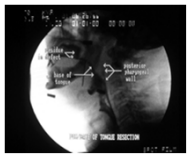
Evidence Based Clinical Decision Making in Dysphagia



Kansas Speech Language and Hearing Association Convention
Kansas City
September 2011

James L. Coyle, Ph.D., CCC-SLP, BRS-S
Department of Communication Science and Disorders
University of Pittsburgh
jcoyle@pitt.edu

1

Medical Speech Language Pathology

- Evolution of the Profession
- Speed of medical technology change
- Discovery of causes of preventable diseases

Our role has changed to include not only…

- Restoration of functions after disease and trauma, but also…
- Prevention of diseases that shorten lives

2

Using Evidence in Practice

- Research consumerism
  - Clinicians are research consumers
    - If not, they'd better be…
- Evidence is essential
  - Buying a product → offering a clinical service
  - Choosing a physician → offering competent service
  - Agreeing to a treatment → choosing the best treatment for our patient

3

Topics

- 1. How to evaluate external evidence
- External Evidence: treatment, diagnosis
  - Controversial methods, common methods
    - Thick liquids, water protocols
    - Clinical signs predictive value

4

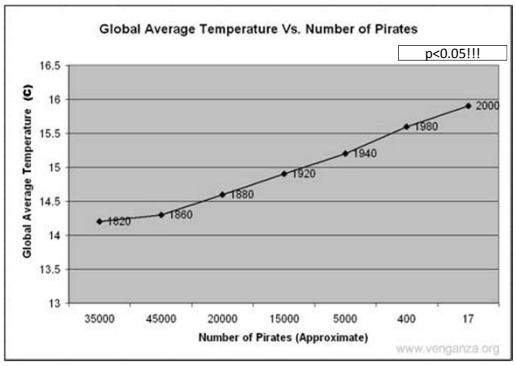
Evidence. What is Evidence?

Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

There is no evidence that parachutes prevent injury or death Smith et al., 2003

5

A Little Data Can Be a Dangerous Thing…



"… significant inverse relationship between pirates and global temperature."

6

What is Evidence-Based Practice?

Report of the Joint Coordinating Committee on Evidence-Based Practice

7

What is Evidence-Based Practice?

- 1. See a patient
- 2. Ask a question
- 3. Seek the best evidence for that question
- 4. Appraise that evidence
- 5. Apply the evidence
- 6. Monitor the change
- 7. Continuously re-evaluate ourselves

University of Oxford
Centre for Evidence Based Medicine
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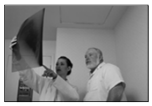
1. See A Patient

- Signs and Symptoms
- Medical Record, Interview
- Examination-Collect Data
- Individual's Characteristics



- Form a list of what is known, what issues need resolution

9

2. Ask a Question

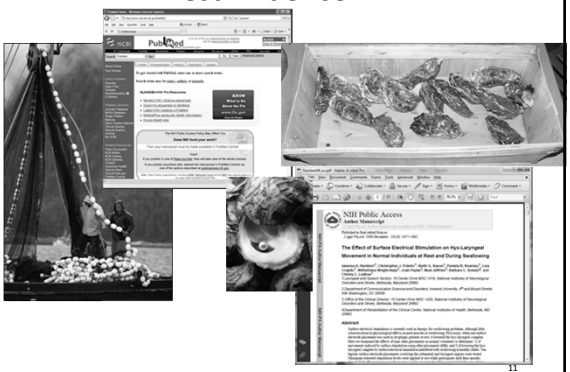
The "Answerable" Clinical Question has 4-Parts

PICO

- 1. Who is the Patient or what is the clinical Problem you are planning to treat?
- 2. What Intervention are you considering?
- 3. What alternative or Comparison treatment is available?
- 4. What clinical Outcomes are you targeting?

