

A Prospective Study to Investigate the Effect of Fesoterodine Treatment on Quality of Life, Anxiety, and Depression in Urge-Type Urinary Incontinence

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Purpose: Urinary incontinence (UI) is a fundamental health problem, can occur at any age but is especially common in older women. Depression and anxiety are also considerable problems for the elderly. UI is one of the geriatric syndromes that are thought to be related to depression and quality of life (QOL).

Materials and methods: This prospective study was conducted for a period of 2 months from February 2020 to April 2020. Women who applied to the outpatient clinic of geriatrics with UI symptoms were taken into the study. The type of UI was determined by using the 3 Incontinence Questions (3IQ). Only patients with urge incontinence were included in the study. Patients were evaluated for QOL, anxiety, depression, disability, and geriatric syndromes before and after treatment. Data analysis was done by using SPSS version 22.

Results: The study population was 42 women; the mean age was 69.7 +/- 4.3 years. QoL, anxiety, and depression symptoms, and ADL were revealed to be improved after treatment. ICIQ-SF, I-QOL, and HADs scores were associated with UI treatment when evaluated with one-way MANOVA ($F [4, 79] = 3.25, p = 0.00, \text{Wilk's } p = 0.859, \text{partial } \eta^2 = 0.14$).

Conclusion: UI is a common problem in the elderly. Patients usually hesitate to tell this complaint to even doctors. That situation affects their physical and psychological condition negatively. In this study, we reached that anticholinergic treatment (fesoterodine) improved ADL, QoL, and psychological symptoms. Those findings represented us that proper treatment of UI is critical for healthy aging.

Keywords: anxiety, depression, quality-of-life, urinary incontinence, urge-type

INTRODUCTION

Urinary incontinence (UI) is defined as “the complaint of involuntary loss (leakage) of urine” by the International Continence Society⁽¹⁾. It is a prevalent problem in the elderly, as it increases with age and affects about 35% and 22% of older women and men, respectively⁽²⁾. UI in women is typically related to dysfunction of the bladder or pelvic floor muscles, with such dysfunction usually begin to occur during pregnancy or childbirth, or at the time of menopause⁽³⁾. There are two main subtypes of UI: stress incontinence and urgency incontinence. According to the International Urogynecological Association (IUGA) and the International Continence Society (ICS) definitions, stress incontinence is the urinary leakage associated with coughing, sneezing, or physical exertion. In contrast, urgency incontinence is the urinary leakage associated with a sudden compelling desire to void that is difficult to defer⁽¹⁾. The most commonly seen subtype of UI in elderly patients is mixed incontinence, which is characterized by the combination of symptoms of these two subtypes⁽⁴⁾.

The diagnosis of UI is missed in 80% of cases due to patients' difficulties in expressing the complaint⁽⁵⁾. Continence is one of the most critical factors that can contribute to physical and mental health, quality of life, and people's well-being in all life stages, especially in old age⁽⁶⁾. It has been widely documented that UI is more prevalent in an older woman and cause a low quality of

life (QOL) and severe complications⁽¹⁾. Dermatological problems fall, psychological problems, impaired sexual performance, and social isolation are complications that cause decreased QOL in patients with UI^(2,7). In this study, we aimed to evaluate QOL, depression, and anxiety levels of patients diagnosed with UI. We also compared the pre-treatment and post-treatment status of the UI patients in terms of these parameters.

MATERIALS AND METHODS

Participants

This prospective study was carried out for a period of three months from February 2020 to April 2020. Patients consulted at the outpatient clinic of geriatrics with urge UI symptoms were included in the study. All of the patients were women and ≥ 65 years old. The study was approved by the Gaziantep University Local Research Ethics Committee. All participants gave informed consent.

Exclusion criteria

Patients below 65 are diagnosed with UI other than urge type, diabetes mellitus, urinary infection, urinary prolapsus, atrophic urethritis and vaginitis, mental retardation, and mobility restriction were excluded from the study. Patients who were using diuretics or on dialysis programs were excluded too.

