

Table 1a. Exclusion articles-methodologic features

| Study/year | Patient characteristics | Study Design | Treatment | Dropouts | Outcome Measures | Possible threats to validity |
|-----------------------|---|------------------|---|---|---|---|
| Bear, et al 1997 | 24 women age 55 years of age and older Living in a rural community Episodes of urinary incontinence 2 or more times per week Average age 68 years | Randomized trial | BMC consisted of three phases Self monitoring 2-4 weeks Scheduling regimen 6-8 weeks PME w/ biofeedback 3 times a week for 12 weeks | Control 6/12 (50%) BMC 9/12 (25%) | Episodes of urine loss as determined by patient diaries Pad tests | Randomization method not described. Authors state design was “quasiexperimental” |
| Bo, et al 1990 | 57 women with SI Mean age 45.5 years (24-64) | Randomized trial | Both groups performed 8-12 maximal PFM contractions 3 times/day for 6 months. Intensive exercise (IE) group also exercised with an instructor for 45 minutes once a week for 6 months performing long-lasting contraction. | 5/57 2 dropouts immediately 1 dropout after week one due to psychiatric problems 1 dropout due to surgery 1 subject in IE group excluded because of poor attendance | Pad tests Urinary leakage index Residual urine PFM strength Urodynamic measures Patient recorded diaries /3day | Randomization method not described Potential for selection bias |
| Burgio, et al 1989 | 20 men with persistent post-prostatectomy incontinence (stress or urge) for at least 6 months. Age range 55-89 years Duration of incontinence 6 months to 9 years | Case Series | 1-5 biofeedback training sessions depending on progress of patient. | 6/20 | Incontinent episodes/week Patient diaries completed for 2-week baseline period, a 2-week period when 2-hour voiding was recommended and 2-weeks immediately after behavioral treatment. | Potential for selection bias – patients were volunteers who responded to announcements. Potential for attrition bias |

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| Elia & Bergman 1993 | 36 women with SI Mean age 59 years (46-75) | Case series | Bi-weekly group sessions for 1.5 hrs for six weeks. Weekly group sessions for 1.5 hrs for six weeks. | | Urodynamic studies Pad count Questionnaire | Potential for selection bias |
| Jackson, et al 1996 | 28 men who had undergone radical prostatectomy Median age = 65 years (54-75) | Case series | Subjects received 10 weekly sessions of 15 minutes duration with a 1,3, 6 and 12 month follow up visit for assessment and follow up and reinforcement if needed. | 1/28 | Urodynamic studies Number of pad changes | No objective measures in the study to quantify degree of incontinence Outcome measures not typically utilized. |
| McDowell, et al 1992 | 47 patients Mean age = 74 years (56-90) Average of incontinence = 6.8 years | Case series | One session/wk up to 12 weeks (mean = 3.8) of behavioral techniques 28 patients had biofeedback training 1 pt received verbal feedback One session per week up to 7 weeks (mean = 1.8) of biofeedback training | 18/47 of the original subjects were either excluded or dropped out: 7 were either unwilling or unable to complete meaningful bladder diaries 11 patients dropped out too early for any outcome data to be acquired | Frequency of accidents Approximate volume of urine loss | Potential for attrition bias Potential for selection bias- several patients were self-referred. |

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| Wyman, et al 1998 | 204 patients with stress incontinence (SI) (n=145) and/or detrusor instability (N=59) Mean age 61 years Mean duration of incontinence was 8 years | Randomized trial with three treatment groups | 12-week intervention program, consisting of 6 weekly office visits and 6 weeks of mail/telephone contact. The PME group and combination group received 4 office biofeedback sessions. | 9 subjects withdrew after randomization or during intervention visits 16 subjects failed to keep follow up appointments or mail in completed instruments at 3 month follow up | Number of incontinent episodes/week Pad weight Quality of life Perceived improvement Satisfaction | Randomization process not described. Examiner not blinded to treatment group assignment. Possible selection bias. |