10

Best Evidence



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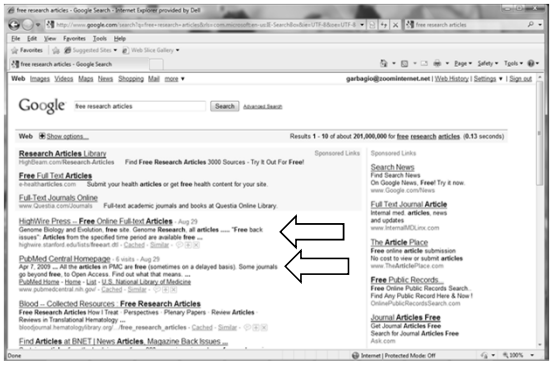

HighWire Press (many free, many open access available)

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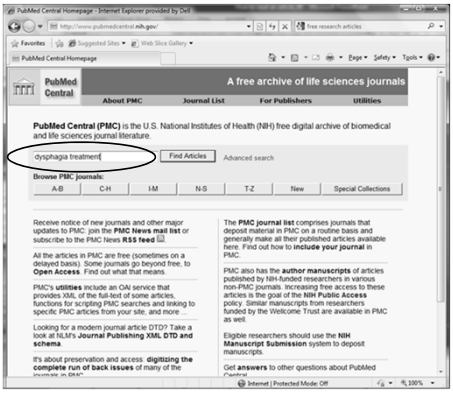
PubMed Central: all free or open access



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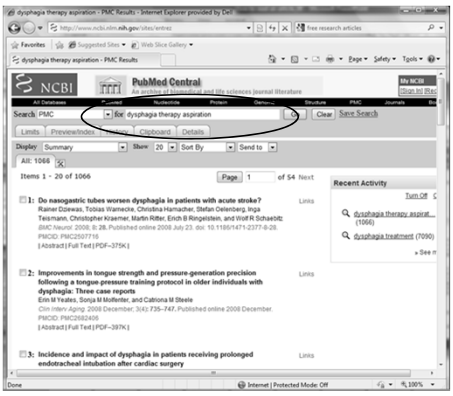
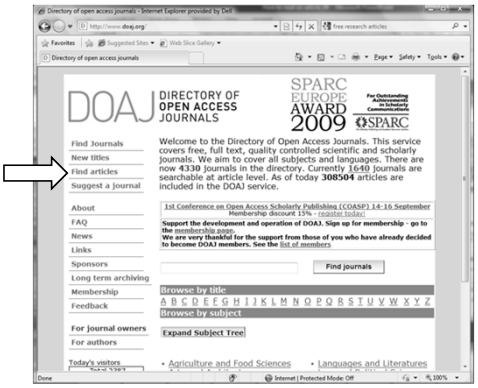


Directory of open access journals (www.doaj.org)



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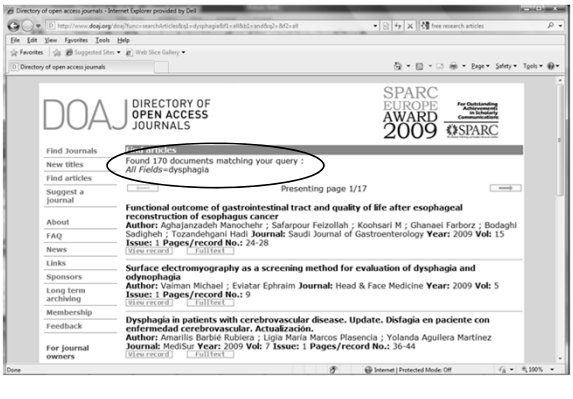
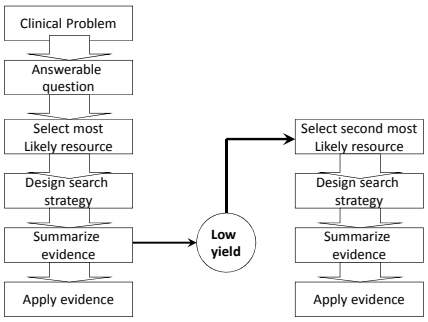


Seek Best Evidence for Question



4. Appraise the evidence

- Read the article(s), evaluate them!
  - Characteristics of good and not-so-good published research…
  - Some "types" of articles are stronger than others.
    - Which article "types" are stronger?
    - Which have better quality?
    - Which are more valid?

20

Design

AMERICAN SPEECH-LANGUAGE-HEARING ASSOCIATION

Table 1. Levels of evidence for studies of treatment efficacy, ranked according to quality and credibility from highest/most credible (Ia) to lowest/least credible (IV) (adapted from the Scottish Intercollegiate Guideline Network, www.sign.ac.uk).