Evaluation of participants

Patients who were diagnosed with urge UI were eval-

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Table 1. Scores of scales and tests used in the study.

| Scales and tests | N | mean | (±SE) (CI:95%) |
|----------------------------|----|-------|-----------------|
| ADL* | 42 | 4.86 | 0.07 |
| IADL* | 42 | 5.6 | 0.32 |
| sMMT* | 42 | 25.57 | 0.76 |
| MNA-SF* | 42 | 11.52 | 0.32 |
| FRAIL* | 42 | 2.67 | 0.19 |
| SARC-F* | 42 | 3.12 | 0.29 |
| Handgrip strength (kg) | 42 | 22.86 | 0.45 |
| SMM* (kg) | 42 | 44.87 | 1 |
| SMMI* (kg/m ²) | 42 | 19.57 | 0.5 |
| Gait speed (m/s) | 42 | 0.69 | 0.03 |
| ICIQ-SF* | 42 | 13.14 | 0.63 |
| I-QOL* | 42 | 65.4 | 3.02 |
| HADS-A* | 42 | 10.17 | 0.63 |
| HADS-D* | 42 | 8.93 | 0.62 |

ADL*: Activities of daily living

sMMT*: Standardized mini mental test

MNA-SF*: Mini nutritional assessment test short-form

FRAIL*: Fatigue, resistance, ambulation, illness, and loss of weight

SARC-F*: Strength, assistance walking, rise from a chair, climb stairs, and falls

SMM*: Skeletal muscle mass

SMMI*: Skeletal muscle mass index

ICIQ-SF*: International Consultation on Incontinence Questionnaire-Short Form

I-QOL*: Incontinence Quality of Life Scale

HADS-A*: The Hospital Anxiety and Depression Scale- Anxiety

HADS-D*: The Hospital Anxiety and Depression Scale- Depression

SE: standard error

uated. Their chronic diseases, drugs, fall history, and complaints about UI were recorded. Comprehensive geriatric assessment (CGA), frailty, and sarcopenia assessment were done on all patients. Validated scales were used for evaluation of the quality of life (QOL), depression, and anxiety. The same evaluation was done after three months of UI treatment. Evaluation of patients took approximately 30 minutes.

UI treatment

Patients were treated with 4 mg fesoterodine. Fesoterodine is a competitive muscarinic cholinergic receptor antagonist with muscle relaxant and urinary antispasmodic properties. Fesoterodine binds and inhibits muscarinic receptors on the bladder detrusor muscle, thereby preventing bladder contractions or spasms caused by acetylcholine. This resulted in the relaxation of bladder smooth muscle and increased bladder capacity, in addition to a reduction in involuntary muscle contractions and involuntary loss of urine.

Evaluation of urinary incontinence

Patients were evaluated for urinary incontinence by International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF)⁽⁸⁾ and 3 Incontinence Questions (3IQ)⁽⁹⁾. The ICIQ-SF questionnaire questioned the frequency, amount, type, and effects of urinary incontinence on daily life and scoring between 0-21 values is made. The Turkish validity and reliability study of the ICIQ-SF test was performed by Çetinel et al⁽¹⁰⁾.

Evaluation of quality of life (QOL)

Patients were evaluated for quality of life by the Incontinence Quality of Life Scale.

(I-QOL). The I-QOL contains three subscales. These are avoidance and limiting behaviors, psychosocial impact, social embarrassment. This scale consists of 22 items; all items are evaluated in a five-category Likert-type scale with values ranging from 1 (extremely) to

5 (not at all). A mean score for each subscale is calculated as well as a total score for all 22 items. The scores are then transformed into a 'Scale score' ranging from 100 points for ease of interpretation⁽¹¹⁾. The Turkish validity and reliability study of the I-QOL test was performed by Eyigor et al⁽¹²⁾.

Evaluation of anxiety and depression

Patients were evaluated for anxiety and depression by The Hospital Anxiety and Depression Scale (HADS). The HADS questionnaire consists of 14 questions, 7 for depression, and 7 for anxiety. Each question has four possible answers. Furthermore, it is calculated between 0-3 points according to the Likert scale. Cut-off values for anxiety and depression are considered 8-10 mild, 11-14 moderate, and 15-21 severe⁽¹³⁾. The validity and reliability study of the HADS test was performed by Aydemir et al⁽¹⁴⁾.

Comprehensive geriatric assessment:

The cognitive evaluation was done by the standardized form of mini-mental state examination (MMSE)⁽¹⁵⁾, assessment of daily living abilities (ADL) by Katz index⁽¹⁶⁾, instrumental activities of daily living (IADL) by Lawton Brody, and nutritional assessment by mini nutritional assessment test-short form⁽¹⁷⁾.

