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Original Article

Rehabilitation combined with dietary intervention improve urinary incontinence in women with obesity: A proof-of-principle study

Paolo Capodaglio[1,2*], Lorenzo Lippi[3,4*], Arianna Folli[3], Giulia Trotti[1], Valentina Aspesi[1], Alessio Turco[3], Alessandro de Sire[5], Marco Invernizzi[3,4]

[1]Orthopaedic Rehabilitation Unit and Research Laboratory in Biomechanics, Rehabilitation and Ergonomics, Istituto Auxologico Italiano, Piancavallo, Italy
[2]Department of Surgical Sciences, Physical Medicine and Rehabilitation, University of Torino, Torino, Italy
[3]Physical and Rehabilitative Medicine, Department of Health Sciences, University of Eastern Piedmont, Novara, Italy
[4]Translational Medicine, Dipartimento Attività Integrate Ricerca e Innovazione (DAIRI), Azienda Ospedaliera SS. Antonio e Biagio e Cesare Arrigo, Alessandria, Italy
[5]Department of Medical and Surgical Sciences, University of Catanzaro "Magna Graecia", Catanzaro, Italy

ABSTRACT

Objectives: This study aimed to assess the impact of add-on pelvic floor exercises on a weight management rehabilitation program.

Patients and methods: This proof of principle study was conducted between July 2019 and December 2019. Ninety-three adult female inpatients with obesity and diagnosis of urinary incontinence (UI) were assessed for inclusion, and the suitable patients were randomly assigned to the experimental group and the control group. Both groups underwent a weight management rehabilitation program, while the experimental group also performed pelvic floor exercises. The primary outcome was UI severity, assessed by the 1-h pad test. Secondary outcomes were urinary symptoms, assessed by the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF), Patient Global Impression of Improvement (PGI-I), and Incontinence Quality of Life Questionnaire (I-QOL).

Results: Sixty female inpatients were randomly assigned to the experimental group [n=30; median age: 64.50 (51.25 to 70.50) years] or the control group [n=30; median age: 67.50 (58.50 to 74.75) years]. The experimental group showed a statistically significant reduction in UI severity [pad test: 2.08 (1.21 to 8.85) g *vs.* 0.54 (0.24 to 1.13) g, p<0.01; ICIQ-SF: 14.00 (10.25 to 17.00) *vs.* 8.00 (6.25 to 11.75), p<0.01; I-QOL: 56.37 (42.28 to 73.64) *vs.* 78.64 (64.32 to 90.68), p<0.01]. Statistically significant differences were found in the between-groups analysis [pad test: 0.54 (0.24 to 1.13) g *vs.* 1.08 (0.83 to 3.86) g, p<0.01; ICIQ-SF: 8.00 (6.25 to 11.75) *vs.* 12.00 (10.00 to 16.00), p<0.01; I-QOL: 78.64 (64.32 to 90.68) *vs.* 68.18 (60.00 to 84.32), p<0.01].

Conclusion: Including pelvic floor exercises might provide additional benefits compared to standard rehabilitation in reducing UI symptoms in obese women.

Keywords: Obesity; pelvic floor exercises; rehabilitation, urinary incontinence, weight management.

Obesity is a chronic disease characterized by a body mass index (BMI) >30 kg/m^2, with an increasing prevalence related to the progressive aging of the population.[1] Several studies reported that obesity leads to a higher risk of morbidity and mortality with detrimental consequences on individual health outcomes and socioeconomic costs.[2,3] Due to the physical, psychological, and social impact of obesity, recent research is now focusing on tailored interventions to improve both function outcomes and health-related quality of life (HR-QoL).[4,5] In this scenario, it has recently been highlighted that obesity should be considered a strong independent risk factor for urinary incontinence (UI).[6]

The International Continence Society (ICS) defined UI as the involuntary and objectively demonstrable loss of urine.[7] Despite strong evidence suggesting that UI plays a key role in patients' overall well-being, it remains a frequently underrecognized and undertreated condition.[8] Interestingly, several

