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ORIGINAL ARTICLE

Depressive symptoms and treatment of women with urgency urinary incontinence

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Abstract
Introduction and hypothesis Depression is more common in patients with urinary incontinence (UI). Drug or rehabilitation therapy have been shown to be effective in reducing urgency UI (UUI) symptoms, but whether these treatments can ameliorate the negative impact of UUI on the psychological aspects of quality of life is unclear.
Methods A secondary analysis of an assessor-blinded randomized controlled trial was performed. The number of depressive symptoms was the primary outcome as measured by the Center for Epidemiologic Studies Depression scale (CES-D).
Results Thirty-six (22 %) subjects had a CES-D score >16 at baseline, the cutoff for having depressive symptoms. A significant association was found between having a CES-D score >16 and lower quality of life related to UI at baseline. The mean CES-D score among those with depressive symptoms at baseline was significantly reduced throughout the study, with a mean of 23.7 at baseline, to 18.3 and 15.2 at the 3-month and 1-year follow-up ($p<0.001$), respectively. The number of participants who had depressive symptoms decreased during the study period only in the physical therapy groups, from 31 at baseline to 28 and 25, at 3 and 12 months, respectively, while there was no such change in the drug group.
Conclusions Patients with UUI who had depressive symptoms showed significant improvement in their depressive symptoms with treatment over 1 year. This improvement occurred regardless of the type of treatment. This study emphasizes the increasingly recognized problem of undiagnosed depression among middle-aged women with UUI.

Keywords Center for Epidemiologic Studies Depression scale (CES-D) · Depressive symptoms · Drug therapy · Pelvic floor physical therapy · Pelvic floor muscle training · Urgency urinary incontinence

Abbreviations

DT	Drug therapy
BT	Bladder training
CES-D	Center for Epidemiologic Studies Depression scale
CPFR	Combined pelvic floor rehabilitation
DS	Depressive symptom
PFMT	Pelvic floor muscle training
QOL-rUI	Quality of life related to urgency urinary incontinence
UI	Urinary incontinence
UUI	Urgency urinary incontinence

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Introduction

Urinary incontinence (UI) and major depression are prevalent and distressing illnesses among women. During their lifetimes, approximately one half of all women will have UI, and 21 % will have one or more episodes of major depression. Both disorders are associated with social stigma, underreporting by patients, and lack of recognition by physicians [1–3]. Depression has been shown to have a marked effect on both social and vocational functioning, with increased disability, mortality, and health care utilization and lost productivity [2, 3]. One of six adults reported depression or anxiety in Israel in 2003 [4], but the true prevalence of depressive disorder is thought to be higher and difficult to determine [3].

Steers and Lee found that among women with UI 15.5 % have depression, which is significantly higher than in women without UI (9.2 %) [5]. Moreover, each 7-episode increase in UI per week was found to be associated with increased depressive symptoms (DS, adjusted odds ratio 1.10, 95 % confidence interval 1.01–1.21, p=0.005) [6]. Compared to stress UI, urgency UI (UUI) exerts a greater impact on quality of life. One reason for this disparity may be the unpredictable nature of UUI and reduced ability to control activities associated with urine loss. The emotional burden of UUI may lead to higher rates of psychiatric disorders such as anxiety or depression compared to nonsufferers [5]. The prevalence of depression in women aged 40–44 with UUI is reported to be 11.7 % [7]. A causal association between incontinence and depression would require community-based prospective studies, but such studies are rare [5]. Although many studies have shown that various treatments reduce the frequency or severity of UUI symptoms, less is known about the impact of treatment on patients' quality of life, particularly in the realm of psychological distress [8]. Only one study which compared short-term outcomes of drug therapy (DT) to bladder training (BT) and pelvic floor muscle training (PFMT) for women aged over 55 with UUI and stress UI evaluated the effect on psychological distress [8].

The goals of this study were (1) to examine whether UUI therapy is more beneficial for UUI women with DS compared to UUI women without DS and (2) to identify which treatments are more beneficial for improvement in the DS. To answer these questions we conducted a supplementary analysis of data from a randomized controlled trial (RCT), in which we compared long-term efficacy of BT, PFMT, combined pelvic floor rehabilitation (CPFR), and DT in women with UUI [9].

Based on our recently published RCT that showed improvement in quality of life in UUI women following UUI therapy [9] we hypothesized that UUI treatment, i.e., DT, BT, PFMT, or CPFR is more beneficial for women with DS compared with women that did not suffer from DS. Our second hypothesis is that the UUI physical therapy interventions are more beneficial for relieving DS than UUI DT in that it provides positive reinforcement and encouragement through psychological support and behavioral intervention [9].

