



Critically Appraised Topic (CAT) 

In non-ventilated patients with tracheostomy, there are mixed results on whether aspiration of food or fluid is exacerbated or increased by the presence of an inflated cuff. There were no studies in mechanically ventilated patients that answered the clinical question. In the non-ventilated cohort two small studies were identified, one suggested an increased risk, the other reported no increased risk in aspiration with cuff up when evaluated on MBS. We are not able to conclusively report either way on whether cuff status increases the risk of aspiration.

2. Clinical [PICO] Question [patient/problem, intervention, (comparison), outcome]:  
In patients with a tracheostomy (+/- mechanical ventilation), does an inflated cuff exacerbate / increase aspiration of food or fluids at the level of the vocal folds compared to a deflated cuff?

3. Search Terms/Systems: Medline and Google Scholar  
Search terms: 'Tracheostomy', 'Swallowing/Dysphagia' and 'cuff' 2000 onwards  
  
Criteria for including an article: Must compare aspiration status via instrumental assessment in the same tracheostomised patient fed under both conditions - cuff up and down.

4. Quantity of the evidence based:  
Number of papers identified: 6 Number of suitable papers actually capped: 2

5. Overall level of the evidence base: (number of studies according to each NHMRC level)  
I      II      III-1      III-2      III-3      IV 2

6. Nature the evidence base: (number of feasibility, efficacy and effectiveness studies)  
Feasibility      Efficacy 2 Effectiveness     

7. Overall findings from the evidence-base are:  
 compelling       suggestive       equivocal  
  
Comments...  
Two level 4 studies with reasonable study design were found to answer the clinical question, unfortunately they contradict each other in results.



**8. Results:** (including comment on the quality of the studies across the evidence based – which may include a summary of SpeechBITE ratings, comments on limitations in participant numbers and /or design)

- **Different findings regarding impact of cuff status and aspiration risk**
  - Only two studies answered clinical question (Davis et al, 2002, and Suiter et al, 2003). These both had small sample sizes (12 and 14 participants respectively) and opposing overall findings, making it difficult to draw conclusions regarding the impact of cuff status on aspiration risk.
  - Davis et al - found that feeding with cuff inflation resulted in 2.7 times higher rate of aspiration than feeding with cuff deflated (i.e. 17.8% vs. 6.5%) however this was not statistically significant (considered 'nearly' statistically significant at  $p=0.0625$ ).
  - Suiter et al - found cuff status had no effect on penetration or aspiration
- **Use of instrumental assessment, blinding of assessors, rating of aspiration**
  - Both studies used MBS to assess swallow function and assessors (Suiter et al – 2 x speech pathologists, Davis et al – 1 x radiologist) were blinded to cuff status when interpreting the MBS.
  - Different scales were used to evaluate aspiration (Suiter et al - Rosenbek's 8-point PAS, Davis et al - 5-point scale focused on amount of aspiration +/- cough). PAS tool is validated, other scale more subjective and ? relevance to practice/validity of tool.
  - Both studies described the need for instrumental assessment for tracheostomised patients due to rates of silent aspiration (Davis et al – 73% of aspiration was silent, Suiter et al – 'majority' of aspiration was silent)
- **Potential for selection bias within inclusion criteria/participants and generalisation of results**
  - The types of patients selected for inclusion in the studies may have impacted the results and limits the ability to generalise the results.
  - In one study, participants were included as they were considered ready for oral intake trials (Davis et al), compared with the other study where participants were included due to suspected oropharyngeal dysphagia with at least one occurrence of aspiration during an initial MBS with cuff deflated (Suiter et al).
  - The two studies focused primarily on patients with a tracheostomy admitted for respiratory related reasons, although some participants were admitted with closed head injuries or sepsis/multiorgan failure. Suiter et al excluded those with history of stroke, H+N cancer, or surgery to upper aerodigestive tract, limiting the ability to generalise the results to other typical tracheostomised caseloads.
  - All participants in both studies had been weaned from the ventilator, limiting generalisation of results to ventilator dependent populations
- **Impact of food/ fluid consistency and aspiration**
  - The two studies used different protocols regarding food and fluids trialled, and had opposing results in regards to which consistencies were more likely to be aspirated.
  - Suiter et al – compared 2 puree and 2 thin fluid boluses. Found PAS score was significantly better (lower) for puree than liquid boluses under both cuff conditions
  - Davis et al – compared thin, thick, puree and solid boluses. Found thick fluid and puree had higher risk of aspiration than thin under the cuff up condition (statistically significant  $p=0.025$ )
- **Methodology comments**
  - Variable methodology make the studies difficult to compare
  - Davis et al study provides limited information regarding methodology and important patient factors (e.g. type of tracheostomy, cannulation days, non-oral nutrition, inter-rater and intra-rater reliability, order/timing of cuff up/cuff down status, amounts of consistencies trialled, previous SP intervention) making replication difficult
- **Other findings of interest**
  - Suiter et al also compared a third condition with cuff inflation and deflation, i.e. placement of one-way speaking valve. PAS score was significantly lower (better) with one-way valve placement compared to cuff inflation. PAS score was significantly lower (better) for liquids with one-way valve placement compared to cuff deflation but no effect with puree bolus between these conditions.
  - Suiter et al also examined a range of swallow duration measures, residue (3-point scale), and hyolaryngeal excursion and compared these across the three conditions
  - Davis et al found that cuff status was an independent predictor of aspiration (statistically significant,  $p=0.032$ )
- **Exclusion of other studies**
  - A number of studies were not considered appropriate for inclusion in the CAT however did investigate swallowing in tracheostomised patients with cuff inflation. Some of the reasons for exclusion include:
    - Study did not compare swallow function with cuff inflation and cuff deflation in the same patient
    - Study did not assess aspiration via instrumental assessment



### 9. Recommendations:

Is *evidence* from current clinical practice the same as clinical bottom-line?

- Yes – Some therapists are feeding with the cuff up, others are not. Evidence is equivocal inferring that clinicians are making individual clinical decisions. More research and clinical practice evidence would be helpful to guide clinicians in decision making in this cohort*

### 10. Application to practice (when change has been indicated): n/a

In light of the summary comments from individual CAPS about relevance of the research to practice, check which of the following applies:

- Change is needed, and it is possible** – briefly state what needs to change, and, how change could be implemented and evaluated.
- Change is needed, but it is not possible** – dot point ideas to address barriers, or, state why change is not possible, and, when the issue will be re-considered.

**Appraised By/Clinical group: Tracheostomy and Critical Care  
Evidence Based Practice and Discussion Group**

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