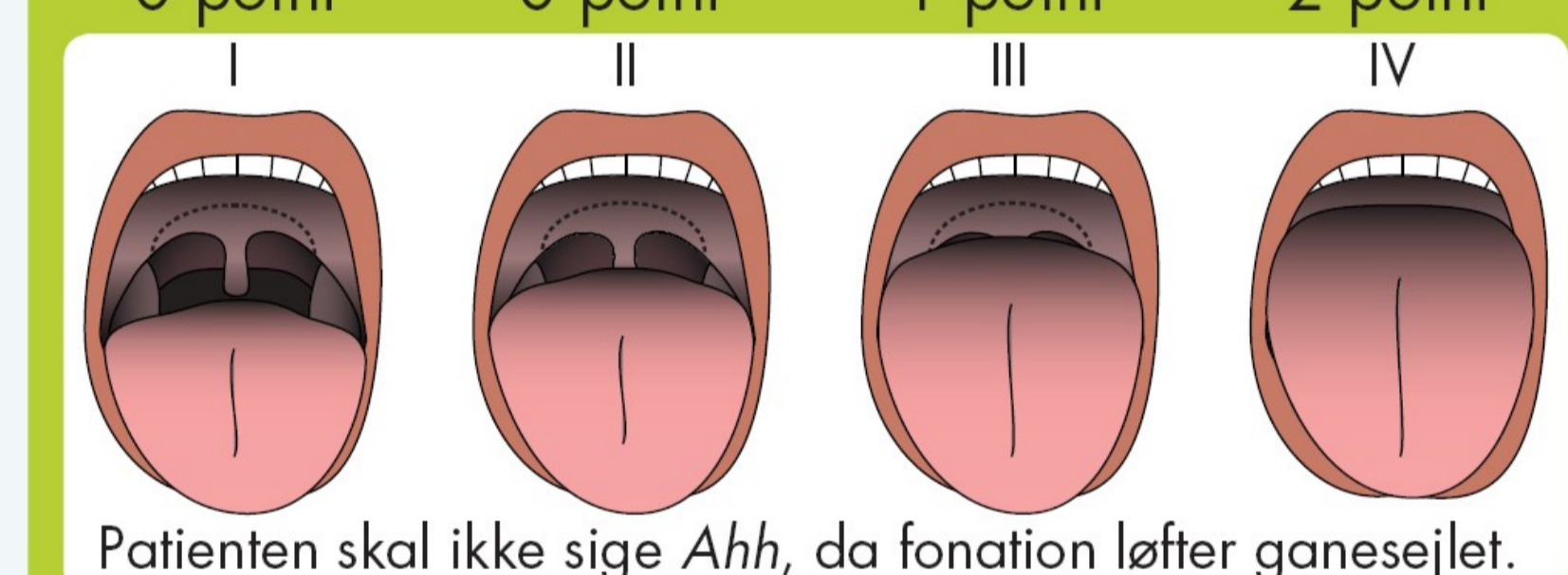
**Mundåbning**  
< 4 cm → 1 point  
≥ 4 cm → 0 point



**Thyromental afstand**  
< 6,0 cm → 2 point  
6,0-6,5 → 1 point  
> 6,5 cm → 0 point

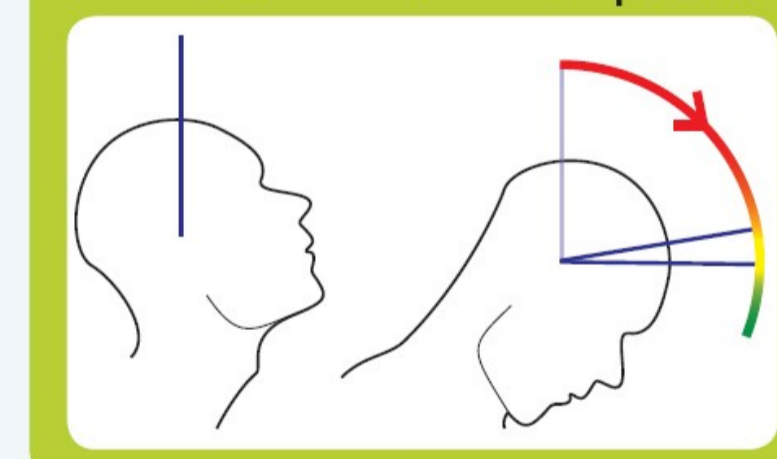


**Mallampati**  
0 point I 0 point II 1 point III 2 point IV

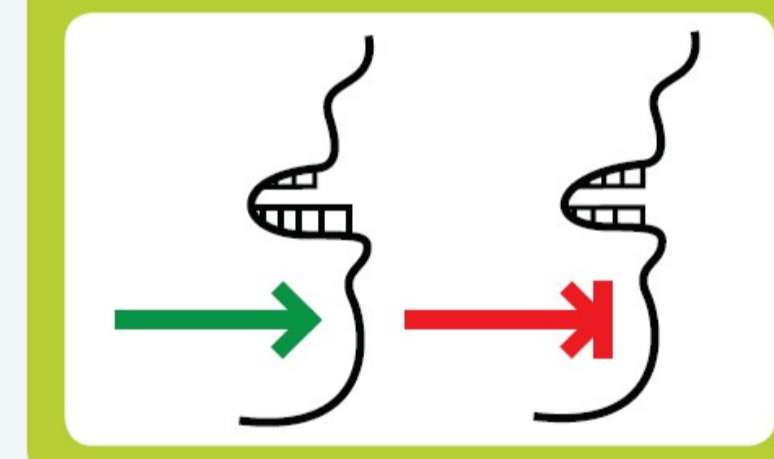


Patienten skal ikke sige Ahh, da fonation løfter ganesejlet.

**Nakkebevægelighed**  
< 80° → 2 point  
80-90° → 1 point  
> 90° → 0 point



**Underbid**  
Ja → 0 point  
Nej → 1 point



**Kropsvægt**  
< 90kg → 0 point  
90-110kg → 1 point  
> 110kg → 2 point

**Tidl. vanskelig intubation**  
Ja, sikkert → 2 point  
Mulig → 1 point  
Nej → 0 point

Point fra hvert punkt summeres til SARI-scoren.  
Score ≥ 4 indikerer ifølge Simplified Airway Risk Index vanskelig intubation ved direkte laryngoskopi.

### Conclusion

The trial will forward understanding of how to predict and reduce unanticipated DI and DMV and how to produce evidence-based recommendations for airway assessment and clinical database development.