NSW Speech Pathology
Evidence Based Practice Interest Group

Critically Appraised Paper (CAP)

CLINICAL BOTTOM LINE:
The results of this study are inconclusive, however adverse events, in particular lung related complications, were noted in the experimental group. Patients in the experimental group did have increased fluid intake and some higher levels of satisfaction on QoL measures but this did not correspond to an overall increase in positive feeling.

Clinical Question [patient/problem, intervention, (comparison), outcome]: In patients with dysphagia what are the benefits and complications of implementing the Free Water Protocol?

Citation: Karagiannis MJP, Chivers L, Karagiannis C (2011) 'Effects of oral intake of water in patients with oropharyngeal dysphagia', *BMC Geriatrics*, 11:9

Design/Method: Randomised controlled prospective study. Speech Pathologists and Nursing Staff were aware of which patients were in the control and intervention group. Medical Officers assessing chest status were blind to allocation.

Participants: Initially 100 patients from acute and subacute settings were recruited to the trial from the Regional Hospital in Victoria, Australia. All patients identified as having dysphagia and had been prescribed a modified or thickened fluid diet by a Speech Pathologist. All patients were 18+ years and without diagnosis of chronic respiratory conditions or prior tracheostomy. Majority of the patients had multiple medical diagnoses (see Table 1 for details). Only 91 completed the trial (5 were discharged prior to completion, 2 were not willing to complete and 2 were excluded due to discomfort with ingestion of thin liquid). For final analysis, patients from the acute setting (n=15) were excluded due to consideration of the serious complications (including aspiration pneumonia) that could occur when "feeding at risk".

Experimental Group: 42 patients (subacute). Both groups received intensive oral care via Nursing Staff (received training and strict protocol). Both groups had thickened fluids only for 3 days. The intervention group had water between meals (thickened fluids with meals) for 5 days. Blinded medical officers assessed the participants' chest status on a daily basis. A total of 18 patients (13 intervention) completed both quality of life surveys.

Control Group: 34 patients (subacute). Both groups received intensive oral care via Nursing Staff (received training and strict protocol). Both groups had thickened fluids only for 3 days. The control group continued to receive thickened fluids only for an additional 5 days. A total of 18 patients (5 intervention) completed both quality of life surveys.

Results: 300 mls on average extra per patient of extra fluid intake. No aspiration pneumonia in control group. 14.3% (n=6) of patients in the experimental group developed lung related complications, with 7.1 % (n=3) diagnosed with aspiration pneumonia and 7.1% (n=3) had lower quadrant bibasal crepitations. Broad non specific QOL questions limit any take home points (overall intervention group reported in post survey higher levels of satisfaction but this reportedly did not correspond to an overall increase in positive feeling).

Comments – Strengths/weaknesses of paper
Strengths: Identifies some weaknesses to study**,** Had inclusions and exclusions**,** theoretically able to be generalised to clinical practice (looked at temp, chest), Australian study, 2nd assessment clinicians, Reasonable sample size**,** Attempts at statistical analysis
Weaknesses: Only one physician, ?no physio involvement, No chest x-ray. Clinical chest exam limited by mobility positioning and other active infective processes, Limited investigation into blood infection makers, No definition of sub acute versus acute, Heterogeneous, hard to generalise to different clinical group, Were they matched on severity of dysphagia, Only defined the primary diagnosis and did not mention co-morbidities, including cognition, Oral care protocol not included and hence not replication, Only some patients had objective swallow assessment. QOL questions too general to draw the conclusions drawn, ? Medical physicians involved

Level of Evidence (NH&MRC): III

Appraised By: Adult Swallowing EBP

Date: 1/11/2011

Form based on Worrall & Bennett, Evidence based Practice: Barriers & Facilitators for Speech-Language Pathologists, *Journal of Medical Speech-Language Pathology* 2:9, xi – xvi **Updated February 2006**

Guidelines for completion of the CAP

Clinical Bottom Line
The consensus of the reviewers on implications of the paper on clinical practice. Whilst this may be somewhat subjective, it is hoped that robust discussion, the Level of Evidence and your comments on the design will enable you to produce a practical/realistic 'bottom line'. Many of the papers in Speech Pathology may have limitations, but the Clinical Bottom line should be aimed to help clinicians apply what evidence there is.

Clinical Question
This should ideally include four components:

- the patient or problem
- the intervention (or diagnostic test or prognostic factor)
- the comparison intervention or test *(optional)*
- the outcome

Design
Refer to pages 12 to 15 of the EBPIG Resource Package for guidance in reviewing the design used.

Comments on Design
Pages 12 to 15 of the Resource Manual should again assist here. You may also find it useful to refer to the forms 'Evaluating case studies/case series' and 'Critical appraisal sheet' adapted from Dr Lil Mikuletic's (see 'Critiquing/Appraising the Evidence).

Level of Evidence
It is recommended that the paper you are reviewing be rated against the NH&MRC Levels of Evidence, as reproduced here. The levels may be updated from time to time by the NH&MRC, but use of the ratings listed here will ensure consistency across CATs and groups. These levels are listed with comments on pages 15 and 16 of the Resource Package.

LEVEL

I. Evidence obtained from a systematic review of all relevant controlled trials

II. Evidence obtained from at least one properly designed randomised controlled trial

III. **1** Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)

2 Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies, or interrupted time series with a control group

3 Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group

IV. Evidence obtained from case series, either post-test or pre-test and post-test