* *The first two authors contributed equally to this manuscript.*

Corresponding author: Alessandro de Sire, MD. Department of Medical and Surgical Sciences, University of Catanzaro "Magna Graecia", 88100 Catanzaro, Italy.
E-mail: alessandro.desire@unicz.it

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mechanisms have been proposed to explain the strict link between obesity and UI, including greater abdominal diameter increasing intra-abdominal pressure,[9] neuroendocrine imbalance, systemic inflammation,[9] and peripheral nerve dysfunction.[1,9]

Pelvic floor rehabilitation is the first-line nonpharmacological intervention in patients with UI.[10] This rehabilitative intervention aims to promote the strengthening, control, and coordination of pelvic floor muscles involved in the support of pelvic organs and optimizing the urethral closure.[11,12] On the other hand, it has been proposed that dietary interventions might have a synergic role with rehabilitation in the management of several disabling conditions,[13-15] and previous studies underlined potential implications of weight management in women with obesity and UI.[12,16] Moreover, a recent review reported that weight loss might improve UI symptoms, while UI surgical interventions might be related to better outcomes in obese patients with lower BMI.[17] In contrast, the recent randomized controlled trial by de Oliveira et al.[11] compared pelvic floor rehabilitation alone and associated with weight loss and failed to demonstrate additional benefits of dietary therapy in UI management of patients with obesity. However, despite these findings, significant benefits were shown in both groups after the intervention supporting pelvic floor rehabilitation treatment of patients with obesity and UI.[11]

No previous study has assessed the effectiveness of a multicomponent rehabilitation intervention including pelvic floor rehabilitation, physical activity, and diet in women with obesity and UI. Therefore, this proof-of-principle study aimed at assessing the effectiveness of a comprehensive rehabilitation treatment including pelvic floor rehabilitation as compared to a standard rehabilitation program (consisting of combined aerobic and resistance exercise sessions) and weight loss program on urinary symptoms and quality of life in women with obesity and UI.

PATIENTS AND METHODS

This proof of principle study assessed a consecutive series of 93 patients referred to the Rehabilitation Department of the Northern Italy Hospital between July 2019 to December 2019. The study protocol has been developed following the CONSORT guidelines.[18] Inclusion criteria were as follows: *(i)* female sex; *(ii)* age between 18 and 80 years old; *(iii)* body mass index (BMI) ≥30 kg/m^2; *(iv)* diagnosis of UI; *(v)* 1-h pad test ≥1 g; *(vi)* International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) score >4. Exclusion criteria were as follows: *(i)* Grade 3 prolapsed bladder; *(ii)* neurologic disorders; *(iii)* subjects unable to walk; *(iv)* cognitive impairment; *(v)* psychiatric disorders; *(vi)* absolute contraindications to physical activity. The eligibility was assessed by a multidisciplinary team composed of an expert physician specialized in physical and rehabilitation medicine and a physiotherapist with years of expertise in UI rehabilitation therapy.

Intervention

After all baseline assessments, the patients enrolled were randomly assigned to two groups through a randomization scheme with a 1:1 allocation without blocks. Both the operators that performed the analysis and participants were blinded to group allocation during baseline testing (T0).

The intervention group (Group A) performed a complex treatment consisting of a personalized dietary program, pelvic floor training, and standard physiotherapy (all together referred as comprehensive rehabilitation program), while the control group (Group B) underwent a personalized dietary program combined with standard rehabilitation only. The comprehensive rehabilitation intervention is explained in detail in the following paragraphs.