Level	Description
Ia	Well-designed meta-analysis of >1 randomized controlled trial
Ib	Well-designed randomized controlled study
IIa	Well-designed controlled study without randomization
IIb	Well-designed quasi-experimental study (Case-control study, cohort, case series)
III	Well-designed nonexperimental studies, i.e., correlational and case studies
IV	Expert committee report, consensus conference, clinical experience of respected authorities

RCT, quasi-experiment, cohort, pre-post, SSD

21

Table 2 Items for methodological assessment of the studies

Items	Description
1	Were the reference test and the index test interpreted independently (blind)?
2	Was the index test applied independent of relevant information on clinical data of the patient regarding the target condition?
3	Was the reference test applied to all patients who received the index test?
4	Was the period between the reference test and the index test short enough to be reasonably sure that the target condition did not change between the two tests? (within 24 hours in acute stroke, and within 7 days in other neurological diseases)
5	Was the selection of the study population valid?
6	Are data presented in enough detail to calculate appropriate test characteristics?
7	Was the study population appropriate to evaluate the proposed use of the index test?
8	Was the index test described in detail so it could be reproduced?
9	Were satisfactory definitions used for normal/abnormal reference test results and normal/abnormal index test results?

Bours et al., 2009

22

1. Eligibility criteria were specified	No ❑	Yes ❑	Where:
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	No ❑	Yes ❑	Where:
3. Allocation was concealed	No ❑	Yes ❑	Where:
4. The groups were similar at baseline regarding the most important prognostic indicators	No ❑	Yes ❑	Where:
5. There was blinding of all subjects	No ❑	Yes ❑	Where:
6. There was blinding of all therapists who administered the therapy	No ❑	Yes ❑	Where:
7. There was blinding of all assessors who measured at least one key outcome	No ❑	Yes ❑	Where:
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	No ❑	Yes ❑	Where:
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analyzed by "intention to treat"	No ❑	Yes ❑	Where:
10. The results of between-group statistical comparisons are reported for at least one key outcome	No ❑	Yes ❑	Where:
11. The study provides both point measures and measures of variability for at least one key outcome	No ❑	Yes ❑	Where:

Figure 1. The Physiotherapy Evidence Database scale was developed to facilitate analysis of research trial design and evidence-based clinical practice guidelines.

23

Internal and external validity

- Internal Validity:
  - How well the study's design controlled the for sources or error
    - Efficacy: outcome under controlled conditions
- External Validity:
  - How well the study matches reality
    - Effectiveness: outcome in typical practice

24

Validity

1. Were all patients similar at start of trial?

2. Were patients randomly assigned to the treatment groups?
   - And was randomization list concealed?

3. Were clinician/judges blinded/subjects masked?

4. Were all patients were treated equally?
   - except for the experimental method

25

Validity

5. Was follow-up sufficiently long and complete?

6. Were all patients analyzed as randomized?
   - Attrition, intention to treat

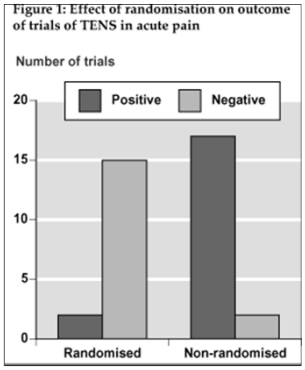
7. Was treatment effect hypothesized at start of trial?

8. Effects of maturation/recovery, test learning?

9. Conflicts of interest ???
10. Is the treatment feasible?

26

Effects of Randomization



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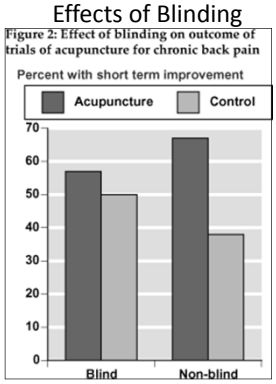
27

Effects of Blinding



http://www.jr2.ox.ac.uk/bandolier

28

Thickened liquids
"Free Water Protocols"
Clinical Examination Precision

Physiologic Principles
Evidence Summary
Comments on Clinical Use

EVIDENCE FOR COMMON AND CONTROVERSIAL THERAPEUTIC INTERVENTIONS

29

Thick liquids

30

Pneumonia and aspiration

- Thin liquids aspirated most frequently
  - Compared to other viscosities
- Spawned experimentation with thick liquids
- Theory for dysphagia use:
  - Slowing the flow
    - Compensates for mistimed airway closure
- What do we know about them?