Materials and methods

A total of 164 women with UUI symptoms were recruited to a randomized single-blind controlled trial. Additional detailed description of this study was reported elsewhere [9]. Women were recruited through invitation letters that were sent to 30,000 potential candidates randomly selected from a population of 520,000 women aged 45–75. Of these, 164 women with UUI symptoms who were diagnosed by health care professionals and fulfilled the inclusion–exclusion criteria were recruited. The inclusion criteria were: women aged 45–75 that experienced at least three episodes of UUI, i.e., a complaint of involuntary loss of urine associated with urgency that was not explained by stress UI symptoms [9, 10]. One of the exclusion criteria was the presence of *clinically diagnosed* depression or other psychiatric disorder. We used this exclusion criterion because of our pilot results which showed that clinical depression treated with antidepressant drugs can bias study results towards treatment failure [9]. Other exclusion criteria were: not being functionally independent, contraindications to DT, current urinary tract infection, neurological disease, previous pelvic floor surgery, and previous pelvic floor physical therapy. All women provided informed consent in accordance with procedures approved by the Institutional Review Board of Maccabi Healthcare Services in Israel (Clinical Trials Registration number NCT00498888).

Procedures

The study was comprised of baseline examination (t0), post testing examination after 3 months of treatment (t1), and 12-month follow-up (t2). The four study arms were: DT (tolterodine SR 4 mg), BT, PFMT, or CPFR. After baseline examination, patients were randomly allocated to one of the four study groups by randomly permuted blocks of four, with random assignment concealed in tamperproof envelopes. The assignment was enclosed in sequentially numbered sealed envelopes by a person not involved in the study. The examiner was blinded to the participant's allocation; however, the participants were not blinded to the group allocation. To minimize the likelihood of assessor bias, participants were asked not to discuss their treatment and/or reveal to the principal investigator any information on group allocation doing the assessments. Patients from the BT, PFMT, and CPFR groups had 4 visit appointments, once

every 3 weeks, with 1 of 20 female physical therapists who specialized in pelvic floor rehabilitation. Each visit lasted 50 min. To ensure standardization of all study procedures, training meetings were conducted by the principle investigator for all participating therapists before and during the trial. The compliance with taking medication was tracked by collecting the blister packs that were used during the trial.

Outcome measures

The primary outcome of this analysis was the number and presence of DS as indicated by the Center for Epidemiologic Studies Depression scale (CES-D). The CES-D was developed by Radloff in 1977 [11, 12]. Although originally developed as a general screening measure, it is widely used as a measure to monitor DS. The 20 items assess the frequency of occurrence of DS symptoms, within the last 7 days, on a 4-point rating scale from 0 (rarely or none of the time) to 3 (most of the time: 5–7 days); therefore, higher scores indicate more DS. CES-D scores ≥16 are considered to be more likely to indicate depression. Internal consistency for CES-D is high (Cronbach's α=0.88) [11].

The secondary outcomes were measures of UUI parameters: urination frequency in 24 h and self-recorded UUI episodes in the last week. Quality of life related to urinary incontinence (QOL-rUI) [13] measures included: (1) Incontinence Quality of Life instrument (I-QOL) (intraclass correlation coefficient 0.83–0.93); (2) each subject was asked to report existence of symptoms known to be related to UI or DT: dry mouth, constipation, sleepiness, fatigue, vision disturbance, dizziness, urination distribution, breathing difficulty, headache, and low back pain [9]; and (3) health status was measured by the EuroQol visual analog scale (EQ VAS) that records the responder's self-rated health on a vertical VAS in which the endpoints are labeled "best imaginable health state" and "worst imaginable health state" [13].

Statistical analysis

Baseline characteristics of the depressed and nondepressed groups were compared using the Kruskal-Wallis U test since the data were not normally distributed (Shapiro-Wilk statistic). To test our first hypothesis that all therapies are more beneficial for subjects with DS compared to women without symptoms, (1) during the first 3 months (t0 to t1) and (2) during the 12 months follow-up, in comparison with baseline measurements (t0 to t2), we applied mixed-effect models for repeated measures to evaluate within group and between group differences. We applied a separate model where the dependent variables were: number of voids per 24 h, self-recording of UUI episodes during the previous week, CES-D score, I-QOL, number of UUI-related symptoms, and the EQ VAS health (continuous measures), while the independent variables were categorical: the study groups (nondepressed vs depressed women) time (t0, t1, and t2) and the interaction effect between group and time.