A personalized dietary program was applied to patients under the comprehensive rehabilitation program. Weight loss therapy was realized by a nutritionist after performing a 24-h dietary recall and the estimation of energy expenditure according to the revised World Health Organization equations (total energy expenditure=basal metabolic rate × activity factor). Allergies, intolerances, and food aversions were assessed to optimize compliance with the dietary program. The nutritional protocol was tailored to target a deficiency in energy intake ranging between 500 and 1000 kcal/day to achieve a weight loss ranging between 0.5 and 1 kg per week. Macronutrients were balanced as follows: 50-60% of energy intake in carbohydrates, 20-30% of energy intake in fat (limiting saturated and trans fats), and 0.8-1 g protein/kg (15-25% of energy intake). Daily energy intake was divided into three meals (breakfast, lunch, and dinner) and two snacks per planned day of diet. The three meals each represented 25% of daily energy intake and each snack represented 12.5% of daily energy intake. All the meals and snacks were individually packaged, labeled, and delivered to each patient during the inpatient treatment. A specific study diary was

provided to each patient to describe any dietary deviation from the provided food.

The standard rehabilitation intervention consisted of a 45-min session performed daily for three weeks, for a total of 15 sessions. The standard rehabilitation program was composed of combined aerobic and resistance exercise sessions. Following 5 min of aerobic warm-up, resistance exercises were performed with light weightlifting, Thera-Band (THERABAND Proven Science, Trusted Performance, Akron, OH, USA), and free-weight proprioception exercises, targeting all major muscle groups at 60-75% estimated one repetition maximum. Subsequently, aerobic exercises were performed with cycle or rowing, targeting an exercise intensity between 60 and 85% of maximal heart rate, based on patients' personal tolerance. This exercise protocol aimed to achieve progressions during days of intervention. Lastly, stretching exercises and core exercises were performed in the cool-down phase.

Pelvic floor rehabilitation was performed in 45-min sessions daily for three weeks, for a total of 15 sessions. Pelvic floor rehabilitation was composed of diaphragmatic breathing and pelvic strengthening exercises. Diaphragmatic breathing exercises consist of supine position exercises combined with upper limb and lower limb movement to promote adequate rib cage and diaphragmatic excursion. The participants were instructed to activate pelvic floor muscles, particularly during the expiration phase. In addition, specific exercises for strengthening the pelvic floor muscles involved in the continence mechanism were performed in different positions (supine, sitting, and standing) and keeping the lower limbs in different static positions. Pelvic muscle strength exercises were performed through 24 to 36 high-intensity contractions (maximal voluntary contraction) held for 6-8 sec, with a progressive increase in exercise volumes. In addition, patients were instructed to contract the pelvic floor muscles every time intra-abdominal pressure increased due to the activities of daily living.

Standard rehabilitation and pelvic floor rehabilitation sessions were supervised by the same physiotherapist with high expertise in pelvic floor rehabilitation, with a therapist/patient rate of 1:1 to guarantee close supervision of the exercise quality.

Data analysis was performed by blinded personnel. The adherence to the rehabilitation program was monitored by session registration. Patients with a compliance rate of less than 80% were registered as drop out. In case of missing rehabilitative sessions, participants performed the exercises an additional three days beyond the three weeks of rehabilitative intervention.

Outcome measures

The operators that performed the analysis were blinded to group allocation during both the baseline testing and after the intervention (T1). Sociodemographic and anthropometric data were collected at T0. Primary and secondary outcomes were assessed at each timepoint.

The primary outcome of our study was the severity of UI assessed with the 1-h pad test, a noninvasive assessment tool to objectively quantify the urinary leak. The 1-h pad test was performed following the testing protocol standardized by the ICS. More in detail, the test was started with a pre-weighted pad worn by the patients. First, the patient drank 500 mL of sodium-free liquid. Subsequently, the patient was asked to walk for at least 30 min, climb up and down a flight of stairs, stand up from sitting (10 times), cough vigorously (10 times), run on the spot (for 1 min), bend to pick up an object from the floor (five times), and wash hands in running water for 1 min. After these activities, the pad was weighted to assess the total amount of urine leaked. In accordance with previous studies,[19,20] "mild icontinence" was identified with a value between 1 and 10 g, "moderate icontinence" was defined between 11 and 50 g, and "severe icontinence" was defined as >50 g.

