



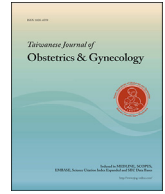
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## Original Article

## Urogynecological survey in a group of Italian women treated for overactive bladder: Symptoms and quality of life analysis during the Covid-19 period

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## ABSTRACT

**Objectives:** The aim of this study is to assess the impact of life change and social distancing measures, during the Covid-19 outbreak, on the OAB symptoms and quality of life in women underwent different types of treatment.

**Materials and methods:** Observational survey analysis in OAB treated patients was performed. The women showed a greater than 50% improvement during specific therapy for OAB. Population had previously completed bladder diary, OAB-Q symptom, OAB HRQL scale, SF-36 and PGI-I questionnaires. Four weeks after the introduction of the restrictive measures, these women were invited to complete the same questionnaires by e-mail for new evaluation during Covid-19 outbreak. Primary endpoint was changes in number of voids/24h, urgent micturitions/24h, urinary incontinence events/24h, nocturia events. Secondary endpoints were the assessment of the change in the OAB-SF, SF-36 questionnaires and PGI-I satisfaction.

**Results:** Six hundred seventy-three patients were considered. The mean age was  $63.21 \pm 10.24$  years. Four weeks after the start of the social distancing measures, the increase in mean number of voids/24h ( $7.13 \pm 1.08$  vs  $9.76 \pm 2.12$ ,  $p < 0.0001$ ), urgent micturition episodes/24h ( $2.65 \pm 1.11$  vs  $4.57 \pm 1.28$ ,  $p < 0.0001$ ), nocturia episodes ( $1.19 \pm 1.21$  vs  $2.83 \pm 0.94$ ,  $p < 0.0001$ ) was observed. The OAB symptom scores ( $32.67 \pm 12.88$  vs  $51.23 \pm 12.11$ ,  $p < 0.0001$ ), OAB-HRQL ( $75.45 \pm 12.76$  vs  $48.23 \pm 10.34$ ,  $p < 0.0001$ ), and SF-36 ( $82.15 \pm 11.78$  vs  $69.39 \pm 10.85$ ,  $p < 0.0001$ ) changed significantly. The satisfaction decreased significantly at the PGI-I during the Covid-19 period 79.8% vs 45% ( $p < 0.0001$ ).

**Conclusions:** The Covid-19 outbreak and the restrictive social distancing measures have negatively influenced the OAB symptoms and quality of life in women underwent different types of treatment.

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## Introduction

Overactive bladder syndrome (OAB) is a chronic disease characterized by urinary urgency with or without urge incontinence, frequency and nocturia. The overall prevalence of OAB in women is 16.9%, however increases with age, reaching 30.9% in women over 65 years of age [1,2]. The quality of life (QoL) is significantly

compromised. Pathophysiology is still unknown, even if it is known that neuropathic alteration and the impairment of nerve afferent could compromise bladder function and the detrusor contractility [3]. Several studies have shown a correlation between OAB and stress; in particular, some groups of women suffering from OAB and urge urinary incontinence have a demonstrated psychological alteration [4]. In addition, in high stress times, these women, could worsen the symptoms of urgency [5]. Today, the whole world is affected by the coronavirus-2019 (Covid-19) pandemic. World governments have had to introduce restrictive social distancing measures due to the severity of the emergency situation [6].

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Actually, more than 12,000,000 confirmed cases of Covid-19, and 560,000 new deaths, have been reported. Italy is the thirteenth most affected country in the world for the number of infected and dramatically the fourth for the number of deaths [7]. Since 11 March 2020 the Italian government has also launched, nationwide, the restriction and social distancing measures. The aim of these measures was to ensure the social distance between people avoiding the people's aggregation. Most of the services and commercial activities have been closed, and in open services, the social distance between individuals of at least 1 m must be guaranteed with protective masks [8].