Table 1b. Exclusion articles-outcomes

| Study/year | Pt recorded diaries | | | | | | Pad test | | | | | Comments |
|-----------------------|--|------|-------|-----------------------|---------------------------|--|--------------|-------------|-----------------------|---------------------------|--------------------|--|
| | Measure | Pre- | Post- | % change ¹ | % pts improv ² | % dry ³ | Pre- | Post- | % change ⁴ | % pts improv ⁵ | % dry ⁶ | |
| Bear, et al 1997 | Authors report a 28% increase in frequency of urine loss for the control group, but did not report data | | | | | | 65 gm/day | 79.3 gm/day | NR | -22% | NR | Limited data provided. No statistical analyses provided. Unclear whether data is significant. Of note, authors used a 3-day bladder diary used instead of a 7-day bladder diary to maximize compliance by frail elders. Authors acknowledge “lack of response to this project by frail elders and their caregivers.” |
| | Authors report a 34% decrease in incontinent episodes for the experimental, but did not provide data | | | | | | 68 gm/day | 45.6 gm/day | NR | 33% | NR | |
| Bo, et al 1990 | Not reported Authors state that 60.1% in the intensive exercise group and 17.3% home exercise group were continent or almost continent. p<0.01 | | | | | | (IE) 27 gm | 7.1gm | | 74% | | Little data is provided to assess. In addition, the 95% CI are broad, including 1. |
| | | | | | | p<0.01 State no change in the HE group. | | | | | | |
| Burgio, et al 1989 | Accidents/week | | | | | | Not measured | | | | | Authors report statistical tests on frequency of data, rather than actual data. Significant dropout rate > 20% No intent-to-treat analysis. |
| | stress | 13.8 | 3.0 | NR | 78.3 | 37.5 | | | | | | |
| | urge | 27.4 | 3.6 | NR | 80.7 | 25 | | | | | | |

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| Study/year | Pt recorded diaries | | | Pad test | | | Comments | | | | | | | | | | | | |
|------------------------------|--|-------------------|--|--------------|--|-------------------|--|-------------|------------|------------------------------|------------|-------------|----------------------|-----------|-----------|---------------|--|--|---|
| | Measure | Pre- Post- | % change ¹ % pts improv ² % dry ³ | Pre- Post- | % change ⁴ % pts improv ⁵ % dry ⁶ | | | | | | | | | | | | | | |
| Elia & Bergman 1993 | Not reported Authors state that 56% of patients considered their stress incontinence improved or cured 3 months after finishing an active Kegel exercise program, whereas 16 considered their urinary control unchanged. | | | NR | | | Little data actually provided. Data which was reported on subjective improvement was not statistically significant. Other measures not reported. ROC data provides questionable clinical significance. | | | | | | | | | | | | |
| Jackson, et al 1996 | Not measured Authors state 13 (48%) had complete success, 7 (26%) had significant improvement, and 7 had failure, for an overall improvement rate of 74%. | | | Not measured | | | Little data provided. No statistical analyses reported. | | | | | | | | | | | | |
| McDowell, et al 1992 | <table border="0" style="width: 100%;"> <tr> <td></td> <td style="text-align: center;">Pre-Tx Mean (SD)</td> <td style="text-align: center;">Post-Tx Mean (SD)</td> </tr> <tr> <td>Urinary Accidents (per week)</td> <td style="text-align: center;">16.9 (27.7)</td> <td style="text-align: center;">2.5 (3.7)*</td> </tr> <tr> <td>Daytime Urinations (per day)</td> <td style="text-align: center;">10.1 (3.4)</td> <td style="text-align: center;">8.6 (1.8)**</td> </tr> <tr> <td>Episodes of Nocturia</td> <td style="text-align: center;">1.8 (1.1)</td> <td style="text-align: center;">1.5 (0.7)</td> </tr> </table> <p style="text-align: center;">* p<0.01 ** p<0.05</p> <p>Author states 10 pts had no accidents after treatment</p> | | | | Pre-Tx Mean (SD) | Post-Tx Mean (SD) | Urinary Accidents (per week) | 16.9 (27.7) | 2.5 (3.7)* | Daytime Urinations (per day) | 10.1 (3.4) | 8.6 (1.8)** | Episodes of Nocturia | 1.8 (1.1) | 1.5 (0.7) | Not measured. | | | Short study period (2 weeks) Wide variation of outcomes Author comments that “there are no reliable predictor variables.” |
| | Pre-Tx Mean (SD) | Post-Tx Mean (SD) | | | | | | | | | | | | | | | | | |
| Urinary Accidents (per week) | 16.9 (27.7) | 2.5 (3.7)* | | | | | | | | | | | | | | | | | |
| Daytime Urinations (per day) | 10.1 (3.4) | 8.6 (1.8)** | | | | | | | | | | | | | | | | | |
| Episodes of Nocturia | 1.8 (1.1) | 1.5 (0.7) | | | | | | | | | | | | | | | | | |