Secondary outcomes were the ICIQ-SF[21] to assess frequency, severity, and impact on the quality of life of UI. Incontinence Quality of Life Questionnaire (I-QOL)[22] was assessed to deeply characterize self-perceived quality of life. Lastly, Patient Global Impression of Improvement (PGI-I)[23] was assessed to characterize self-perceived effects of the intervention.

The ICIQ-SF is a self-administered questionnaire proposed by the World Health Organization-sponsored International Consultation on Incontinence to assess UI severity and impact on quality of life.[21] The score is calculated by the sum of the singular items, ranging between 0 to 21. Higher scores are related to greater impairment due to UI.[21]

The I-QOL is a self-administered measure composed of 22 items. Every item is scored by a 5-point Likert-scale. The questionnaire is divided into three domains: eight elements evaluate avoidant or limiting behaviors, nine elements evaluate psychosocial impact, and five evaluate social embarrassment.[24]

It is calculated by the sum of each item and converted into a score ranging between 0 and 100. The higher scores correspond to a higher quality of life, while lower scores are related to lower quality of life.

The PGI-I questionnaire is a global rating scale with seven possible answers from 1=very much better to 7=very much worse. The patient was asked to describe how urinary symptoms improved after the treatment.[23]

The complications that occurred during the rehabilitation treatment were recorded to characterize the safety of the therapeutic intervention.

Statistical analysis

Sample size calculation was performed with the G*Power software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). The effect size was calculated considering the primary outcome variable (1-h pad test). The results obtained by Heydenreich et al.[25] were used to calculate the effect size (d=0.76). As a result, the sample size required was 30 patients in each group, with an alpha error of 0.05 and a power (1-beta) of 0.80, supposing a two-tail Gaussian distribution.

GraphPad Prism 7.0 (GraphPad Software Inc., San Diego, CA, USA) was used to perform statistical analysis. Descriptive statistics were used to summarize the adverse effect of the treatment. Continuous variables were described as median (interquartile range), while categorical variables were represented as numbers and ratios. The Shapiro-Wilk statistic was used to assess the non-Gaussian distribution of variables. The patients enrolled were analyzed according to the group they were originally assigned to according to the intention-to-treat principle. Intragroup differences were assessed with the Wilcoxon signed-rank test. Fisher exact test was performed to compare the percentages of the qualitative variables between groups. Differences between groups for continuous variables have been assessed with the Mann-Whitney U test. A p-value <0.01 was considered statistically significant.

RESULTS

Out of 93 patients assessed for eligibility, 60 patients fulfilled the inclusion criteria and were randomly assigned to Group A [n=30; median age: 64.50 (51.25 to 70.50) years; median BMI: 45.25 (40.53 to 50.26) kg/m^2 and Group B (n=30; median age: 67.50 (58.50 to 74.75) years; median BMI: 44.18 (40.03 to 48.53) kg/m^2]. Among the 33 patients excluded, 19 patients had a 1-h pad test score <1 g, 10 patients had an ICIQ-SF <4, one patient suffered from a prolapsed bladder of Grade 3, and three patients