To test our second hypothesis that the physical therapy interventions are more beneficial than DT for all subjects (with or without DS), (1) during the first 3 months (t0 to t1) and (2) during the 12 months follow-up, in comparison with baseline measurements (t0 to t2), we applied a model where the dependent variable is CES-D score (a continuous one), while the independent variables were categorical: the study groups (DT vs BT vs PFMT vs CPFR) time (t0, t1, and t2) and the interaction effect between group and time. The proportion of subjects with DS in each group over time was determined. The p values reported are based on two-sided comparisons. A p value of 0.05 was considered statistically significant.

All data were analyzed by intention-to-treat methodology. For participants who dropped out of the study, the last value available was carried forward to account for missing data [14]. Statistical analyses were performed using SPSS Statistics version 15 (SPSS Inc., Chicago, IL, USA).

Results

Of 164 women, 36 (22 %) showed DS as the CES-D scores suggest at baseline (CES-D score >16). Also, there was no significant difference in this proportion between subjects who finished the study protocol (28/137, 20.4 %) and those who dropped out (8/27, 30 %) (p=0.313). Baseline characteristics, including age, parity, body mass index, frequency of voids, and UUI episodes, were not significantly different between women with and without DS. Women with DS showed a significantly higher prevalence of fatigue and headache symptoms compared with women without DS (83.3 vs 58.6 % and 44.4 vs 22.7 %, p<0.01, respectively). Table 1 shows that women with DS also showed significantly lower scores on the QOL-rUI assessment and significantly lower EQ VAS scores compared to women without DS (63.7±21.2 vs 73.7±20.9 and 62.7±22.0 vs 78.7±15.1, p<0.001, respectively).

Women with and without DS showed a significant improvement over the study periods, with significant main effect of time for primary and secondary outcome measures (Table 2). Significant interaction effects between groups (with or without DS) and time were found for CES-D score and number of UUI-related symptoms, suggesting that the improvement in UUI symptoms and DS was greater for participants who had baseline DS compared with non-DS women. The interaction effects between groups for the EQ VAS health suggests that the EQ VAS health score in the DS women almost reached statistical significance compared with women without DS (p=0.055). The CES-D scores of

Table 1 Characteristics of women suffering from DS vs women that do not suffer from DS at baseline (n=164)

Characteristics	Full sample n=164	Women with DS	Women without DS	p value
Age	56.7±8.0	56.9±8.2	56.0±7.2	0.703
Education (years)	14.4±3.0	14.5±2.9	14.0±3.4	0.563
Married	121 (73.8 %)	96 (75 %)	25 (69.4 %)	0.591
Number of births	2.7±1.5	2.8±1.5	2.4±1.3	0.111
Body mass index	28.2±5.8	27.9±5.3	29.3±7.3	0.662
Number of UUI episodes/week	7.0±8.7	6.9±9.0	7.3±7.4	0.292
Number of voids per 24 h	12.1±4.6	11.9±4.6	13.1±4.7	0.096
I-QOL	71.7±21.3	73.9±20.9	63.7±21.2	0.010
EQ VAS	75.2±18.0	78.7±15.1	62.7±22.0	<0.001
Number of UUI-related discomforts	2.4±1.8	2.2±1.7	3.5±1.9	<0.001
Dry mouth	60 (36.6 %)	42 (32.8 %)	18 (50 %)	0.059
Constipation	36 (22 %)	27 (21.2 %)	9 (25 %)	0.618
Fatigue	105 (64 %)	75 (58.6 %)	30 (83.3 %)	0.006
Headache	45 (27.4 %)	29 (22.7 %)	16 (44.4 %)	0.010
Low back pain	59 (36 %)	43 (33.6 %)	16 (44.4 %)	0.232

Values represent mean±SD for continuous data and n (%) for categorical data. All p values are based on the Kruskal-Wallis test for continuous variables and chi-square test for categorical variables

36 participants who had DS at baseline decreased significantly throughout the study intervention period, from a mean of 23.7±8.7 at baseline to 18.3±12.8 after 3 months and 15.2±10.5 after 1 year follow-up (p<0.001), which is clinically important since a CES-D score below 16 is considered as not having DS.

No significant interaction effects between the four treatment groups and time for CES-D score were found for both the DS and non-DS women (Table 3). The results showed a significant main effect of time where the CES-D score improved for women with DS (F=9.190, p<0.001). UUI women without DS ,however, showed a small increase in CES-D scores (F=4.584, p=0.01) well below the CES-D score of 16 that is considered to indicate depression.

