Clinical Bottom Line:
It is too difficult to make any definitive conclusions as to whether thickened fluids reduce the risk of aspiration pneumonia. It appears that the rate of pneumonia was lower than expected for this population however we are unable to say if one treatment was responsible for this above the others.

Clinical Question [patient/problem, intervention, (comparison), outcome]:
Do thickened fluids reduce the risk of aspiration pneumonia?


Design/Method: Randomised, controlled parallel-design trial

Participants:
- 515 patients with dementia or Parkinson’s disease who aspirated on thin liquids as demonstrated by videofluoroscopy.
- Of the 515, 504 were followed until death of for 3 months.
- Inpatients and outpatients form 47 hospitals and 79 subacute hospitals.
- Inclusion criteria:
  - Physician-identified diagnosis of dementia (Alzheimer’s type, single or multistroke type, or other nonresolving type) or Parkinson’s disease.
  - Aged between 50-95 years
- Exclusion criteria: tobacco use in last year, ETOH, history of H&N cancer, IDDM for longer than 20 years, NGT, neurological disease or pneumonia within 6 weeks of enrolment.
- 70% were male and 59% were aged 80 years or older. 50% had dementia, 30% had Parkinson’s disease without dementia and 20% had Parkinson’s disease without dementia.

Experimental Group:
- The 515 patients were randomly assigned to either one of two groups:
  1. Chin-tuck posture group (n= 259)
  2. Thickened fluids group (n= 256)
- Of the 256 patients in the thickened fluids group, 133 patients were randomly assigned to nectar thick fluids intervention and 123 were randomly assigned to the honey thick fluid intervention.
- Participants were randomly assigned centrally by a telephone system controlled by the Statistical and Data Centre at the EMMES Corporation.
- Neither the participants nor the caregivers were blinded to the intervention assignment.
- All participants continued non-liquid nutritional intake in the same manner as before enrolment.
- Primary Outcome of the pneumonia was definite pneumonia. Definite pneumonia was defined as evidence of pneumonia on CXR or 3 or more of the following:
  - Sustained Fever
  - Rales or Rhonchi on chest auscultation
  - Sputum Gram stain showing substantial leukocytes
  - Sputum culture showing respiratory pathogen
- Suspected pneumonia was defined as at least 2 of the 4 features of definite pneumonia.
- Of the 515 participants:
  - 413 completed 3 months follow-up with no incidence of pneumonia
  - 39 without previous incidence of pneumonia were followed up until death
  - 52 developed pneumonia of whom 21 subsequently died
  - 11 without previous incidence of pneumonia had incomplete follow-up.
- Adherence to the intervention:
  - Initially all participants were monitored at all meals by caregivers and study staff for adherence with the assigned intervention.
  - Ultimately a goal of meal monitoring for 300 participants distributed evenly across the 3 interventions was selected.
  - Measured weekly across assessed meals and classified on a monthly basis as 0% to 25%, 26% to 50%, 51% to 75% or 76% to 100%.
- Follow-up procedures:
  - Exit forms were completed for participants at the end of the study or if participants discontinued the intervention before the end of the 3-month follow-up
  - Regardless of when participants exited the intervention, their health outcomes were followed for 3 months.
  - If patients had pneumonia they were referred to their SLP for dysphagia Mx.
- Clinicians assessed adverse events, which were defined as any clinically significant event possibly related to the assigned intervention (e.g. dehydration). Adverse events were rated as mild, moderate, severe or life threatening.
Control Group: No control group (a “no treatment” group would have been unethical)

Results:

- Cumulative incidence of pneumonia was much lower than expected overall.
  - Pneumonia:
    - Chin-down group = 24 events
    - Thickened fluids = 28 events (10 events for nectar thick fluids and 18 events for the honey thick fluids)
  - Pneumonia or death:
    - Chin down group = 46 events
    - Thickened fluids = 46 events (21 events for the nectar thick fluids and 25 for the honey thick fluids)
  - Adverse events:
    - 14 participants withdrew from the study because of an adverse event or hospitalisation
    - 23% of the participants had at least 1 adverse event during the study
    - The combined outcome of at least 1 dehydration, UTI or fever was more frequent in the thickened fluid group
    - Withdrawals due to adverse events were more frequent for the thickened fluid group.
    - Increased breathing difficulty was more frequent for the chin down group
    - Diarrhoea was frequent for the nectar thick group than the honey thick group
    - Occurrence of a serious adverse event was balanced across primary and secondary intervention groups.

- Median length of stay in hospital for pneumonia:
  - 18 days for the honey thick fluid group
  - 6 days for the chin tuck posture
  - 4 days for the nectar thick fluid group

- Adherence to the Intervention:
  - A higher proportion of patients with Parkinson’s disease in the chin-down group had adherence greater than 50% when compared to participants with dementia or Parkinson’s disease with dementia.
  - Adherence greater than 50% to the nectar thick intervention across 3 months of follow up was fairly even across the diagnoses
  - Adherence greater than 50% to the honey thick intervention across 3 months of follow up was highest amongst the participants with dementia.

Comments – Strengths/weaknesses of paper

Strengths:
- Level II evidence.
- Statistical analysis

Limitations:
- No control group
- Unable to blind
- Short follow-up period
- Adherence to the interventions was problematic.
- Using a chin down posture with patients with dementia → how well were they able to understand? → ? May account for the low proportion of adherence to this intervention for patients with dementia or PD & dementia when compared to the patients with just PD.
- No comment as to how advanced diseases was for each patient or co-morbidities → ? May have impacted on LOS in hospital with pneumonia or recovery from pneumonia.
- ? Whether caregivers who participated in meal monitoring were trained as to correct chin-tuck posture.
- Patients for whom one or two interventions worked were excluded from the 3 month follow-up with regard to adverse outcomes. This means we do not know if the patients who had not aspirated with honey thick for example (when they were still aspirating nectar and thin with chin down) would have been less likely to experience adverse outcomes if treated with this, than those who were still aspirating.
- No comment as to the severity of Parkinson’s disease or dementia.

Level of Evidence (NH&MRC): Level II

Appraised By: NSW Adult Swallowing EBP Group
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