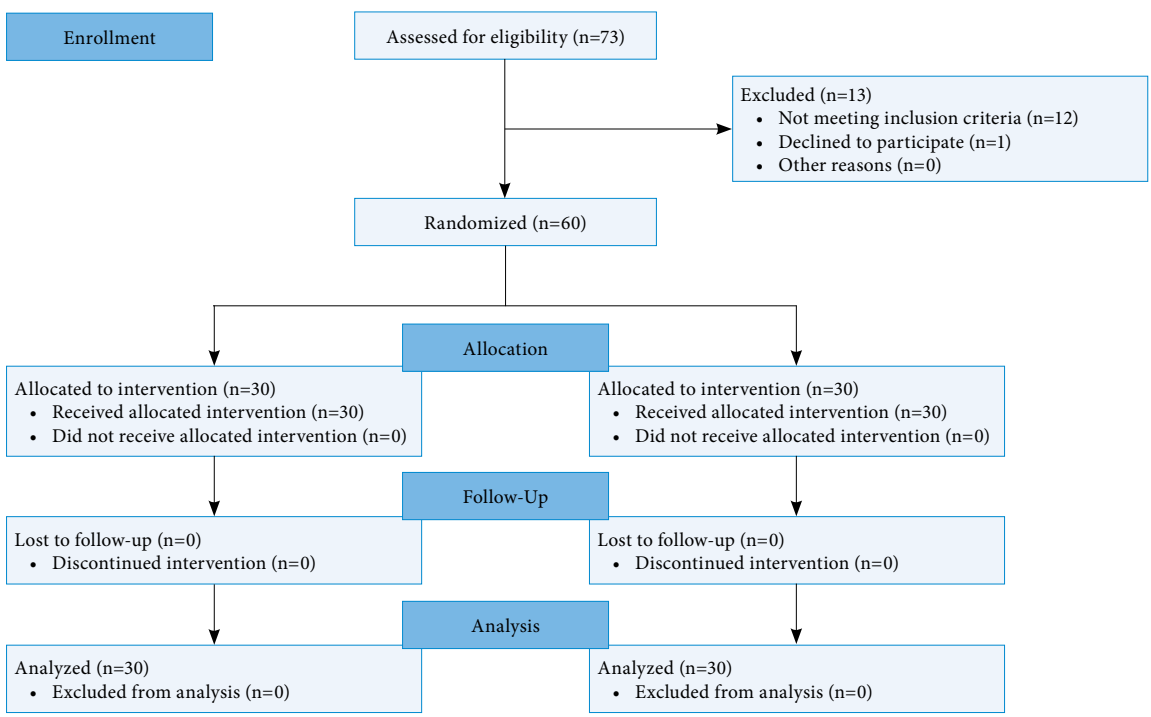

Figure 1. CONSORT 2010 flow chart.

did not provide informed consent. Further details are shown in Figure 1. In Group A, 16.7% of participants suffered from stress UI, while mixed UI affected 83.3% of the subjects. In Group B, stress UI affected 26.7% of patients, and mixed UI affected 73.3% of participants. No significant differences were found in the intergroup analysis for all the baseline characteristics assessed. Table 1 demonstrates the baseline characteristics of both groups in more detail.

The mean adherence to the rehabilitation program was 95% in Group A and 93% in Group B. No significant differences were reported in terms of adherence to the rehabilitation program in the between-groups analysis. No patient was lost during the study protocol, and all the participants were included in the outcomes analysis assessed after the rehabilitation treatment.

Table 1 shows the results of the 1-h pad test and the between-group and within-group differences after the rehabilitation treatments. After the intervention, the median 1-h pad test value in Group A was 0.54 (0.24 to 1.13) g and 1.08 (0.83 to 3.86) g in Group B. Significant between-group differences were reported in the primary outcome measure ($p<0.01$). The within-group analysis showed significant improvement after the comprehensive rehabilitation program in the intervention group, underlining a 71.1% reduction in the 1-h pad test ($p<0.01$). No significant differences were reported in the control group (mean change: 19.6±29.4%; $p>0.01$).

After the rehabilitation intervention, significant differences between groups were reported in terms of ICIQ-SF score [8.00 (6.25 to 11.75) *vs.* 12.00 (10.00 to 16.00), $p<0.01$]. Significant differences in the within-group analysis were reported only in the intervention group [14.00 (10.25 to 17.00) *vs.* 8.00 (6.25 to 11.75), $p<0.01$].

Similarly, significant results were found in the within-group analysis of quality of life, with a change in I-QOL scores from 56.37 (42.28 to 73.64) to 78.64 (64.32 to 90.68; $p<0.01$). In contrast, no significant changes were reported in the control group [70.00 (55.23 to 79.55) *vs.* 68.18 (60.00 to 84.32), $p=0.50$]. In addition, significant differences between groups were reported after the rehabilitation intervention [78.64 (64.32 to 90.68) *vs.* 68.18 (60.00 to 84.32), $p<0.01$].