31

Thickened liquids

- Reduces aspiration of thin liquids
  - Kuhlemeier et al., 2001; Logemann et al., 2008
- Swallow apnea later/longer with thick liquids
  - Hiss et al., 2004; Butler et al., 2004
- More effort needed to clear thick
  - Nicosia et al., 2001

32

Thickened liquids

- Patients do not like thick liquids
  - Garcia, 2005: prepackaged vs. mixed
    - Prepackaged better : Whelan, 2001
- Great variability in thick liquids
  - Prepackaged & mixed: UW/VA Swallowing Research Lab, 1999 → →
  - Prepackaged: Garcia, et al., 2005; Steele, 2005
  - Mixed by clinician: Glassburn & Deem, 1998→ →

33

Thickened liquids

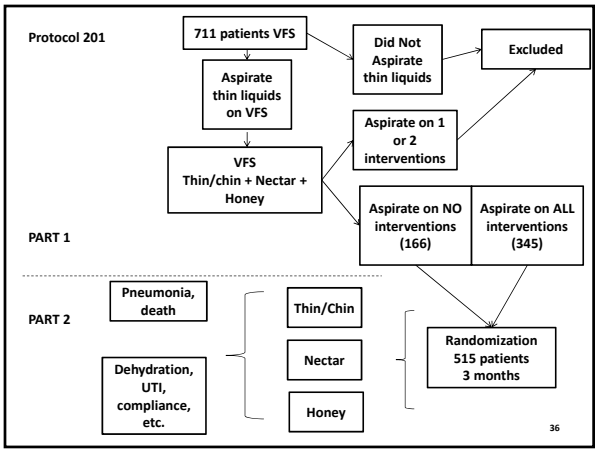
- Hydration and thick liquids
  - Sharpe et al., 2007
    - Assessed water absorption
    - >95% water absorbed from thick mixtures
    - No difference between water, thick water
- Hydration and thick liquids
  - Reduced fluid intake when thick prescribed
    - Whelan, 2001, Mean fluid intake = 455 mL/day
    - Finestone et al., 2001 – deyhdration without tube

34

Thickened liquids

- Large study data
  - Logemann et al., 2008; Robbins et al., 2008
    - 711 Patients with Parkinson disease, dementia
    - Aspiration on qualifying VFSS
    - Randomized order of presentation
      - Chin-down/thin, Nectar, Honey

35



36

Thickened liquids

- Part 1: eliminating liquid aspiration
  - Honey → nectar → chin down posture (all groups)
    - Overall aspiration: 53%, 63%, 68%
  - Half of patients aspirated on all 3
    - More aspiration on later trials
  - Patient preference:
    - Chin down posture, nectar, honey
- Part 2 →

37

Thickened liquids

- Results – Protocol 201 Part 2
  - 52/515 patients developed pneumonia (11%)
    - Much less than expected
- Median hospital LOS with pneumonia
  - Honey (18 d.), nectar (4 d.), CDP (6 d.)
- Dehydration: Thin: 2%, Thick: 6%
- UTI: Thin: 3%, Thick: 6%
- 3 times longer hospital stay in honey-thick who developed pneumonia

38

	Chin down/thin	All Thick Liquid	Nectar Thick	Honey Thick
All Pneumonia	24/259 (9.3%)	28/256 (10.9%)	10.133 (7.5%)	18/123 (14.6%)
Pneumonia/ aspiration on **no interventions**	6/76 (7.8%)	4/94 (4.2%)	0/46 (0%)	4/48 (8.3%)
Pneumonia/ aspiration on **all interventions**	18/183 (9.8%)	24/162 (14.8%)	10/87 (11.5%)	14/75 (18.7%)

39

Thickened liquids

- Summary on thickened liquids
  - Reduces aspiration but is not preferred
  - Thick liquids do not dehydrate
  - Aspiration of thick liquids may produce a worse pulmonary consequences than thin liquid aspiration