In MMSE, patients were evaluated for six different areas: orientation, registration, attention, calculation, language, and recall. Patients whose scores were ≤ 24 were accepted for the presence of dementia⁽¹⁵⁾. Katz index of ADL evaluated patients for personal hygiene, continence, dressing, feeding, and ambulating. Scores were between intervals of 0 and 6; higher scores mean higher independence⁽¹⁶⁾. Lawton Brody index was used for evaluating IADL like house cleaning, doing the laundry, marketing, managing medications, cooking, communicating with others, using transportation, and doing financial management; higher scores mean higher independence⁽¹⁸⁾. MNA-SF scores ≤ 7 indicate mal-

Table 2. Comparison of pre-post treatment scores of scales and tests.

| | Pre-treatment (n=42) | Post-treatment (n=42) | p= |
|----------------------------|----------------------|-----------------------|--------|
| SARC-F* | 3.12 ± 0.29 | 3.07 ± 0.17 | 0.91 |
| Handgrip strength (kg) | 22.86 ± 0.45 | 25.52 ± 0.6 | 0.82 |
| SMM* (kg) | 44.87 ± 1 | 44.68 ± 1.3 | 0.89 |
| SMMI* (kg/m ²) | 19.57 ± 0.5 | 19.28 ± 0.65 | 0.64 |
| Gait speed (m/s) | 0.69 ± 0.03 | 0.70 ± 0.04 | 0.76 |
| ADL* | 4.86 ± 0.07 | 5.12 ± 0.09 | 0.049* |
| sMMT | 25.57 ± 0.76 | 27.07 ± 0.8 | 0.1 |
| MNA-SF* | 11.52 ± 0.31 | 12.17 ± 0.27 | 0.12 |
| ICIQ-SF* | 13.14 ± 0.63 | 10.12 ± 0.57 | 0.005* |
| I-QOL* | 65.40 ± 3.02 | 75.95 ± 3.5 | 0.02* |
| HADS- A* | 10.17 ± 0.63 | 7.83 ± 0.68 | 0.022* |
| HADS- D* | 8.93 ± 0.62 | 6.14 ± 0.72 | 0.013* |
| FRAIL* | 2.67 ± 0.19 | 2.24 ± 0.24 | 0.09 |

ADL*: Activities of daily living

sMMT*: Standardized mini mental test

MNA-SF*: Mini nutritional assessment test short-form

FRAIL*: Fatigue, resistance, ambulation, illness, and loss of weight

SARC-F*: Strength, assistance walking, rise from a chair, climb stairs, and falls

SMM*: Skeletal muscle mass

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ICIQ-SF*: International Consultation on Incontinence Questionnaire-Short Form

I-QOL*: Incontinence Quality of Life Scale

HADS-A*: The Hospital Anxiety and Depression Scale- Anxiety

HADS-D*: The Hospital Anxiety and Depression Scale- Depression

nutrition⁽¹⁷⁾.

Assessment for sarcopenia

For defining sarcopenia, muscle strength, mass, and physical performances were assessed. SARC-F (strength, assistance walking, rising from a chair, climb stairs, and falls) test was used to select cases to evaluate muscle strength⁽¹⁹⁾. The handgrip test was performed if the patient had point ≥ 4 from SARC-F to diagnose probable sarcopenia. The handgrip test was performed by using a hand dynamometer with the dominant hand⁽²⁰⁾. For females < 16 kg (kilograms), for males < 27 kg was accepted as probable sarcopenic. A bio-impedance test was carried out on probable sarcopenic patients to assess skeletal muscle mass. Sarcopenia was diagnosed by skeletal muscle mass index. In this study, we used skeletal muscle mass index (SMMI) adjusted to height. SMMI was calculated by dividing skeletal muscle mass by the square of height⁽²¹⁾. We evaluated gait speed with a four-meter gait speed test to diagnose severe sarcopenia⁽²²⁾.

Assessment of frailty

We performed a frailty assessment by the FRAIL scale. The FRAIL scale includes five parameters: Fatigue, resistance, ambulation, illness, and loss of weight. Frail scale scores range from 0–5 (best to worst). Scores 3-5 were considered frail⁽³⁻⁵⁾, 1-2 pre-frail, and 0 robust⁽²³⁾.