We also examined the proportion of DS patients in each treatment group over time. Because of the small sample size we attempted comparison of DT with any physical therapy (which aggregated women from the BT, PFMT, and CPFR groups). This demonstrated that in the DT group 5 (12 %) women had DS at baseline without changing throughout the study period, whereas in the physical therapy group 31 (25 %) women had DS at baseline and 28 (22 %) and 25

Table 2 Baseline value and changes from baseline for outcome measures, showing participants with or without DS at baseline

		Measurements			ANOVA (t0–t2)	
Variable	Baseline DS	t0	t1	t2	Time	Time × group
Number of voids per 24 h	Without DS	11.9±4.6	9.7±3.9	9.1±4.1	F=18.334 (p<0.001)	F=1.653 NS (p=0.193)
	With DS	13.1±4.7	11.0±3.6	11.6±5.6		
Number of UUI episodes/week	Without DS	6.9 ±9.0	3.2±4.6	3.5±7.2	F=9.763 (p<0.001)	F=0.697 NS (p=0.499)
	With DS	7.3 ±7.4	4.9 ±6.7	5.3 ±7.0		
CES-D score	Without DS	5.6±4.2	6.2±5.8	7.3±6.7	F=11.509 (p<0.001)	F=24.779 (p<0.001)
	With DS	23.7±8.7	18.3±12.8	15.2±10.5		
I-QOL	Without DS	73.9 ±20.9	90.2 ±19.9	91.8 ±19.4	F=54.121 (p<0.001)	F=1.126 NS (p=0.326)
	With DS	63.7 ±21.2	76.1±22.3	76.9±24.7		
Number of UUI-related symptoms	Without DS	2.2 ±1.7	2.0 ±1.8	1.8 ±1.5	F=12.961 (p<0.001)	F=4.232 (p=0.015)
	With DS	3.5 ±1.9	2.6±2.1	2.3 ±1.8		
EQ VAS health	Without DS	78.7±15.1	79.7 ±16.5	79.7±15.7	F=5.374 (p=0.005)	F=2.920 NS (p=0.055)
	With DS	62.7 ±22.0	69.7±18.7	69.4±19.3		

Analysis of variance (ANOVA) with repeated measures for all outcome measures with main effects of groups (with DS and without DS) and time (t0 and t2) and the interaction effect between group and time. Values are mean±SD. Statistical significance set at p<0.05

t0 = baseline, *t1* = 3 months, *t2* = 12 months, *NS* not significant

Table 3 Changes from baseline (t0) to t1 and t2 for CES-D measures, by treatment groups

		CES-D score			ANOVA (t0–t2)	
Participants	Treatment group	t0	t1	t2	Time	Time x Treatment group
Participants without DS at baseline, n=128	DT	4.9±4.4	5.0±5.3	6.9±7.5	F=4.584 (p=0.01)	F=0.313 (p=0.930)
	BT	5.6±4.3	7.0±6.3	7.4±6.1		
	PFMT	6.3±4.5	6.7±6.1	7.2±6.7		
	CPFR	5.9±3.5	6.3±5.7	8.0±6.3		
Participants with DS at baseline, n=36	DT	27.8±12.1	23.0±15.3	14.2±19.6	F=9.190 (p<0.001)	F=0.618 (p=0.715)
	BT	22.6±10.8	17.7±15.6	12.6±7.5		
	PFMT	22.8±5.3	17.0±8.4	18.8±5.8		
	CPFR	23.7±6.1	17.9±11.5	16.3±11.2		

Analysis of variance (ANOVA) with repeated measures for CES-D score with main effects of treatment groups (DT, BT, PFMT, and CPFR) and time (t0, t1, and t2) and the interaction effect between group and time. Values are means±SD. Statistical significance was set at p<0.05

t0 = baseline, *t1* = 3 months, *t2* = 12 months, *DT* drug therapy, *BT* bladder training, *PFMT* pelvic floor muscle training, *CPFR* combined pelvic floor rehabilitation

(20 %) women had DS at 3 months and 12 months follow-up, respectively. This change, however, did not reach statistical significance.

The reported adherence to physical therapy treatment (BT=85 %, PFMT=90 %, and CPFR=95 %) was significantly higher than in DT (64 %) (p=0.01) at the 3-month follow-up assessment. Dropouts were defined as participants who took either less than three monthly packs of DT or attended less than three appointments with the physical therapist. Reasons for dropout from the DT group included 13 women that were unsatisfied with their group allocation, acute back pain (1 woman), and dizziness (1 woman). Two women withdrew from BT because of their medical condition (1 woman) and no response to treatment (1 woman). Six women withdrew from PFMT due to their medical condition (1 woman) and no response to treatment (5 women), with an additional two women withdrawing because of their medical condition at 1 year. Four women withdrew from the CPFR because of no response to treatment.

