Cuff-leak test for the diagnosis of upper airway obstruction in adults: a systematic review and meta-analysis

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CRD summary
A positive cuff-leak test (no leak) indicated a high risk of upper airway obstruction, but the presence of a leak did not rule out an obstruction, nor reintubation. The data were poor and the analysis was weak. The conclusions were reasonable, given the high estimates of specificity in most studies, but should be viewed cautiously.

Authors' objectives
To assess the accuracy of the cuff-leak test in diagnosing an upper airway obstruction secondary to laryngeal oedema in adults and in predicting reintubation secondary to upper airway obstruction.

Searching
MEDLINE, EMBASE, CINAHL, CANCERLIT, Pascal Biomed, ACP Journal Club, the Cochrane Library, DARE, Current Contents, and Web of Science were searched to December 2008. No language restrictions were applied and the search terms, including methodological terms for diagnostic accuracy studies, were reported. Abstracts, conference proceedings and review articles were handsearched for further studies.

Study selection
Studies with more than 50 patients, which assessed the diagnostic accuracy of the cuff-leak test for upper airway obstruction secondary to laryngeal oedema and/or reintubation due to upper airway obstruction, were eligible for inclusion. Included studies were required to report sufficient data to construct two-by-two contingency tables (the numbers of true positive, false negative, false positive, and true negative results).

Study populations included both medical and surgical patients and the mean age of participants, where reported, was between 59 and 71 years. The mean number of days intubated, where reported, ranged from 3.5 to 13. The method of assessing a leak, criteria for a positive cuff-leak test, and method of diagnosing upper airway obstruction (or reference standard used) varied across studies, and these were described in full for each study.

Two reviewers independently assessed studies for inclusion.

Assessment of study quality
The quality of the included studies was assessed by two reviewers, using a checklist based on the 14-item Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool. The quality of the methods was reported as a total score (maximum 28), which appeared to be the sum of the scores of both reviewers.

Data extraction
Data were extracted to calculate the sensitivity and specificity and positive and negative likelihood ratios, with 95% confidence intervals, for each study. They were extracted separately for the diagnosis of upper airway obstruction and the prediction of reintubation. The mean and standard deviation of the absolute volume of leak (mL), in cases of obstruction compared with no obstruction, were also extracted.

Three reviewers independently extracted data and any disagreements were resolved by consensus.

Methods of synthesis
Pooled estimates of the sensitivity and specificity, positive and negative likelihood ratios, and diagnostic odds ratios, with 95% confidence intervals, were calculated using DerSimonian and Laird's random-effects model. Separate estimates were calculated for the diagnosis of upper airway obstruction and for the prediction of reintubation.
The threshold effect (the effect of using different cut-off points on the estimates of diagnostic performance) was assessed using the Littenberg and Moses method and summary receiver operating characteristic curves were presented. The between-study heterogeneity was assessed using the Cochran Q and the $I^2$ statistics. Meta-regression was used to assess the effect of study quality on the estimates of diagnostic performance.

Publication bias was assessed visually using funnel plots and statistically using the Egger test.

**Results of the review**

Eleven studies, with a total of 2,303 participants, were included. The median QUADAS score was 12 points (interquartile range 9 to 14), out of a maximum of 28 points.

**Diagnosis of upper airway obstruction** (nine studies): Obstruction was defined, in eight studies, as the presence of an inspiratory stridor and, in one study, as laryngeal oedema observed in a fibreoptic bronchoscopy. The leak cut-off value was different in every study, but no threshold effect was detected. The overall incidence of upper airway obstruction was 6.9% (range 0.6 to 36.8). The pooled estimate of sensitivity was 0.56 (95% CI 0.48 to 0.63) and the pooled estimate of specificity was 0.92 (95% CI 0.90 to 0.93). The pooled estimate of positive likelihood ratio was 5.90 (95% CI 4.00 to 8.69) and the pooled estimate of negative likelihood ratio was 0.48 (95% CI 0.33 to 0.72). There was significant between-study heterogeneity for all measures. The pooled diagnostic odds ratio was 18.78 (95% CI 7.36 to 47.92) and regression analysis showed no significant relationship between the QUADAS score and diagnostic odds ratio.

**Prediction of reintubation** (three studies): The overall incidence of reintubation was 7%. The pooled estimate of sensitivity was 0.63 (95% CI 0.38 to 0.84) and the pooled estimate of specificity was 0.86 (95% CI 0.81 to 0.90). The pooled estimate of positive likelihood ratio was 4.04 (95% CI 2.21 to 7.40) and the pooled estimate of negative likelihood ratio was 0.46 (95% CI 0.26 to 0.82). There was significant between-study heterogeneity in the estimates of specificity. The pooled diagnostic odds ratio was 10.37 (95% CI 3.70 to 29.13).

Tests suggested the presence of publication bias.

**Authors' conclusions**

Despite limitations in the data, a positive cuff-leak test (absence of a leak) indicated a high risk of upper airway obstruction. The presence of a detectable leak did not rule out an upper airway obstruction, nor the need for reintubation.

**CRD commentary**

This review addressed a clearly stated research question and defined some inclusion criteria; the reference standard used to determine a diagnosis of upper airway obstruction was not defined and varied across studies. A range of sources were searched, without language restrictions, to identify relevant studies. The search terms included methodological descriptors designed to identify diagnostic accuracy studies, but the use of these terms can reduce the sensitivity of searches and may result in the omission of relevant studies. Measures to reduce error and bias were reported throughout the review process. The quality of included studies was assessed and its impact upon accuracy estimates was investigated, but the quality assessment generated an overall score and this method has been shown to be unreliable. The use of overall scores to assess the impact of study quality on the results may mask the effects of individual components of study quality. It was clear from the summary receiver operating characteristic plot that there was considerable heterogeneity in the diagnostic performance characteristics reported by studies and the generation of pooled estimates was, therefore, not informative. The authors' highlighted some of the limitations of their review.

The conclusions were a reasonable interpretation of the data (estimates of specificity from individual studies were mainly over 90% and high specificity indicates utility in ruling-in the target condition), but should be viewed with caution given the limitations described.

**Implications of the review for practice and research**
Practice: A positive cuff-leak test (absence of a leak) should alert the clinician to a high risk of upper airway obstruction, but the presence of a detectable leak should not rule out an upper airway obstruction, nor the need for reintubation.

Research: The authors made no recommendations for future research.

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