However, although these procedures serve to decrease the spread of the virus, people are experiencing, suddenly, a change in their daily routine, limiting many personal and work activities. Consequently, during social distancing period, people could demonstrate mental health disorders (e.g. post-traumatic stress disorder, anxiety disorders, depression, somatization), and lowered perceived health [9]. Previous research has shown a significant psychosocial impact on people during times of global epidemic [10].

People are likely to experience negative emotions due to the closure of social gathering places like schools and business.

A stressful event affects bladder function, especially in women, increasing daily urination and worsening bladder compliance [11]. In addition, psychoanalysis and mental relaxation sessions have proven to be useful to reduce the symptoms of OAB [12,13].

Currently, in the literature, there are no data regarding the change in OAB symptoms in women undergoing different types of treatment during the social restriction measures taken due to the covid-19 epidemic. Probably the fear of contagion, the stressful situation and the change in daily life may affect the bladder function of the women examined.

The aim is to assess the impact of life change and social distancing measures caused by the Covid-19 pandemic on the OAB symptoms and quality of life in women undergoing different types of treatment.

## Materials And Methods

An observation survey analysis of patients treated for OAB, between February 2017 and February 2020, who had completed the bladder diary and specific OAB and QoL questionnaires which showed a greater than 50% improvement during specific therapy for OAB, in the 6 months preceding the start of social distancing measures for the Covid-19 epidemic.

Four weeks after the introduction of the social distancing measures due to the Covid-19 outbreak, they were invited to respond to the questionnaires again. All data were evaluated from a Gynecological and Urogynecological internal database. The research was conducted according to Good Clinical Practice Guidelines, Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines. The Institutional Review Board approved the study.

During the Covid-19 epidemic period (at least 4 weeks after the introduction of the restrictive measures), given the impossibility of returning patients to the specific outpatient of the department, these women were invited to answer the same questionnaire to re-evaluate bladder function and quality of life. Questions were sent by email, to avoid the telephone interview that could influence the answers of the women interviewed. The sample of the analyzed women is conditioned by the inclusion and exclusion criteria and by the adherence of the women. A time limit of 3 days was offered to respond to the questionnaires.

The inclusion criteria were as follows: signed informed consent and permission for the processing of health data; OAB treatment for

at least 12 weeks, filling in the questionnaires related to the OAB impact (The OAB-Q Short Form symptom and OAB health-related quality of life HRQL scale), to the quality of life (The Short Form 36 Health Survey, SF-36) and to the satisfaction (Patient impression of global improvement, PGI-I) with the ongoing treatment, within 6 months from the start of the social distancing measures [14–17].

OAB diagnosis was assessed clinically with following anamnestic criteria: urgency, frequent urination (equal or more than 8 times in the daytime and 2 times at night) and/or urgent urinary incontinence in absence of pathologic or metabolic conditions that may cause or mimic OAB.

The exclusion criteria were as follows: stress urinary incontinence or mixed urinary incontinence (mainly stress incontinence) confirmed by urodynamic testing; neurogenic bladder; gynecological tumours; urological tumours; urinary tract infection or chronic inflammation; history of pelvic radiotherapy; pelvic organ prolapse  $\geq$  grade 3 (according to POP-Q classification); interstitial cystitis; bladder pain syndrome; urinary retention, neurologic abnormalities.

Four weeks after the start of the social distancing measures, the patients responded again to the specific questionnaires and gave a satisfaction index of the ongoing treatment with PGI-I. The women were asked about their eating habits and their fluid intake during the day.

Primary endpoint was changes in the total number of voids/24h, urgent micturitions/24h, urinary incontinence events/24h, nocturia events 4 weeks after the start of the social distancing measures. Secondary endpoints were the assessment of the change in the OAB-SF, SF-36 questionnaires and PGI-I satisfaction.

Statistical analysis was carried out with Wilcoxon matched pairs test for the continuous variables  $\chi$ -square test for the frequency data. Quantitative data were expressed as mean  $\pm$  SD (standard deviation) in tables. To demonstrate the differences, Student-t and Mann–Whitney U test was used. Matched t-test was applied to determine the change in OABSS and SF-36 questionnaires values. Correlations between numerical parameters were computed using the Spearman coefficient of correlation. All analyses were conducted using the Statistical Package for the Social Sciences (SPSS) 22.0 for Mac (SSPS, Chicago, IL, USA). Significance was set at a p-value of  $<0.05$ .