Accordingly, significant differences between groups were reported in terms of self-perceived effects

TABLE 1
Anamnestic, demographical, and clinical characteristics of study population

	Group A (n=30)				Group B (n=30)				
Sample characteristics	n	%	Median	IQR	n	%	Median	IQR	*p*
Age (year)			64.50	51.25-70.50			67.50	58.50-74.75	0.240
Sex									
Female	30	100.0			30	100.0			0.999
Weight (kg)			121.65	115.85-131.42			115.14	105.16-127.17	0.374
Height (m)			1.58	1.56-1.62			1.58	1.55-1.60	0.248
Body mass index (kg/m^2)			45.25	40.53-50.26			44.18	40.03-48.53	0.752
Smokers (habitual smokers)	3	10.0			4	13.3			0.999
Comorbidities									
Hypertension	13	43.3			14	46.6			0.999
Diabetes	10	33.3			11	36.6			0.999
Dyslipidemia	14	46.6			14	46.6			0.999
Type of urinary incontinence									
Stress	5	16.7			8	26.7			0.996
Mixed	25	83.3			22	73.3			0.996
1-h Pad test			2.08	1.21-8.85			1.53	1.05-3.40	0.191
ICIQ-sf			14.00	10.25-17.00			11.00	10.00-16.75	0.279
I-QOL			56.37	42.28-73.64			70.00	55.23-79.55	0.090

IQR: Interquartile range; ICIQ-sf: International Consultation on Incontinence Questionnaire Short Form; I-QOL: Incontinence Quality of Life Questionnaire; P values are considered significant when *p* is less than 0.01.

TABLE 2
Within-group and between-group differences in outcome measures

Outcome	Intervention group (n=30)					Control group (n=30)				
	T0		T1			T0		T1		
	Median	IQR	Median	IQR	*p*	Median	IQR	Median	IQR	*p*
1-h Pad test (g)	2.08	1.21-8.85	0.54	0.24-1.13	<0.01	1.53	1.05-3.40	1.08	0.83-3.86	0.99
Weight (kg)	121.65	115.85-131.42	108.95	103.15-115.41	<0.01	115.14	105.16-127.17	110.25	101.70-121.68	<0.01
ICIQ-sf	14.00	10.25-17.00	8.00	6.25-11.75	<0.01	11.00	10.00-16.75	12.00	10.00-16.00	0.31
I-QOL	56.37	42.28-73.64	78.64	64.32-90.68	<0.01	70.00	55.23-79.55	68.18	60.00-84.32	0.50
PGI-I	-	-	2.00	2.00-3.00	-	-	-	4.00	3.00-4.00	-
p	-		-			-		-		<0.01

T0: Baseline; T1: After rehabilitation; IQR: Interquartile range; ICIQ-sf: International Consultation on Incontinence Questionnaire Short Form; I-QOL: Incontinence Quality of Life Questionnaire; PGI-I: Patient Global Impression of Improvement; P values are considered significant when *p* is <0.01.

assessed with PGI-I [Group A: 2.00 (2.00 to 3.00) *vs.* Group B: 4.00 (3.00 to 4.00), p<0.01]. No significant differences between groups were underlined in terms of weight loss (p=0.41). Further details about the between-group and within-group analysis are shown in detail in Table 2. The most common adverse events reported were perineal discomfort (n=5) in Group A and a minor hypoglycemia episode (n=1) in Group B.

DISCUSSION

Despite nonpharmacological interventions are a cornerstone to treat UI in patients with obesity, the optimal rehabilitation approach is still debated. In light of this consideration, this proof-of-principle study assessed the effectiveness of a comprehensive rehabilitation intervention to treat female patients with obesity and UI.