40

Evidence Summary for using Free Water Protocols

"FREE WATER" PROTOCOLS

41

- Frazier Rehab Institute Water Protocol
- "... Concern over patient and family non-compliance with thin liquid restrictions both within the facility and after discharge …"

Retrieved 01/20/09 from http://www.speech-languagepathologist.org/archives/chat/SLP/April212003.html

42

Free Water Protocols

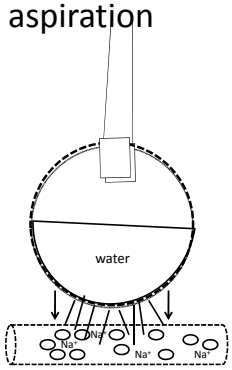
- Literature search
  - 1. "Free Water", + Deglutition Disorders
  - 2. Panther, K.
  - NO RESEARCH ON THIS "PROTOCOL" despite "thousands of patients…"
  - Claim: 2/234 patients developed pneumonia (<1%)
    - Stroke patients have about 10% pneumonia rates*
- Developers discuss
  - Safety of Water, Hydration, Compliance

*Panther, 2005

43

Pneumonia and aspiration

- Drowning
  - Water fills air spaces
- Plasma is hypertonic
  - Meaning: it contains lower concentration of water
- At membrane, water flows into capillary

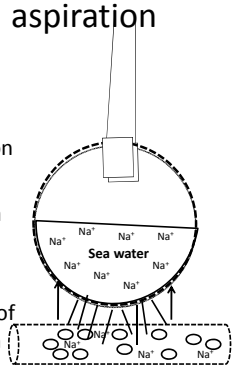


Effros, et al., 2000

44

Pneumonia and aspiration

- Example: seawater contains
  - High NaCL concentration
  - Is hypertonic
    - Compared to plasma
  - Seawater drowning
    - Plasma enters lung
  - Similar with aspiration of any hypertonic solution



45

Free Water Protocols Evidence

- Bronchoalveolar lavage
- Whelan et al. (2001) reduced fluid intake in patients prescribed thick liquids
- Numerous citations on dehydration in dysphagia
- Animal studies of water aspiration

46

Free Water Protocols Evidence

- Garon et al., 1997
  - 20 aspiration-documented CVA patients
    - Aspirated liquid only on VFSS
    - Randomized to protocol or thick liquids
    - Duration: treatment + 30 day follow up
- Small and underpowered study
  - Yet the main evidence for protocol
- Outcome variables
  - Pneumonia, hydration, time to no aspiration
    - Fluid intake

47

- Garon et al., 1997
  - Results
    - No patient in either group developed pneumonia, dehydration, complications
  - Intake of fluids comparable between groups
    - 1210 mL (C) - all thick
    - 1318 mL (E): 855mL thick, 463mL thin
  - "Much less water than expected" by investigators ("we were surprised…")

48

Free Water Protocols

- A recent study
  - Presented at ASHA 2008
    - Becker et al., 2008. An oral water protocol in rehabilitation patients with dysphagia for liquids.
- Randomization to water protocol or prescribed dietary fluid (26 patients)
- 17 patients requiring feeding assistance
  - 8 assigned to control, 9 to treatment
- 9 independent feeding patients
  - 3 assigned to control, 6 to treatment
- All received oral care four times per day

49

Free Water Protocols (#2)

- Dependent Variables
  - Adverse events (pneumonia, UTI, death)
    - Objective measures not assigned by clinician/judges
- Results
  - Pneumonia: 1 patient in each group
  - UTI: 2 patients in each group
  - **Death: 2 treatment deaths, no control deaths**
- Other findings:
  - Independent patients consumed significantly less fluid than dependent patients ($p<.01$), regardless of group

Becker, et al., 2008

50

Free Water Protocols (#2)

- Discussion
  - The presence of two deaths in the treatment group cannot be ignored
    - …and may underscore the importance of clinical judgment in applying this and other treatments
      - Both patients that died had chronic pulmonary conditions

Becker, et al., 2008

51

Diagnostic Methods

52

Diagnostic Methods

- What clinical signs are most predictive of aspiration, pneumonia risk?

53

Citation 1

- Martino R, Pron G, Diamant N, (2000). Screening for oropharyngeal dysphagia in stroke: insufficient evidence for guidelines. *Dysphagia 15*: 19-30.