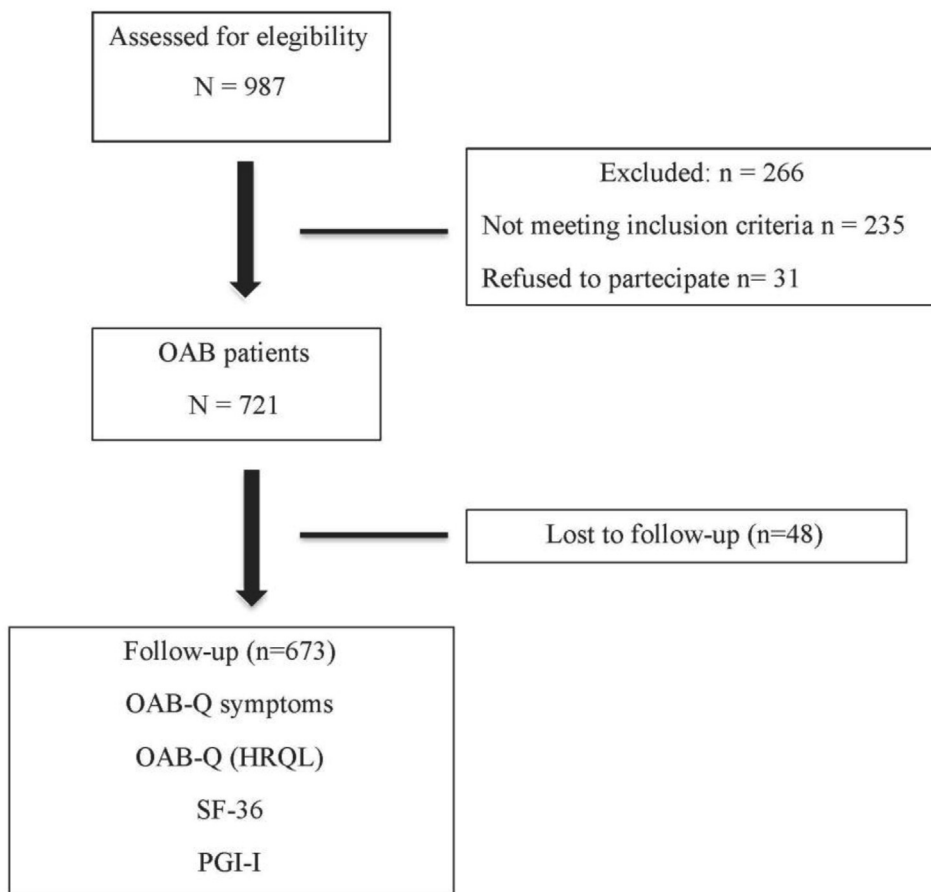
## Results

Nine hundred eighty-seven patients were enrolled in the study; 235 were excluded from the analysis because they did not meet the proposed inclusion criteria, 31 refused to participate and 48 were lost to follow up (Fig. 1). Therefore, 673 patients were considered for the final survey analysis. The mean age was  $63.21 \pm 10.24$  years.

Patients in treatment with pelvic floor rehabilitation sessions were 165 (24.5%), with nutraceuticals were 154 (22.9%), with standard drug therapy were 259 (38.5%), with PTNS sessions were 27 (4%), with Sacral Neuromodulation (SNM) were 40 (5.9) and finally in treatment with Intradetrusor onabotulinumtoxin A injections (BoNT-A) were 28 (4.2%).

The other baseline demographic and clinical characteristics of the patients are shown in Table 1.

