
Pelvic PT Distance Journal Club
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**Aim:** To provide detailed rationale and methodology for the development and implementation of a perioperative behavioral and pelvic floor exercise research protocol for women who self-chose surgical intervention and who may or may not have been offered behavioral treatments initially. This is part of the ESTEEM trial (Effects of Surgical Treatment Enhanced with Exercise for Mixed Urinary Incontinence Trial).

**Inclusion/Exclusion criteria:** A separate study by Sung et al, details inclusion/exclusion criteria and primary/secondary outcomes (see below: “Methods for a multicenter randomized trial for mixed urinary incontinence: rationale and patient centeredness of the ESTEEM trial”)

**Methods:** (The ESTEEM trial is an ongoing multisite, prospective randomized trial of female patients with MUI, who are randomized to standardized “perioperative” behavioral and PFM exercise intervention plus MUS vs surgery alone, with the aim of to understand which approach is superior.)

This paper outlines the behavioral/PFM exercise interventions and their standardization

- Postulated that PFM contraction raises urethra against pubis, prevents urethral descent and improves pelvic organ support.
- PFM hypothesized to induce muscle hypertrophy, improve external mechanical pressure on urethra and improve bladder neck support during increased IAP
- They define PFM as instruction on contracting/relaxing PFM correctly for strength/coordination as well as teaching to use Knack (functionally using muscles to occlude urethra during activities which caused increased IAP and possibly UI) They also teach quick PFM contractions for bladder inhibition and urgency suppression
- They used consensus based guidelines, behavioral therapy principles and adherence literature as well as exercise strength recommendations from the American College of Sports Medicine guidelines. Their ESTEEM protocol: 15 contractions, 3x/day, = 45 PFM contractions
- Also, to prevent SUI or UUI, they used skill motor learning: with augmented feedback : (in addition to patient sensory learning, patients are given augmentation of gradually decreased verbal feedback) and transfer (specific PFM function criteria are used to advance body position from supine, to sitting and to standing)
- Bladder Training (BT) – goal is to restore normal bladder function via Edu and self-adjusted voiding schedule. Possible mechanisms include 1) improving central control over bladder sensations and urethral closure and 2) changing a patient’s behavior to improve “reserve capacity” (to decrease frequent voiding, which may contribute to frequency, decreased bladder capacity and UUI This may help stop cycle of urgency, frequency and OAB).
- Bladder training, (BT): involves pt. Edu regarding LUT function, setting voiding schedules, teaching urge control to improve delay and schedule adherence. Effectiveness of BT with urge suppression for UUI shown to reduce UI by 60-80% but inconclusive research to date on comparison of this alone vs with PFMT.
- The ESTEEM BT/PFMT protocol: included individualized, progressive PFMT and BT strategies for urge suppression, improving voiding intervals and prevent or decrease UI.
• **Protocol** used 2 interventionists/site (PTs and or nurses/NPS), trained in protocol (Table 1). With use of a manual detailing all procedures and also possible protocol deviations, also their standardized Edu and certification of interventionists for LUT patient Edu, evaluation and treatment,
• Drift was avoided by audiotaping all interventions, as well as auditing twice, giving feedback (with extra auditing/feedback if drift noted).
• **Adherence** was monitored by a questionnaire they gave at every post op visit.
• A treatment booklet was given to patients as reference for HEP and changes of PFM ex’s, behavioral training/strategies including for adherence, were recorded at each visit.
• **Goal of** “Behavioral and PFM exercise interventions” were to increased patient knowledge of bladder and pelvic floor and voiding habits and to improve ind. performance of PFM ex’s, and BT strategies (urge suppression and delay to decrease frequency and PFM strategies to prevent SUI and control urgency.
• **Each visit** included digital assessment of PFM contraction with decreased verbal feedback in first and subsequent sessions.
• **Each visit**, Pt did previous week: 3-day bladder diary recording voids (not quantity), presence of urgency/UI, and reasons for UI and pad total/wet/day. (Table 2) and was used to monitor and coach with the appropriate behavioral strategy (urgency/frequency suppression/managementTable 3).
• .ESTEEM “Behavioral Intervention” was done over 6 months-
• **Baseline visit** at 2-4 weeks pre-op, then a F/U phone call, 2-4 days post hospital DC, then 5 visits at 2,4,6,8 weeks and 6 months.
• **Baseline visit** included Edu as mentioned above, correct PFM contraction, BT using urge suppression, and use of Knack to prevent SUI
• **PFM pre-op HEP**, pt did 3 sets of 10 PFM. **First set** or “Block was to “verify” (teach?) non forceful contractions w/o accessory muscles, of 1 sec contract 2 sec relax.
• **Second set** was 3 sec each, contract/relax, with PT or nurse feedback, 1-2 min rests and exercise modifications (Table 4), such as to do in supine or side lying if patient had trouble.
• **Third set** was a retention or test, for HEP Rx: patient attempted 10 reps at the duration held consistently at second set. HEP included number of reps as performed correctly, as well as duration of C/R and position via Standardized criteria for prescription on Table 4. (All participants to do max of 3 sets of 15 reps/day).
• **Post op Phone call**: in 2-4 days, interventionist determined patient readiness for HEP: if still having catheter, or discomfort, no PFM ex’s until after. Patient then got non PFM ex instructions for urgency suppression. If no discomfort, Pt was told to re-start HEP in 2-4 days post-surgery and to include PFM contractions for urgency suppression and SUI prevention.
• **Post op visits 2, 4, 6 and 8 weeks**: Pt evaluated for changes in PFM function and bladder sx, as well as for adherence/barriers to performing HEP. Remediation/or reinforcement of correct PFM exercise, BT, Knack use for SUI and urge suppression given. Also HEP (Table 5) was modified as needed/progressed. If patient reported no urinary sx, they were educated on import, to prevent recurrence and maintain integrity of surgical repair.
• Patient’s bladder diary and adherence questionnaire were reviewed to assess PFM ex and behavioral strategy status and adherence. If patient had no PFM contraction or weak and/or had barriers to ex or behavioral adherence, Table 4 strategies were recommended.
• Also Table 5 included strategies for women with barriers to physical activity adherence
• HEP prescription was based on similar to pre-op, but only 2 sets of 10 contractions: first set to verify correct PFM C/R with interventionist feedback, practice and modifications. Contractions were held at max duration achieved post op (or 3 sec at 2 wks., 5 and 7 s at 4 and 6 wks. The
HEP was determined by the second set, (see Table 4). Patients then given 2 wk. HEP of 45 contractions/day, (15x, 3 sets/day).