Statistical analysis

The variables were analyzed for their distribution normality using the Kolmogorov–Smirnov and Shapiro Wilk test. ICIQ, OAB V8, and HADS A variables were disturbed normally ($p > 0.05$), and other variables were not disturbed normally. The independent sample t-test was used for the comparison of two groups for normally distributed data. Wilcoxon tests were used for the comparison of two groups for not normally disturbed data. Numerical variables were denoted as mean \pm standard error. The IBM SPSS for Windows, version 22.0 (IBM

Corp., Armonk, NY, USA) was used for statistical analysis.

RESULTS

Forty-two female patients who were followed up and treated in the geriatric outpatient clinic due to the diagnosis of urge UI were included in the study. The mean age of them was 69.7 ± 4.3 (minimum 65 years old, maximum 74 years old).

The average body mass index (BMI) of the patients was 33.50 ± 1 . Seven-point-one percent of them were normal weight ($n = 3$), 26.1% were overweight ($n = 11$), 52.6% were obese⁽²²⁾, and 14.2% were morbid obese ($n = 6$). All our participants had at least one chronic disease. The average number of medicine that patients used was 3.6 ± 0.6 . Polypharmacy was present in 23.8% of the patients

Educational status, marital status, social status, place of residence, smoking and/or alcohol consumption, driving and physical exercise status of the patients were not associated with ICI

Q-SF, IQOL, HADS-A and HADS-D scores ($p > 0.05$). Number of pregnancies, number of normal vaginal deliveries, history of cesarean section, history of abortion and history of induced abortion were also not associated with ICIQ-SF, IQOL, HADS-A and HADS-D scores ($p > 0.05$).

The mean ICIQ-SF scores of the patients were 10.12 ± 0.63 , the mean IQOL score was 75.95 ± 3.02 , the mean HADS-A score was 7.83 ± 0.63 , and the HADS-D score was 6.14 ± 0.63 . The first scores of scales and tests used in the study were summarized in **Table 1**.

All these measurements were repeated after three months of treatment and pre-post treatment values were compared. There was a significant improvement in the ADL score after treatment ($p = 0.049$). There was also a significant upturn in the I-QOL score ($p = 0.02$). The Katz and I-QOL scores were positively related to UI treatment. The frequency of incontinence and its effects

on daily life significantly improved with urinary incontinence treatment ($p = 0.005$). Improvement in anxiety ($p = 0.022$) and depression ($p = 0.013$) after treatment was revealed too. HADS-A and HADS-D scores were significantly decreased after treatment. ICIQ-SF and HADS scores were negatively related to UI treatment. ICIQ-SF, I-QOL and HADS scores were correlated with UI treatment when evaluated with one-way MANOVA ($F [4, 79] = 3.25, p = 0.00, \text{Wilk's } \Lambda = 0.859, \text{partial } \eta^2 = 0.14$). A comparison of pre-post treatment values was summarized in **table 2**. ADL and I-QOL scores were positively correlated with treatment status ($r=0.292, p = 0.007; r = 0.232, p = 0.02$). ICIQ-SF, HADS-A and HADS-D scores were negatively correlated with treatment status ($r = -0.304, p = 0.006; r = -0.279, p = 0.022; r = -0.349, p = 0.002$).

Patients were also evaluated for anticholinergic-related side effects. Anticholinergic side effects were not observed in 25 (59.5%) of the patients. Dry mouth was observed in 10 patients (23.8%), constipation in 4 patients (9.5%), and tachycardia in 3 patients (7.1%). There was no significant correlation between the development of anticholinergic-related dry mouth, constipation and tachycardia and I-QOL scores ($p = 0.746, 0.072, 0.146$).

DISCUSSION

Urinary incontinence is one of the most common geriatric syndromes in the elderly. Patients generally hesitate to tell this complaint even to doctors. This situation could negatively affect the physical and psychological status of the patients. In this study, we revealed improvements in patients' activities of daily life, frequency of incontinence and its effects on daily life, quality of life, and psychological status after 3 months of UI treatment. After the treatment, an increase in Katz score and I-QOL score and a decrease in ICIQ-SF score were found. Regarding I-QOL, a significantly good result was found in all scales (limitation of behavior, psychosocial influence, social isolation) after treatment.