The women interviewed showed no differences in terms of eating habits and liquid intake between the two periods. Four weeks after the start of the social distancing measures, the significant increase in the mean number of voids/24h ( $7.13 \pm 1.08$  vs  $9.76 \pm 2.12$ ,  $p < 0.0001$ ), urgent micturition episodes/24h ( $2.65 \pm 1.11$  vs  $4.57 \pm 1.28$ ,  $p < 0.0001$ ), nocturia episodes ( $1.19 \pm 1.21$  vs  $2.83 \pm 0.94$ ,  $p < 0.0001$ ) was observed. The Urinary incontinence episodes/24h did not increase significantly ( $0.70 \pm 0.92$  vs  $0.78 \pm 1.23$ ,  $p = 0.18$ ) (Table 2). The scores of the OAB



**Fig. 1.** Eligible patients in the study. **Abbreviations:** OAB-Q: The Overactive Bladder Questionnaire Symptoms and health-related quality of life (HRQL) short-form; SF-36: Short Form (36) Health Survey; PGI-I: Patient impression of global improvement.

symptom ( $32.67 \pm 12.88$  vs  $51.23 \pm 12.11$ ,  $p < 0.0001$ ), OAB-HRQL ( $75.45 \pm 12.76$  vs  $48.23 \pm 10.34$ ,  $p < 0.0001$ ), and SF-36 ( $82.15 \pm 11.78$  vs  $69.39 \pm 10.85$ ,  $p < 0.0001$ ) questionnaires have changed significantly. In particular, the change in the specific questionnaires was: in the Pelvic floor rehabilitation group [OAB Symptom ( $33.21 \pm 13.76$  vs  $68.12 \pm 11.89$ ,  $p < 0.0001$ ), OAB HRQL ( $74.99 \pm 12.11$  vs  $34.34 \pm 11.23$ ,  $p < 0.0001$ ), SF-36 ( $80.23 \pm 12.22$  vs  $55.23 \pm 11.45$ ,  $p < 0.0001$ )], in the Nutraceuticals group [OAB

Symptom ( $33.87 \pm 12.45$  vs  $69.65 \pm 12.34$ ,  $p < 0.0001$ ), OAB (HRQL) ( $74.23 \pm 13.97$  vs  $31.45 \pm 12.63$ ,  $p < 0.0001$ ), SF-36 ( $78.66 \pm 12.74$  vs  $51.45 \pm 12.81$ ,  $p < 0.0001$ )], in the Pharmacologic treatment group [OAB Symptom ( $32.99 \pm 12.59$  vs  $69.56 \pm 12.11$ ,  $p < 0.0001$ ), OAB (HRQL) ( $73.99 \pm 12.33$  vs  $32.58 \pm 12.67$ ,  $p < 0.0001$ ), SF-36 ( $79.45 \pm 13.19$  vs  $53.93 \pm 12.43$ ,  $p < 0.0001$ )], in PTNS group [OAB Symptom ( $30.67 \pm 11.67$  vs  $60.41 \pm 13.58$ ,  $p < 0.0001$ ), OAB (HRQL) ( $72.21 \pm 11.48$  vs  $39.43 \pm 10.71$ ,  $p < 0.0001$ ), SF-36 ( $80.45 \pm 11.33$  vs  $61.43 \pm 11.56$ ,  $p < 0.0001$ )], in SNM group [OAB Symptom ( $78.19 \pm 12.76$  vs  $72.78 \pm 14.57$ ,  $p = 0.08$ ), OAB (HRQL) ( $70.12 \pm 14.48$  vs  $63.55 \pm 15.83$ ,  $p = 0.07$ ); SF-36 ( $80.45 \pm 15.33$  vs  $68.43 \pm 14.56$ ,  $p = 0.006$ )] and in BoNT-A group [OAB Symptom ( $77.29 \pm 16.29$  vs  $69.90 \pm 16.91$ ,  $p = 0.12$ ); OAB (HRQL) ( $72.61 \pm 15.48$  vs  $64.93 \pm 15.71$ ,  $p = 0.10$ ); SF-36 ( $79.34 \pm 13.76$  vs  $70.34 \pm 13.87$ ,  $p = 0.02$ )]. In addition, the rate of patients satisfied with their treatment decreased significantly at the PGI-I evaluation before and after the Covid-19 period [537 (79.8%) vs 303 (45%)  $p < 0.0001$ ] (Table 3).

