Disclosure Statement

• Dr Carnaby has been funded by:
  – Florida Department of Health
  – University of Florida
  – & the American Cancer Society to complete the “pharyngocise” research trials.

• Dr LaGorio- no disclosures
Background

• Preventative programs for allied health not routine in the USA

• Rehab -(average) 3 months after onset of problems- potential for gain is limited.

• Preliminary data suggests- exercise based interventions may offer relief to symptoms associated with CRT
Issues

• How does exercise help?
• What exercises help?
• When should we offer services?
• How to offer preventative services and get paid?
Theoretical support

1. Swallowing uses a muscular system
   - Swallowing muscle is plastic & responsive

2. Swallowing decline is iatrogenic and linear throughout CRT
   - CRT results in muscle inflammation, edema, fatty infiltration and atrophy of muscle

3. Muscles can be re-trained
1. Muscle composition and function for swallowing in head / neck cancer
   “Pharyngocise Study”

2. Preventative exercise for dysphagia following head / neck cancer: “dose response study”


Trials ID: NCT00796952
Funded FDOH- BM009
Study 1

- Single Center RCT (n=58)
- 3 arms
  - control, placebo, intervention
- Longitudinal:
  - baseline, 6 weeks 6months
- Subjects
  - Patients with confirmed HNC - oropharyngeal or adjacent regions (XRT +/- Chemo)
    - No previous XRT or Surgery for H/N Ca.
- Intent to treat
- Double blind
Outcomes

**Muscle-\textit{T}_2\textit{MRI}**
- Functional swallowing ability (MASA, FOIS)

**Secondary Outcomes**
- Nutrition/weight
- Taste
- Smell
- Salivation
- Mouth opening
- Psychosocial-pain, fatigue, mood, depression, HRQOL
- Compliance
Intervention

1. **Active = Pharyngocise**: Battery of exercises
   - Falsetto, jaw resistance, hard swallow and tongue resistance. Completed twice daily *(during CRT)* at 40 cycles/ea/session.

2. **Sham = Valchuff**: quick lip blowing, mouth opening & puffing tasks.
   - Completed twice daily *(during CRT)* at 40 cycles/ea/session.

3. **Control =** focused attention - phone review / diary cards
MRI Outcomes

**Genioglossus**
- length, $p \leq .03$
- $T2$ value, $p \leq .01$

**Hyoglossus**
- length, $p \leq .01$
- $T2$ value, $p \leq .037$

**Mylohyoid**
- Thickness, $p \leq .02$
- $T2$ value, $p \leq .017$
Results – Study 1

- **Pharyngocise**
  - Improved functional swallowing
  - Maintenance of full oral diet
  - Preservation of:
    - Salivation, Taste, Mouth opening

- **Pharyngocise: independent predictor of favorable outcome during XRT:** OR = 6; 95% CI: 1-37.2.

Ok but can HNC folks do it themselves???
(cheaper and less burdensome)
Preventative exercise for dysphagia following head / neck cancer: dose response study

- Single Center RCT (n=130)
- 3 arms
  - control, home program, therapist directed
- Longitudinal:
  - Baseline, 3wks, 6wks, 3mths
- Subjects
  - Patients with confirmed HNC - oropharyngeal or adjacent regions (XRT +/- Chemo)
  - No previous XRT or Surgery for H/N Ca.
- Intent to treat
- Single blind
Outcomes

- Muscle-$T_2$ MRI.
- Functional swallowing ability (MASA, FOIS)

Secondary Outcome

- Compliance / adherence to program
- Mouth opening
- Weight
- Psychosocial-pain, fatigue, mood, depression, HRQOL
Trial Profile

Eligible pts n=253

Recruited n=130

Randomize Assess

Control (28) 6 weeks Tx
  death =1
  lost = 3
  WD = 2
  Assess Outcome 3 month n=22

Home based (52) 6 weeks Tx
  death = 5
  lost = 10
  WD = 5
  Assess Outcome 3 month n=32

Therapist based (50) 6 weeks Tx
  death = 1
  lost = 2
  WD = 11
  Assess Outcome 3 month n=36

N=109

N=90
MRI RESULTS

**Genioglossus**
- Length, p ≤ .0001
- Width, p ≤ .001

**Hyoglossus**
- Length, p ≤ .027

**Mylohyoid**
- Thickness, p ≤ .036

***Program adherence***
Program Adherence

- Total work = cycles performed * sessions

Adherence = >90 cycles* sessions
Se: 72.0, SP:85, AUC = 76%
+LR = 4.8

35% non adherence in Pt directed group
20% non adherence in Therapist directed group
Worse for CRT!
Functional swallowing

Significant preservation of “functional” swallowing by exercise (total work performed) at 6 weeks

[F(1,81) 17.4, P<.0001]
Peg Placement

More work performed = less PEG dependence

F = (1,88) 9.58, p < .003
Bottom Line – Take Home

- Program “pharyngocise” works to prevent dysphagia
  - Dose of XRT – did not influence outcome
  - Tumor size – did not influence outcome
  - Amount of exercise performed – influenced outcome

- Issue surrounds **adherence** to program.
Why does it work?

