June 7, 2017 - Pelvic Physiotherapy Distance Journal Club
Presenter’s names: Meghan Swenck, PT, DPT, WCS
Name of Article: Comparison of the efficacy of perineal and intravaginal biofeedback assisted pelvic floor muscle exercises in women with urodynamic stress urinary incontinence.
Authors and citation information: Aysun Ozlu MD, Necmettin Yildiz MD, Ozer Oztekin MD. Neurourology and Urodynamics. 2017;9999:1-10.

Introduction: PFM exs have known level A evidence for improvement of SUI, and the addition of biofeedback also has a Grade A recommendation. What has been less studied is the application of biofeedback of perineal surface EMG or rectal probe EMG.

Aim/Primary Aim: To compare SUI outcomes using intravaginal probe pressure assisted and perineal surface assisted biofeedback methods and compare both of these methods to HEP exercise only patients.

Study Design/Study Format: prospective, randomized controlled trial recruited 88 patients from the Urogynecological Rehabilitation Unit in Turkey (but the authors state this is the first study about this topic in the English literature!) from July 2012 to January 2014.

Methods:
- 53 women randomized into 3 groups: 1- PFM HEP alone, 2- PFM HEP + intravaginal P-BF assisted exs, 3- PFM HEP + perineal EMG-BF assisted HEP.
  - HEP: weeks 1-2 = 30 reps daily (5 sec on:10 sec off), weeks 3-4 = 60 reps daily (10 sec on: 20 sec off), weeks 4-8 = 90 reps/day (3 x 10 reps in each of 3 positions – lying, sitting, standing at 10 sec on:20 sec off).
  - BF for both vaginal and perineal setup: 40 cycles of 10 sec on/20 sec off, performed 3 days per week for 8 weeks (with MD @ facility). Electrodes placed medial to ischial tub (figure 2, p4).
- Outcome measures: 1 hour pad test, perineometer (strength test), social activity index, IIQ7, treatment success and satisfaction ratings.

Results:
- All groups demonstrated statistically significant improvements in ALL parameters
  - Higher satisfaction scores (76.5% group 2, 88.2% group 3, 41.2% group 1) and higher cure and improvement (82.4% groups 2 and 3 vs 47.1% group 1) in both BF groups compared to group 1, and with equal cure and improvement rates in both groups 2 and 3.
  - Biofeedback groups (2 and 3) were statistically equivalent in their improvements and were superior to Group 1 in: strength, SAI, severity of incontinence at 8 weeks p = <0.0167.
  - No complications were reported.

Discussion: Authors conclude BF-assisted PFM training in addition to HEP improves SUI rates more effectively than HEP alone.

Strengths:
- Randomized
- UD testing to R/o OAB or ISD.
- Low drop-out rates
- Good choices in outcomes measures.

Weaknesses:
Authors cite:
- potential effect of having direct contact with health professionals in BF groups.
- both BF groups had in fact more overall exercise – the HEP PLUS the BF component (3 days a week)
- no long term follow up

My own observations:
- did not include “severe” SUI – why?
- did not provide information about the biofeedback methods (for reproducibility) – whether the patient was prompted by the machine to initiate contraction and relaxation or if Pt was responsible for counting.
- Did not explain the training required of the PFM testing researcher – this is not a good measure via intrarater reliability and therefore inappropriate individuals may have been included or excluded. Out of 88 original women recruited, only 53 were randomized (60%). The authors did not specify how many were excluded for each reason….
- poor details of the “familiarize with location of the PFM and pelvic anatomy” and “PFM were taught to the patients via digital palpation technique” indicates it was by a physician but does not specifically state this.
- perineal BF – did not even mention crosstalk issues or monitoring surrounding muscle groups at all.
- should have run the study at least 12 weeks to allow ms strengthening to cont. and/or had another 12 week f/u or even further out.
- one cannot reproduce this study with the information provided.

Clinical Application: Treatment compliance may be optimized with allowing patients to choose vaginal pressure probe or perineal EMG electrode set-up for biofeedback assisted PFM training, as they offer similar outcomes overall for management of stress urinary incontinence.

List discussion questions:
1. Given the number of methodological concerns in this study, what one thing can you take away and use in the clinical setting?
2. Do you think this study could be set up in a home-based EMG-assisted program using audio feedback with weekly or biweekly in-clinic sessions to update thresholds for contraction as needed? (patient’s would need to apply perineal electrodes on their own!). Or perhaps with once per week sessions in the clinic? (This is more likely feasible in a clinical situation.)