The relationship between UI and depression was investigated in several studies. Felde et al. revealed that UI was a risk factor for both depression and anxiety with a dose-dependent trend (Felde et al. 2015). In that study, 16263 women over 20 years of age were followed for 10 years. Mild anxiety was detected in one of ten patients with urinary incontinence, and moderate or severe anxiety was detected in one of twenty patients. A significant relationship between UI and mild depression development was also found. Lai et al. showed that 27.5 % of overactive bladder (OAB) patients had depression in their study. They also reported OAB patients with depression had more severe incontinence symptoms (ICIQ-UI) and more impact on quality of life compared to OAB patients without depression⁽²⁴⁾. The relationship between UI, psychological problems, and quality of life could be explained by the patient's necessity to plan every detail in life due to UI and their fear to perform physical activities. This, in turn, can lead to feelings of loss of control and distress and can reduce the quality of life.

The causal relationship between UI and anxiety/depression can be explained by serotonergic and sympathetic pathways. Serotonergic pathways play a role in the regulation of both depression and continence functions. Serotonin inhibits the voiding reflex pathway and increases the tonus of the urethral sphincter. Serotonin levels are

low in clinically depressed individuals. Therefore, serotonin reuptake inhibitors may have positive effects in the treatment of stress-type urinary incontinence⁽²⁵⁾.

In many studies investigating the relationship between IU and depression, the distinction between incontinence types has not been made⁽²⁶⁾. However, there are also studies analyzing the subject by distinguishing the types of urinary incontinence from each other, such as our study. Walters and colleagues found no differences in psychological tests between women with detrusor instability and genuine stress incontinence⁽²⁷⁾. Conversely, Lee et al. concluded that women with urinary incontinence have more depression and stress than those who do not. The situation is similar for those women with both stress UI and urge UI as well as those with mixed UI⁽²⁸⁾.

The relationship between UI and quality of life (QoL) was also investigated in several studies. Saboia et al. concluded that mixed urinary incontinence decreased the quality of life more than stress urinary incontinence and urinary incontinence⁽²⁹⁾. In the study of Nygaard et al., it was shown that urinary incontinence negatively affects the quality of life and is more common in obese women⁽³⁰⁾. Pizzol et al. concluded that the presence of urinary incontinence negatively affects the quality of life in their meta-analysis. It was also observed that studies supporting this result were mostly performed using the SF-36 and Incontinence Impact Questionnaire (IIQ-7)⁽³¹⁾. Different from them, in our study, quality of life was evaluated with I-QOL. In the study of Ptak et al., it was revealed that pelvic floor muscle exercises positively affect the life quality of women with stress UI⁽³²⁾. Another study analyzing the effect of urge urinary incontinence treatment on quality of life has not been found in the literature.

In this study, we evaluated the change in the quality of life, anxiety, and depression in patients who had received three months of fesoterodine treatment for urge UI. Our study is the first study that evaluated the change in the quality of life, anxiety, and depression status of patients before and after treatment for urge urinary incontinence by an anticholinergic drug. The major strengths of our study are that it is a prospective study and similar studies showing the effects of urge UI treatment on quality of life, anxiety, and depression were not present.

In our study, an improvement was also observed in the SARC-F, MNA-SF, sMMT, and FRAIL scores after treatment. However, these were not statistically significant. Large-scale studies with more patients are needed to explain these relationships.

Some limitations of the study should be mentioned. The number of patients included in the study is small and the degree of urinary incontinence has not been fully investigated (eg by ped test). Another limitation is that the study was conducted three months after the UI treatment. Improvements in other parameters could be seen with longer follow-up. The absence of an untreated control group is major limitation of the study. The reason we designed the study in this way was our ethical reservations about depriving some patients of treatment. Therefore, we preferred to make the comparison between the pre- and post-treatment conditions of the patients, not with a control group that did not receive treatment.

CONCLUSIONS

Urinary incontinence is a geriatric syndrome that is common in the elderly. This situation can be skipped in many patients because patients generally hesitate to tell healthcare professionals about this complaint.

The negative effects of urinary incontinence on quality of life and the increase in anxiety and depression can be attributed to many reasons. The first of these is social isolation that occurs with urinary incontinence. The quality of life of the individual, who moves away from his daily activities and social environment, decreases significantly. Anxiety and depression are inevitable. In addition, we often come across elderly individuals avoiding fluid intake in order to prevent urinary incontinence. This situation and its consequences negatively affect the quality of life. In addition, urinary incontinence leads to urinary system infections and dermatological problems, thus negatively affecting the general health status and quality of life of the person. Therefore, early diagnosis and treatment of urinary incontinence is very important.

In this study, we showed that urge UI treatment with fesoterodine has a positive effect on the quality of life and psychological symptoms of patients.

CONFLICT ON INTEREST

None declared by the authors.

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