Our findings underlined significant improvement in UI severity and HR-QoL in patients undergoing pelvic floor rehabilitation, physical exercise, and dietary intervention compared to physical exercise and dietary intervention only. Furthermore, the within-group analysis found a statistically significant decrease in the 1-h pad test for the intervention group (p<0.001) and no statistically significant differences in the 1-h pad test for the control group (p=0.99). Significant differences were shown in the between-group analysis supporting the key role of pelvic floor rehabilitation in the complex management of UI patients. According to the Clinical Practice Guideline from the American College of Physicians,[26] nonpharmacological therapies, including pelvic floor rehabilitation, are an effective therapeutic strategy to improve UI symptoms with a consequent benefit on patients' continence.

It should be noted that several topics are still in discussion about the effects of strength training in UI patients. More in detail, it has been recently proposed that high-intensity strength training and weight-lifting might increase the intra-abdominal pressure with possible negative consequences on pelvic floor muscles and ligament stress, worsening UI, and pelvic floor dysfunction.[27] Nevertheless, it should be noted that our findings did not report negative effects of combined physical exercise training, suggesting that pelvic floor rehabilitation might counteract the negative effects of strength training alone in UI patients. In addition, recent research is now emphasizing that a comprehensive therapeutic approach is needed focusing on the overall well-being of obese patients, without focusing on UI only.[28]

Accordingly, our results underlined positive effects on both HR-QoL and perceived global effects, supporting the need for a multitarget approach to improve the overall well-being of UI obese patients. In addition, a multidimensional assessment of patients with obesity should be mandatory, given the psychological and social burden related to UI. In this context, recent guidelines[4,5,29] provided strong recommendations for a tailored lifestyle intervention, including a dietary approach and physical activity, as the first-line treatment to improve health-related outcomes in patients with obesity.[30]

Nevertheless, our data showed no significant improvement in UI severity in the control group, despite a significant weight loss. These findings are in contrast with the recent systematic review performed by the American Urogynecologic Society,[31] reporting that weight loss intervention might improve UI severity. However, it should be noted that the authors found significant benefits after 1-2.9 years from the weight loss intervention.[31] In contrast, our data highlighted significant changes in the primary outcome measure after only three weeks, suggesting a synergic role of pelvic floor rehabilitation and dietary therapy in boosting the positive results induced by weight loss alone.[31]

Despite these positive results, we are aware that the present work is not free from limitations. First, this is a monocentric study assessing a small sample of patients with obesity and UI. Therefore, it is not possible to draw strong conclusions about the results obtained. However, to the best of our knowledge, this is the first study in the literature assessing the role of a comprehensive rehabilitation approach targeting the multilevel interaction between obesity and UI. Second, the lack of long-term follow-up represents a major limitation of our study. Nonetheless, it should be noted that the positive short-term results appeared after three weeks of intervention, suggesting a potential synergic role of the different therapeutic modalities.

In conclusion, this is the first proof-of-principle study assessing the effectiveness of a comprehensive rehabilitation approach targeting the multilevel interaction between obesity and UI in a rehabilitation inpatient setting. Our findings suggest that a tailored comprehensive rehabilitation approach including pelvic floor rehabilitation, physical exercise, and dietary intervention might be an effective, feasible, and safe intervention in women with obesity and UI, improving UI and HR-QoL.

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Ethics Committee Approval: The study protocol was approved by the Azienda Ospedaliera di Alessandria Santi Antonio e Biagio e Cesare Arrigo Ethics Committee (date: May 2019, no: 0016395). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author, L.L, upon reasonable request.

Author Contributions: Concept: PC, LL. Design: PC, LL. Supervision: PC, LL, AdS, MI. Resources: PC. Materials: PC. Data Collection And/Or Processing: LL, AdS, MI. Analysis And/Or Interpretation: LL, AF, GT, VA, AT. Literature Search: LL, AF, GT, VA, AT. Writing Manuscript: PC, LL, AF, GT, VA, AT, AdS, MI. Critical Review: PC, LL, AF, GT, VA, AT, AdS, MI.

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