**Table 1**  
Demographic and clinical characteristics of 673 patients.

Variables	n
Age, y (mean $\pm$ SD)	63.21 $\pm$ 10.24
BMI (mean $\pm$ SD)	25.72 $\pm$ 2.57
Menopausal patients (%)	578 (85.9)
Hormonal Replacement Therapy (%) <sup>a</sup>	165 (28.6)
Local Estrogen therapy (%) <sup>a</sup>	223 (38.6)
Parity (range)	2 (0–3)
Smoke (%)	94 (13.9)
Previous pelvic surgery (%)	112 (16.6)
Ongoing treatments	
Pelvic floor rehabilitation (%)	165 (24.5)
Nutraceuticals (%)	154 (22.9)
Pharmacologic treatment (%)	259 (38.5)
Peripheral tibial nerve stimulation (PTNS) (%)	27 (4)
Sacral Neuromodulation (SNM) (%)	40 (5.9)
Intradetrusor onabotulinumtoxin A injections (BoNT-A) (%)	28 (4.2)

**Abbreviation:** SD: Standard Deviation; BMI: Body Mass Index.

<sup>a</sup> The percentage is calculated on menopausal patients.

### Discussion

The study showed an increase in OAB symptoms and a worsening of the QoL in women underwent various specific treatments during the social restriction period due to the Covid-19 epidemic. In particular, four weeks after the start of the social containment measures, the increase of the mean number of voids, the urgent micturition episodes and the nocturia episodes was observed. The

**Table 2**  
Comparison of Voiding Diary, Quality of Life Questionnaires, before and during Covid-19 period.

Variables	Before Covid-Period	During Covid-Period <sup>a</sup>	p value
Mean number of voids (24 h)	7.13±1.08	9.76±2.12	<0.0001
Mean number of urgent micturition events (24 h)	2.65±1.11	4.57±1.28	<0.0001
Mean number of urinary incontinence events (24 h)	0.70±0.92	0.78±1.23	0.18
Mean number of nocturia events	1.19±1.21	2.83±0.94	<0.0001
OAB-Q symptoms	32.67±12.88	51.23±12.11	<0.0001
OAB-Q (HRQL)	75.45±12.76	48.23±10.34	<0.0001
SF-36	82.15±11.78	69.39±10.85	<0.0001

**Abbreviations:** OAB-Q: The Overactive Bladder Questionnaire Symptoms and health-related quality of life short-form.  
SF-36: Short Form (36) Health Survey.

<sup>a</sup> The analysis was carried out at least 4 weeks after the start of the social distancing measures due to the Covid-19 outbreak period.

stressful period that patients are experiencing, changes bladder function, worsening the symptoms of OAB that were stable until the last control. About half of the patients report dissatisfaction with the current therapy and total satisfaction decreased from 79.8% to 45%. Social distancing measure refers to efforts that aim, through a variety of means, to decrease or interrupt transmission of Covid-19 in a population by minimizing physical contact between potentially infected individuals and healthy individuals [18,19].

Nevertheless, in this atmosphere of generalized alarm and social restriction, the way of life is inevitably changed. With the spread in infections across the nation, fear increased in people, especially, in the most vulnerable people [20]. Inevitably, women suffering from pathologies with a psychological component show a worsening of symptoms [21]. Probably stress, depression and anxiety negatively affect the pathophysiological mechanism of OAB [22,23]. It is recognized that bladder control is implemented via a spino-bulbo-spinal reflex pathway. Under normal circumstances, however, at the time of bladder filling, ascending stimuli from the urethra or bladder are conveyed to a supra-tentorial system called the brain-bladder control network [24]. This system judges if bladder emptying is suitable and consequently provides stimuli that trigger or hinder bladder emptying. It may be assumed that somatic and psychological triggers temporarily interfere with the brain-bladder control network function causing involuntary activation of the spino-bulbosplinal reflex.

