

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.
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						

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														
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)*																	
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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.

Table bibliography:

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Key to Tables

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