Working theory

XRT/ CRT

- Oxidative stress
- Cascade of cytokines
- Antioxidant enzyme

Swallow exercise

- Blood flow → Vascular adaptation + antioxidant enzyme protection

- Inflamation + Microvascular impairment + tissue remodelling

- Toxicty is sequential but pace differs

Regular exercise attenuates muscle loss (protects) [Leeuwenburg 2001]
What predicts adherence to pharyngocise?

Extension study

PURPOSE:
• To identify any baseline demographic and/or psychosocial factors that may predict exercise non-adherence

- HYPOTHESIS: High levels of pain, depression, and fatigue would predict non-adherence
Subjects

Therapist-Directed Pharyngocise
n = 50

Patient-Directed Pharyngocise
n = 52

10 withdrew prior to testing

Adherence Study
n = 92
Exercise Adherence

• Exercise Program:
  – 4 cycles/session
  – 2 sessions/day
  – 5 days/week during 6 weeks of CRT

• 3 Adherence Levels:
  – Full: ≥ 90 cycles
  – Partial: 50-89 cycles
  – None: ≤ 49 cycles
Baseline Factors Reviewed

- **Demographics**
  - Age
  - Gender
  - Race
  - Ethnicity
  - Marital status
  - Education
  - Smoking, Drinking
  - HPV status

- **Tumor-related**
  - Staging (Tx Nx Mx)
  - Location
  - Planned CRT
  - Pre-treat Neck Dissection

- **Swallowing-Related**
  - Current Diet (FOIS)
  - PEG at start of CRT
Measures Used

• **General Mood**
  - *Profile of Mood States* (POMS)

• **Depression**
  - *Center for Epidemiologic Studies-Depression Scale* (CES-D)
  - *POMS Depression Sub-Scale* (POMS-D)

• **Pain**
  - *Pain Disability Index* (PDI)

• **Fatigue**
  - *Functional Assessment of Chronic Illness Therapy* (FACIT-An)
  - *Multi-Dimensional Fatigue Symptom Inventory-SF* (MFSI-SF)
<table>
<thead>
<tr>
<th>Factors</th>
<th>Related</th>
<th>Not related</th>
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### Predictors of Non-Adherence

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<tr>
<td>Fatigue (MFSI-SF)</td>
<td>0.036</td>
<td>0.013</td>
<td>0.007</td>
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This means:

for every 10 point change in MFSI-SF
odds of not adhering to the program increase by
OR =1.43

* Explains 75% variance
Conclusions

XRT/CRT + FATIGUE → Non adherence
How do I do pharyngocisise?

• Daily
• 4 Cycles per Session
• 2 sessions/day

• 4 Exercises
  – Falsetto
  – Tongue Press
  – Effortful Swallow
  – “TheraBite”*
    • Jaw Stretch
    • Jaw Press
Progress Tracking

• Progress Grid
• Enter Every Session:
  – # of cycles of each exercise
  – Total # of minutes exercising/session
## Exercise Diary Card

You should record all of the exercises on this diary card. Please date all exercise sessions done at home, include the length of time taken to complete the session, the number of applications completed for each exercise in the protocol, and circle a rating based on the scale below.

<table>
<thead>
<tr>
<th>Session</th>
<th>Date</th>
<th>Length (mins)</th>
<th>Maneuver</th>
<th>No. Completed Cycles</th>
<th>Success Rating (circle)</th>
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<tbody>
<tr>
<td>1</td>
<td>10/5/08 am (at home)</td>
<td>45 minutes</td>
<td>Falsetto</td>
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Please rate success on a scale of

1 = Extreme difficulty – unable to complete
5 = No difficulty to complete
Common Questions

1. Q: When do I start this?
   A: as close to diagnosis as you can

2. Q: Do I use a bolus?
   A: No – does not need a bolus

3. Q: Can it be done less often (< 2 x daily)?
   A: Yes- but results may be less pronounced
Questions

4. Q: What if patients says S/he cant tolerate it?
   A: do as much as you can - encourage to do more later

5. Q: Can it be used for treatment after CRT?
   A: No- we don’t believe it is intensive enough for rehab.

6. Q: How do I get paid for prevention?
   A: You don’t!...... you bill this as therapy during CRT.
Further Questions?

• Contact:
  – Giselle Carnaby- gmann@phhp.ufl.edu