- a. How well do non-instrumental tests predict aspiration?
- b. How well do non-instrumental tests predict health outcomes in dysphagics?
  - Does screening affect length of stay, mortality, pneumonia incidence, etc.?

54

Methods

- *Systematic Review* with calculation of Predictive Value of each clinical sign
- End points/Outcomes
  - (a). Physiology: aspiration, residue detection
  - (b). Health: pneumonia, mortality, PEG

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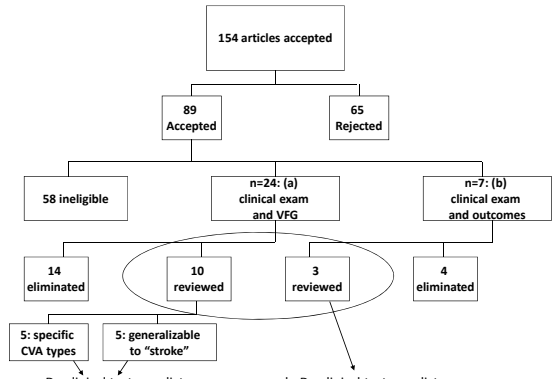

56

Clinical Test precision

- 39 clinical signs predicted VFG findings
  - 5 of them, when present, were 2-5 times more likely than a coin toss, to predict aspiration.
    - Failed water swallow test (30mL)
    - Failed water swallow test (50mL)
    - Cranial nerve IX sensory abnormality
    - Abnormal pharyngeal sensation
    - Facial weakness

57

Clinical Test precision

- 10 clinical examinations reveal signs that predict pneumonia, mortality, future PEG placement
  - Only one had a weak (but clean) predictive value
- 50mL water swallow

58

Clinical Test precision

	50mL H_2O swallow	"Acute Stroke Pathway" 2 years			"Acute Stroke Pathway" - 1 year	
	Pneumonia	Aspiration pneumonia	Mortality	PEG tube inserted	Aspiration pneumonia	PEG tube inserted
ARR	**0.13**	0.07	0.06	0.02	0.03	0.01
RRR	**81.2%**	35.1%	70%	18%	38.8%	6.7%
NNT	**7.69 (8)**	14.3 (15)	16.7 (17)	50	33.3 (34)	100

59

Daniels, S. K., Ballo, L. A., Mahoney, M. C., & Foundas, A. L. (2000). Clinical predictors of dysphagia and aspiration risk: outcome measures in acute stroke patients. *Archives of Physical Medicine & Rehabilitation, 81*(8), 1030-1033.

TABLE 1. Guidelines for the Diagnosis and Treatment of Dysphagia in Stroke Patients

Step 1: Clinical examinations
- Cognitive status
- Gross motor skills
- Oral motor skills
- Sensation
- Respiration
- Voice
- Swallowing

Step 2: Screening procedures
- Identification of 2 of 6 risk factors
  - Abnormal volitional cough
  - Abnormal gag reflex
  - Dysarthria
  - Dysphonia
  - Cough after trial swallow
  - Voice change after trial swallow
- Trial swallow assessment
  - Calibrated water volumes
  - Measured volumes of various consistencies

Step 3: Diagnostic evaluation
- Videofluoroscopic swallow study
- Videoendoscopy

Step 4: Treatment
- Compensatory
  - Postural changes
  - Bolus modifications
- Rehabilitative
  - Thermal-tactile application
  - Swallowing maneuvers
  - Exercise programs

Table 2: Operational Definitions of the Six Clinical Predictors of Risk of Aspiration

Dysphonia	A voice disturbance in the parameters of vocal quality, pitch, or intensity.
Dysarthria	A speech disorder resulting from disturbances in muscular control affecting the areas of respiration, articulation, phonation, resonance, or prosody.
Abnormal gag reflex	Either absent or weakened velar or pharyngeal wall contraction, unilaterally or bilaterally, in response to tactile stimulation of the posterior pharyngeal wall.
Abnormal volitional cough	A weak response, verbalized response, or no response on given the command to cough.
Cough after swallow	Cough immediate or within 1 minute of ingestion of calibrated volumes of water (5, 10, and 20mL presented in duplicate).
Voice change after swallow	Alteration in vocal quality following ingestion of calibrated volumes of water.

2 or more present significantly Predictive of aspiration on VFSS (p<.01).

