Abstract #563



Biofeedback-Assisted Pelvic Floor Muscle Training Combined with a Short-Duration Drug Regimen is Safe and Effective in Women with Overactive Bladder : A Randomized Controlled Trial

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Hypothesis / aims of study

We hypothesized that combination therapy would provide a synergistic effect to improve treatment outcomes for overactive bladder (OAB), thus enhancing the motivation for continuous exercise, and that it would be associated with fewer adverse events than monotherapy. Therefore, we investigated whether biofeedback-assisted pelvic floor muscle training (PFMT), drug therapy, or a combination of both would be more effective in improving the symptoms of OAB.

Study design, materials and methods

This randomized controlled trial included women diagnosed with OAB. Group 1 received biofeedback-assisted pelvic muscle floor training (PFMT) for 12 weeks; group 2 took 5 mg of solifenacin/day for 12 weeks; and group 3 received 5 mg of solifenacin/day in combination with biofeedback-assisted PFMT during the first 4 weeks and biofeedback-assisted PFMT for another 8 weeks. All participants had 5 follow-up visits. The primary outcomes were objective improvement of OAB symptoms and quality of life. The secondary outcomes were treatment-related adverse events, subjective improvement of OAB symptoms, and electromyographic activity of pelvic floor muscle (PFM) contraction.

Results and interpretation

All participants reported significant improvement of OAB symptoms and quality of life. Participants in group 2 experienced more pronounced adverse events than those in group 3. Intervention duration was positively associated with subjective improvement in OAB symptoms in all groups, with significant improvements at weeks 4, 8, and 12. When week 4 was used as the reference, only group 3 showed significant improvement of OAB symptoms at week 12. Drug-related adverse events, including dry mouth, myalgia, and restlessness, had a negative impact on the subjective improvement of OAB symptoms in group 2. In group 1, exercise adherence was positively correlated with subjective improvement of OAB symptoms provement of OAB symptoms in group 2. In group 1, exercise adherence was positively correlated with subjective improvement of OAB symptoms in group 2. In group 1, exercise adherence was positively correlated with subjective improvement of OAB symptoms.

Table 3 Subjective improvement of overactive bladder symptoms in the different intervention groups over 12 weeks according to linear mixed model analysis

Intervention Group	Variable		Subjective improvement				
			В	SE	P-Value		
1	Treatment duration	Week 2 (ref.)					
		Week 4	0.89	0.55	0.11		
		Week 8	0.45	0.59	0.440.18		
		Week 12	0.81	0.60			
		Week 4 (ref.)					
		Week 8	-0.43	0.82	0.6		
		Week 12	-0.08	0.76	0.92		
2	Treatment duration	Week 2 (ref.)					
		Week 4	0.41	0.09	<0.0001**		
		Week 8	0.60	0.10	<0.0001****		
		Week 12	0.62	0.01	<0.0001****		
		Week 4 (ref.)					
		Week 8	0.18	0.09	<0.05*<0.05*		
		Week 12	0.20	0.09			
3	Treatment duration	Week 2 (ref.)					
		Week 4	0.19	0.11	0.09		
		Week 8	0.29	0.12	<0.05*		
		Week 12	0.88	0.1	<0.0001***		
		Week 4 (ref.)					
		Week 8	0.10	0.12	0.41		
		Week 12	0.69	0.12	<0.0001***		

Table 1 Improvement of overactive bladder symptoms and qualityof life before and after the intervention

Group	Variable	Before	After	P-value [‡]	Effect
					size
1	Micturitions/24 h	10.0 (3.8)	7.9 (2.5)	<0.001***	0.8
n=58	Urgency episodes/24 h	4.3 (3.5)	2.1 (2.6)	<0.001***	0.7
	Incontinence episodes/24 h	1.93 (3.5)	0.4 (1.3)	<0.05*	0.4
	Urine amount (ml)/per micturition	208.9 (75.9)	243.4 (82.8)	<0.01**	0.6
	Water intake amount (ml)/per day	1536.4 (328.3)	1657.4 (468.4)	0.14	0.3
	King's Health Questionnaire	48.6 (18.3)	35.8 (12.7)	<0.001***	0.9
2	Micturitions/24 h	11.4 (3.8)	9.3 (3.1)	<0.001***	1.1
n=66	Urgency episodes/24 h	3.0 (1.9)	1.6 (1.9)	<0.001***	1.0
	Incontinence episodes/24 h	1.2 (2.9)	0.3 (1.6)	<0.05*	0.4
	Urine amount (ml)/per micturition	189.6 (67.1)	238.4 (110.9)	<0.01**	0.5
	Water intake amount (ml)/per day	1775.1 (647.9)	1962.6 (647.2)	<0.05*	0.4
	King's Health Questionnaire	41.9 (9.3)	32.5 (8.7)	<0.001***	0.9
3	Micturitions/24 h	9.7 (3.1)	7.7 (2.5)	<0.001***	1.0
n=41	Urgency episodes/24 h	3.1 (2.1)	0.8 (1.2)	<0.001***	1.2
	Incontinence episodes/24 h	0.8 (1.5)	0.3 (0.9)	0.06	0.5
	Urine amount (ml)/per micturition	230.1 (56.1)	279.5 (95.4)	<0.05*	0.6
	Water intake amount (ml)/per day	1560.0 (396.9)	1806.0 (491.3)	0.1	0.4
	King's Health Questionnaire	49.2 (14.9)	33.2 (10.7)	<0.001***	1.2