Table 1b. Exclusion articles-outcomes

| Study/year | Pt recorded diaries | | | | Pad test | | | | | Comments |
|----------------------|-------------------------|-----------|-----------|-----------------------|---|--------------------|------|-------|-----------------------|--|
| | Measure | Pre- | Post- | % change ¹ | % pts improv ² | % dry ³ | Pre- | Post- | % change ⁴ | |
| Wyman, et al 1998 | Number of episodes/week | | | | Not reported | | | | | Study design to detect a minimum difference between treatment groups of 2.5 incontinent episodes per week – is this reduction clinically significant? No difference between BT and PME with respect to incontinent episodes. Since each of the 3 interventions had similar effects 3 months after treatment, the authors conclude that the specific treatment used for urinary incontinence may not be as important as having a structured intervention program with education, counseling, and frequent contact. |
| | BT | 14.6±11.2 | 10.6±16.3 | 18% | Authors note that because of the large amount of missing data, particularly at the 3 month follow up after treatment, results on pad weights lacked sufficient power to draw meaningful conclusions | | | | | |
| | PME | 16.8±17.1 | 9.6±110.8 | 13% | | | | | | |
| | Comb | 14.9±13.8 | 6.8±10.7 | 31% | | | | | | |
| | BT:PME p=0.796 | | | | | | | | | |

¹ % change – Defined as the percent decrease in the frequency of incontinence over a specified time period, calculated by the following equation:

$$\frac{\text{pretreatment episodes/period} - \text{posttreatment episodes/period}}{\text{pretreatment episodes/period}} \times 100$$

² % pts improv – Defined as the percentage of patients with 50% or greater decrease in the frequency of incontinence, as calculated by the previous equation.

³ % cure – Defined as the percentage of patients with 100% decrease in frequency of incontinence, i.e., no incontinent episodes over the specified time period.

⁴ % change – Defined as the percent decrease in the amount of urine lost in grams, following provocative maneuvers, calculated by the following equation:

$$\frac{\text{pretreatment pad weight difference} - \text{posttreatment pad weight difference}}{\text{pretreatment pad weight difference}} \times 100$$

⁵ % pts improv – Defined as the percentage of patients with 50% or greater decrease in the amount of urine lost in grams following provocative maneuvers.

⁶ % cure – Defined as the percentage of patients with 100% decrease urine loss, ie no urine lost following the provocative maneuvers.

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Key to Tables

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|------------------|---|
| BF | biofeedback |
| BMC | Behavioral Management for Continence |
| DI | detrusor instability |
| MI | mixed incontinence (stress and urge incontinence) |
| %change | percent change in incontinence (frequency by pt recorded diary or urine loss on pad test) |
| %cure | percent of patients with no further incontinence |
| % pts improv | percent of patients with >50% decrease in incontinence (frequency by pt recorded diary or urine loss on pad test) |
| PME | pelvic floor muscle exercise |
| SI | stress incontinence |
| UI | urge incontinence |
| Selection bias | Imbalances in patient characteristics between groups with potential for differences to affect outcomes |
| Performance bias | Inequality in the intensity of treatment given between groups |
| Attrition bias | Significant number of dropouts in one or more study arms, not taken into account in the statistical analysis |