These results suggest a vulnerability of the spinal-bulbo-spinal reflex pathway to psychological stimuli and to surrounding environment perception on bladder control [25].

Therefore, the significant impact that the change in daily life and the growing fear of Covid-19 infection has on the psychological aspect of the patients examined, can be considered as a potential explanation for the worsening of OAB. These symptoms, in fact, may be stimulated or aggravated by various somatic and psychological triggers which seem to add burden to their QoL [26].

**Table 3**  
Patient impression of global improvement (PGI-I) before and during the Covid-19 period in 673 patients.

Variables	Before Covid-Period (%)	During Covid-Period (%) <sup>a</sup>	p value
1: very much better (%)	425 (63.2)	218 (32.4)	<0.0001
2: much better (%)	112 (16.6)	85 (12.6)	
3: a little better (%)	56 (8.2)	54 (8)	
4: no improvement (%)	69 (10.3)	102 (15.2)	
5: a little worse (%)	9 (1.4)	125 (18.6)	
6: much worse (%)	2 (0.3)	80 (11.8)	
7: very much worse (%)	0	9 (1.4)	
Success (%)	537 (79.8)	303 (45)	

<sup>a</sup> The analysis was carried out at least 4 weeks after the start of the social distancing measures due to the Covid-19 outbreak period.

It is interesting to note, therefore, the deterioration of the quality of life with the SF-36 questionnaire, but above all of the quality of life linked to urinary symptoms with the specific OAB-SF questionnaires.

In particular, patients undergoing pelvic floor rehabilitation, nutraceutical or pharmacological treatment, and those undergoing PTNS, surprisingly, showed a significant deterioration in their quality of life. In contrast, women treated with SNM or BoNT-A showed a not-significant decrease compared to pre-Covid-19 period.

Certainly, government containment measures have a greater impact on women who need constant care over time.

Therefore, due to the suspension of non-urgent activities, rehabilitation or PTNS sessions were not performed and appointments were postponed after the end of the restrictive measures, reducing the effectiveness of treatments. In addition, the PTNS cure rate is time dependent, decreasing significantly in the break periods [27].

Women, during this period, change their lifestyle and daily activities paying substantial attention to the purchase of basic necessities and protective equipment against infection. Furthermore, due to the temporary loss of work and the lower amount of money available, patients do not buy the anti-incontinence drugs because in Italy, there is no reimbursement of the products by the national health system. Consequently, conservatively treated women, not knowing the evolution of the epidemic situation, tend to be more fragile psychologically and repeated psychological stress results in lasting alterations in micturition frequency, interval, and volume with a worsening of OAB symptoms and QoL [28,29].

In social containment situation, patients treated with SNM and BoNT-A, although overall QoL is reduced to SF-36, are less affected. Surely, the invasive treatments, thanks to the constant action and the autonomous function, remain effective even during a period of strong stress, besides, open medical clinics are not necessary for any therapeutic session [30].

Overall, the stressful period has a negative impact on patients treated for OAB and psychological help during the period of social restriction would be desirable to try to reduce the influence on mental health. A significant worsening of symptoms and QoL in patients with OAB has reduced satisfaction with the current treatment. Consequently, subsequent visits will be useful to re-evaluate the effectiveness of the treatment. To our knowledge, this is the first study in the literature that analyzes the change in symptoms and QoL in many OAB treated patients during the Covid-19 outbreak. However, the different number of examined patients within each group and the non-randomized design prevents us from drawing definitive conclusions. Moreover, the short-term evaluation can influence the satisfaction for the different treatments.

Further randomized prospective studies on a greater number of patients with an assessment of mental stress are needed to confirm



these findings and the possible association between the psychological triggers and the pathophysiology of OAB.

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### Declaration of competing interest

The authors report no conflict of interest.

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