- **At 8 weeks**: most participants were expected to demo correct ex, then allowing HEP prescription, otherwise they did another set of 10. (Max was 9 sec).
- **To promote long term adherence**: at 8 weeks, maintenance was set at 3 x /week of 45 contractions (as previously). (They cite study showing no difference in urine loss, PFM strength and QOL at 6 months, with HEP of 1x vs 4x/week- Borello-France et al, JPT 2008).
- **All post op visits**: included pt. edu on healthy voiding habits and BT specifically: urge suppression and stress strategies PRN to decrease LUTS
- **At 6 month visit**: Patient’s skill/progress in PFM ex’s and behavioral strategies to decrease LUTS assessed. This visit was same as 8 wk. except patients who still had no palpable PFM contraction were told to discontinue contractions. Also, although diary analysis and BT strategies were given as needed, patients were expected to be independent with these. Maximum achieved hold was 10 seconds. HEP was same as at 8 weeks.

**Data collection and Statistical Analysis** not done yet (awaiting enough data due to patients having difficulty SUI on diary despite reporting SUI sx on UDI, also patient difficulty in coming to intervention visits and also surgeon concerns about performing MUS due to some controversy and also high prevalence of excluded population due to previous sling procedures. See previous, “Methods” paper).

**Results (Conclusion and Discussion)**: Paper detailed behavioral intervention methods and how they maintained standardization of interventions. This is unlike most published studies on behavioral interventions and UUI. They also discussed behavioral adherence barriers and strategies to improve adherence, (which is also rare). In this study, they developed and published guidelines for interventionists, which included modifications for special circumstances such as when patients had poor PFM function or trouble with adherence to the program. They standardized interventions by requiring standardization training and certification in all elements of the ESTEEM protocol. They did audits and recordings to insure quality control. They expect these measures to enable more accurate measurement of the impact of their interventions to reduce LUTS in women with MUS. They anticipate these methods could be a standard for future research that includes behavioral interventions to improve LUTS in women.

**Questions**

1) Do you see patients pre and post-op Mid urethral sling procedures? If so, do you or would you use these sorts of interventions/progressions?

2) What do you think about their rationale (on Table 5) for sidelying posture vs upright, if weak? What about overflow?

3) What did you learn that you may apply in your practice- (such as from Table 4: suggestions modifications for special circumstances)?