*i*CAHE JC Critical Appraisal Summary

Journal Club Details

Journal Club	Lyell McEwin Hospital
JC Facilitator	Nicolette Varvounis
JC Discipline	Speech Pathology

Review Question/PICO/PECO

P adults in the acute setting

I laryngeal cough reflex testing for laryngeal aspiration

C Oral trials only versus laryngeal cough reflex testing and oral trials

O dysphagia

Article/Paper

Miles A, Zeng ISL, McLauchlan H, Huckabee ML (2013) "Cough Reflex Testing in Dysphagia Following Stroke: A Randomized Controlled Trial" *J Clin Med Res* 2013;5(3):222-233.

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Article Methodology:	Randomised Controlled Trial
Journal Club Meeting on:	05/09/2013

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Ques No.	Yes	Can't Tell	No	Comments
1	✓			***Did the study ask a clearly focused question?*** This study aimed to assess the utility of cough reflex testing (CRT) for reducing pneumonia in acute stroke patients.
2	✓			***Was this a randomised controlled trial and was it appropriately so?*** The authors are looking at the ability of an intervention (cough reflex testing) to change an outcome (reduce pneumonia in stroke patients). Thus an RCT is an appropriate study design to do so. Is it worth continuing? Yes
3	✓			***Were participants appropriately allocated to intervention and control groups?*** Participants were randomly assigned to the control group or the experimental group based on a simple randomisation procedure using one computer-generated random numbers list held in the research office remote from the study environments. Participating clinicians at each research site telephoned the research office after gaining consent from each patient and were immediately given a randomization assignment to either the control group or the experimental group.
4			✓	***Were participants, staff and study personnel 'blind' to participants study group?*** A non-blinded study design was unavoidable for patients, the ward clinicians, multi-disciplinary team and the researcher collecting the outcome data. This is because it was essential that the results of the cough reflex test were incorporated into management decisions in order to translate to change in outcomes. Documentation of cough reflex test results in a patient's clinical notes was therefore an integral component of the protocol. The research office providing the randomization code was blinded to research site, clinician and any patient details.
5	✓			***Were all of the participants who entered the trial accounted for at its conclusion?*** The authors don't report any drop outs during the course of their study.

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6	✓			***Were the participants in all groups followed and data collected in the same way?*** For those in the control group, clinical swallowing evaluation was executed as defined by local clinical protocols. This involved a case history, cognitive/communication screen, cranial nerve examination and observation of oral ingestion of foods and fluids. For participants in the experimental group, the standard evaluation was augmented with the inclusion of CRT prior to oral trials. Eight hours of training, protocols, procedural flow charts and management guidelines were provided to the clinicians who were involved with data collection. The CRT was administered using a PulmoMate Compressor/ Nebuliser with a predetermined free-flow output of 8 litres per minute and a restricted flow output of 6.6 litres per minute. The primary outcome measure was the proportion of patients with confirmed pneumonia within 3 months post recruitment. Secondary patient outcome measures included length of acute hospital stay in days and the percentage of patients with readmissions for chest infection within 3 months post recruitment to the study.
7	✓			***Did the study have enough participants to minimise the play of chance?*** Yes. The authors conducted an A priori minimal sample size of 268 participants (134 per experimental group) was calculated for an estimated effect size of 0.4 at the 0.05 significance level to achieve 90% statistical power.
8				***How are the results presented and what is the main result?*** The results are presented statistically with p values, confidence intervals and odd ratio. They are demonstrated in graphs and tables. The main results indicates no significant differences between groups in pneumonia rate (P = 0.38) or mortality (P = 0.15). Results of CRT were shown to influence diet recommendations (P < 0.0001) and referrals for instrumental assessment (P <0.0001).
9				***How precise are these results?*** The p values are very low which indicates that the results are very significant. Confidence intervals reported are quite wide which triggers thought as to whether the decision to use this intervention would be the same at the upper confidence limit as at the lower confidence limit?
10				***Were all important outcomes considered so the results can be applied?*** *Journal club to discuss and answer*