60

Clinical Evaluation

- Bours et al., 2009
  - Systematic Review
    - 407 studies identified
    - 86 qualified
    - 35 were eligible

Inclusion criteria	1. Screening compared with videofluoroscopic or fibreoptic endoscopic evaluation of swallowing 2. Cross-sectional design or (randomized) clinical trial 3. Aspiration and/or penetration as endpoint 4. Predominant adult patients with neurological disorders 5. Non-invasive screening method 6. Written in English, German or Dutch	
Excluded papers		51
Included papers	35	

61

- 11/35 studies "good enough" to evaluate

Table 2 Items for methodological assessment of the studies

Items	Description
1	Were the reference test and the index test interpreted independently (blind)?
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3	Was the reference test applied to all patients who received the index test?
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8	Was the index test described in detail so it could be reproduced?
9	Were satisfactory definitions used for normal/abnormal reference test results and normal/abnormal index test results?

480

Table 3 Quality of the included studies

	Items									
	Validity						Generalizability	Reliability		
References	1	2	3	4	5	6	7	8	9	Conclusion
Chong *et al.* 2003	+	−	+	+	+	+	+	+	+	Sufficient
Daniels *et al.* 1997	+	+	+	−	+	+	+−	+	+	Sufficient
Leder and Espinosa 2002	+	−	+	+	+	+	+	+	+	Sufficient
Lim *et al.* 2001	+	+	+	+	+	+	+	+	+	Sufficient
Logemann *et al.* 1999	+	−	+	+	+	+	+−	+	+	Sufficient
Mann 2002	+	+	+	−	+	+	+	+	+	Sufficient
Mari *et al.* 1997	+	−	+	+	+	+	+	+	+	Sufficient
McCullough *et al.* 2001	+	+	+	+	+	+	+	+	+	Sufficient
Smith *et al.* 2000	+	+	+	+	+	+	+	−	+	Sufficient
Smithard *et al.* 1998	+	+	+	+	?	+	+	+	+	Sufficient
Trapl *et al.* 2007	+	−	+	+	+	+	+	+	+	Sufficient

What this paper adds

- A water test combined with pulse oximetry using coughing, choking and voice alteration as the endpoints is currently the best method to screen patients for dysphagia.
- Single clinical features such as abnormal gag, volitional cough or medical history components are not useful to identify patients at risk of aspiration/penetration.
- Further research is needed to determine the most effective procedure for administrating water tests and the value of pulse oximetry in addition to a trial swallow.

63

Summary Clinical Examination

- Combining results of these studies
  - More than one sign (fail) is necessary
  - Some signs are more predictive than others
    - Abnormal pertinent cranial nerve exam
    - Coughs during water swallow portion of exam
    - Some evidence for pulse oximetry ONLY when combined with other observations

64

Clinical Test precision

- Clinical exams should include:
  - Signs with strong predictive value for dysphagia
    - Failed water swallow test
    - Cranial nerve sensory/motor abnormalities
      - Facial Weakness
  - These have weak predictive value; do not use solely:
    - Weak voluntary cough, Dysphonia, Abnormal motor exam (extremities)

65

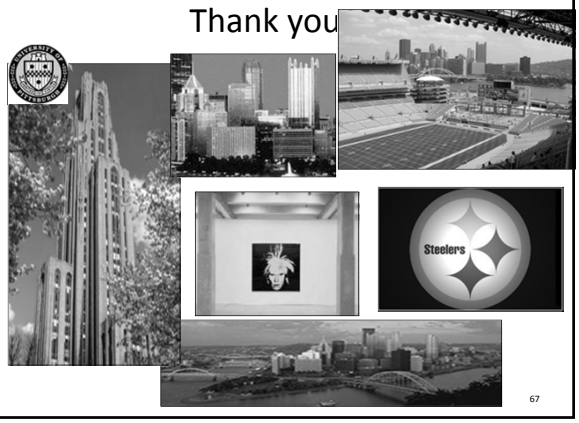
Summary

- Evidence is useful when the evidence is good
- Evidence utilization is work but not too much
- Things constantly change – need to keep up
- No one study tells all

- All methods have advantages and disadvantages, risks and benefits
  - Nothing has just advantages and benefits.

66

Thank you



67