Discussion

Our analysis revealed two important findings. Despite the clinical depression exclusion criterion, 22 % of our study population had DS according to the CES-D. It is assumed that women who showed CES-D scores ≥16 are depressed [12], although they were not clinically diagnosed and not treated for depression. Our results showed significant improvement in CES-D scores post interventions. Furthermore, clinically meaningful improvement was found in the CES-D scores in these UUI women, i.e., scores less than 16, 12 months after treatments. This finding emphasizes the increasingly recognized problem of undiagnosed depression. Moreover, if we had not excluded the clinically depressed women from the study, the prevalence of DS in the study population would probably be higher. Depression, anxiety, and UI are all associated with social stigma [7], and depression was found to be associated with poorer perception of physical health and quality of life in Israeli primary care patients [3]. Our finding of significantly lower QOL-rUI and health scores in participants with DS strengthens this knowledge.

We also found that physical therapy or DT for UUI women improved DS (Table 3). A recent review conducted by Ströhle (2009) suggests that exercise training may be clinically effective in depression and panic disorder [15]. However, research regarding the effect of conservative treatment of UI on psychological distress is sparse [8]. For example, Burgio et al. [8] found that psychological distress was significantly reduced after behavioral or drug treatment for UUI, regardless of the type of treatment, and the reduction of distress was not correlated consistently with reduction of incontinence. Also, Tadic et al. [16] found that behavioral treatment improved psychological burden, especially in those with a history of depression. Our results are in agreement with the above studies. Similar to Burgio et al. [8], we found that regardless of the type of treatment there was improvement in DS. In contrast to UUI women, no significant differences were found between baseline and 8 weeks follow-up, for both anxiety and depression scales [17], in a group of 21 women with stress incontinence (mean age 54.5 ±9) who were awaiting surgery and received 6 weeks of biofeedback training of the pelvic floor muscles.

To our knowledge this is the first randomized single-blind controlled trial that compares the long-term clinical effectiveness of two different approaches to relieve UUI symptoms (i.e., drug vs behavioral treatments). Previous studies have not examined the clinical effect on DS in women with pure UUI with a strict protocol (drug vs behavioral). Furthermore, women who had biofeedback assisted PFMT were instructed to continue taking

anticholinergic medications for UI throughout the study [16], and the placebo control included bladder diary monitoring and therapist contact as well [8].

Many women with bladder incontinence self-manage their condition by restricting their activities and by using various coping mechanism such as "toilet mapping" and defensive voiding. This self-management approach often leads to social withdrawal, relationship difficulties, and fear of engaging in everyday life, aggravating a cascade of social and psychological distress [18]. In our study, in comparison to women without DS, women with DS had significantly lower self-rated health as evaluated by the EQ VAS. They also had significantly more complaints of UUI-related symptoms such as fatigue and headache. These symptoms overlap those of DS, so it is unclear if these symptoms are due to depression or due to UUI.

Based on Ströhle [15] it is reasonable to suggest that treatment with physical therapy which effectively reduces physical symptoms can also reduce the DS in UUI women. Unlike DT, which is a treatment that does not require physical activity, the aim of pelvic floor physical therapy in UI is to alter the individual's activities or their environment in order to improve bladder control [19]. However, in our study sample, we were unable to prove superiority of physical therapy treatments over DT.

The study has several limitations. First, our study sample was small, especially the DT group with DS. It might be that low sample size was the cause of inability to find statistically significant differences between physical treatments and DT. Second, we assessed UUI women who volunteered to the RCT study; it is well known that volunteer participants tend to have higher compliance in studies that require physical activity when compared with the general population. Thus, generalizing our findings to the population of UI patients should be done with caution. Third, we were unable to include an additional control group with no behavioral or drug treatments, due to the aforementioned ethical considerations. A nontreatment group would provide further information regarding the pure influence of time. It might be the time was the cure of the DS in UUI women.

In conclusion, our study suggests that a large proportion of UUI women suffer from DS that were undiagnosed. Also, it appears that UUI physical treatments or UUI drug treatments are able to improve DS in UUI women who suffer from DS. These results reflect the importance of enhancing the awareness of clinicians about the depressive component in UUI treatment as a component of overall health-related quality of life in UUI women. Future controlled studies with larger samples are needed to confirm our results.

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Conflicts of interest None.

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