Values are expressed as numbers (variances).

Group 1: biofeedback-assisted pelvic floor muscle training only; group 2: drug therapy only; group 3: combination of both

*/**/*** statistically significant; [‡] paired sample t test

*/** statistically significant

Group 1: biofeedback-assisted pelvic floor muscle training only; group 2: drug therapy only; Group 3: combination of both

Abbreviations: B, unstandardized beta; SE, standard error; ISVC,

increased sustained voluntary contraction; ref., reference

Table 4 Subjective improvement of overactive bladder symptoms in the different intervention groups over 12 weeks according to linear mixed model analysis

Intervention Group	Variable		Subjective improvement					
			В	SE	P-Value			
1	Adverse events	Dry mouth	-0.11	0.15	0.46			
		Constipation	-0.09	0.16	0.59			
		Myalgia	-0.13	0.15	0.36			
		Restlessness	-0.10	0.18	0.57			
		Heartburn	-0.10	0.19	0.59			
	ISVC	Supine	-0.0004	0.003	0.92			
		Standing	0.003	0.01	0.56			
		Sitting	-0.004	0.01	0.43			
	Effect of biofeedback	Supine	-0.24	0.23	0.30			
		Standing	-0.32	0.20	0.11			
		Sitting	-0.17	0.19	0.38			
	Exercise adherence		0.31	0.14	<0.05*			
2	Adverse events	Dry mouth	-0.17	0.07	<0.05*			
		Constipation	-0.05	0.07	0.51			
		Myalgia	-0.21	0.08	<0.01**			
		Restlessness	-0.26	0.08	<0.001**			
		Heartburn	0.06	0.14	0.64			
3	Adverse events	Dry mouth	-0.09	0.07	0.20			
		Constipation	-0.04	0.08	0.59			
		Myalgia	-0.006	0.11	0.96			
		Restlessness	-0.12	0.13	0.35			
		Heartburn	-0.13	0.63	0.84			
	ISVC	Supine	-0.01	0.003	0.06			
		Standing	0.01	0.002	<0.001**			
		Sitting	0.01	0.005	<0.01**			
	Effect of biofeedback	Supine	0.15	0.19	0.42			
		Standing	-0.17	0.18	0.34			
		Sitting	0.01	0.004	<0.05*			
	F		-0.70	0.13	0.59			

Table 2 Adverse events in women with an overactive bladder after the 12-week intervention period (linear mixed model analysis) Abbreviations: B. unstandardized beta: ref., reference: SE, standard error

Treatment	Variable	Dry mouth		Constipation Myalgia		Restlessness		Heartburn			
duration		В	P-Value	В	Р-	В	P-	В	P-	В	Р-
		(SE)		(SE)	Value	(SE)	Value	(SE)	Value	(SE)	Value
Week 4	Intervention Group										
	3 (ref.)										
	1	-0.33	<0.05*	-0.30	<0.05*	-0.06	0.69	-0.08	0.53	0.03	0.71
		(0.16)		(0.14)		(0.15)		(0.12)		(0.07)	
	2	0.65	<0.001*	0.08	0.54	0.33	<0.05*	0.29	<0.05*	0.17	<0.05*
		(0.16)	**	(014)		(0.14)		(0.12)		(0.07)	
Week 12	Intervention Group										
	3 (ref.)										
	1	0.47	0.77	0.03	0.75	0.05	0.73	0.01	0.90	0.03	0.66
		(1.59)		(0.11)		(0.14)		(0.11)		(0.08)	
	2	0.92	<0.001*	0.35	<0.001	0.27	<0.05*	0.14	0.22	0.16	<0.05*
		(0.16)	**	(0.11)	***	(0.13)		(0.11)		(0.08)	



Fig. 1. Subjective improvement curves of overactive bladder symptoms in the three groups. Group 1: biofeedbackassisted feedback pelvic floor muscle training; group 2: drug therapy; group 3: combination therapy.

Conclusions

Biofeedback-Assisted Pelvic Floor Muscle Training Combined with a Short-Duration Drug Regimen is Safe and Effective in Women with Overactive Bladder.