

# Moderate weight loss in obese women with urinary incontinence: a prospective longitudinal study

Wael Auwad · Pippin Steggles · Luigi Bombieri ·  
Malcolm Waterfield · Terrance Wilkin ·  
Robert Freeman

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**Abstract** This study assessed the effect of moderate weight loss in obese women with urodynamically proven urinary incontinence using the International Consultation on Incontinence recommended outcome measures. Sixty-four incontinent women were offered a weight reduction programme with a target loss of 5–10%. This included a low-calorie diet and exercise. An anti-obesity drug (Orlistat) was offered to those who failed to achieve their target. Forty-two (65%) achieved the target weight loss and had significant reduction in body mass index and girth. Weight loss was associated with significant reduction in pad test loss (median difference, 19 g; 95% confidence interval, 13–28 g;  $p < 0.001$ ). There was also a clinical and statistically significant improvement in quality of life measures. These results suggest that weight reduction of 5% of initial body weight can improve urinary incontinence severity and its effects on quality of life in obese women.

**Keywords** Urinary incontinence · Obesity · Weight loss · Diet · Exercise · Orlistat

## Abbreviations

UI urinary incontinence  
BMI body mass index  
QoL quality of life

LCD low calorie diet  
KHQ Kings Health Questionnaire  
FVC frequency volume chart  
BIA bioelectric impedance analysis  
USI urodynamic stress incontinence  
DOI detrusor overactivity incontinence

## Introduction

In the UK, nearly one quarter of adult women are obese [1], while in the USA, the figure is more than one third [2]. Obesity and urinary incontinence (UI) are serious health problems adversely affecting quality of life (QoL), with obesity being identified as a risk factor for UI in many epidemiological studies [3]. There is evidence that the prevalence of both urge and stress incontinence increases proportionately with rising body mass index (BMI) [3] and that a significant proportion of patients who undergo incontinence surgery are overweight or obese [4].

Although a direct cause–effect relationship between obesity and incontinence has not yet been established, there is evidence that weight reduction might be beneficial for incontinent women [5, 6, 7, 8, 9] and might make subsequent surgery (if required) easier and safer to perform [10].

While it has been shown that surgically induced weight loss [5, 6, 9] can improve UI in grossly obese women, few studies have evaluated the effect of more conservative methods of weight loss, e.g. diet, exercise and drug therapy on UI. In those studies that evaluated such effect [7, 8], the populations have not been strictly defined in terms of weight and urodynamic diagnoses. The Third International Consultation on Incontinence (ICI) has recommended that such studies be a research priority [11].

W. Auwad (✉) · P. Steggles · L. Bombieri · M. Waterfield ·  
R. Freeman  
Urogynaecology Unit level 7, Derriford Hospital,  
Plymouth, Devon PL6 8DH, UK  
e-mail: Wauwad@aol.com

T. Wilkin  
Department of Endocrinology and Metabolism,  
Peninsula Medical School,  
Plymouth, Devon PL6 8DH, UK

This study investigates the effects of moderate weight reduction on obese women (i.e.  $BMI \geq 30 \text{ kg/m}^2$ ) with urodynamically proven UI, using outcome measures as recommended by the International Continence Society (ICS) [12] and the ICI [13]. Possible mechanisms for improvement are also investigated.

## Materials and methods

Initially, the design was a randomised controlled trial (RCT). After recruiting the first 20 patients, a preliminary analysis was performed, which showed a considerable ‘Hawthorne effect’ [14], i.e. the control group started dieting and losing weight. It was likely therefore that the hypothesis could not be tested using this design. A longitudinal cohort study of all participants with urodynamic diagnosis of UI was therefore undertaken. None of the women who participated in the RCT took part in the cohort study.

All participants were offered a commercially run programme of diet and exercise (Rosemary Conley Diet and Fitness Clubs, UK). Those who did not lose 5% of their starting weight within 9 months of diet and exercise were offered the anti-obesity medication Orlistat.

A full medical history was obtained. General, abdominal, pelvic and neurological examination were performed. Exclusion criteria included the following: history of anti-incontinence surgery, patients on drug treatment for detrusor overactivity (who did not wish to discontinue therapy), pelvic organ prolapse greater than stage II, neurogenic detrusor overactivity, pregnancy and those undergoing supervised pelvic floor muscle training.

The following investigations were performed at the beginning of the study and after weight loss: BMI, waist circumference measurement (as a measure of abdominal fat) [15], body composition analysis to assess body fat percentage using bioelectric impedance analysis (BIA) [16], 24-h pad test, urodynamic studies, QoL assessment using Kings Health Questionnaire (KHQ) and 3-day frequency/volume chart (FVC).

To investigate possible mechanisms of improvement, bladder neck mobility and pelvic floor strength were also assessed before and after weight loss. Perineal ultrasound was performed to assess bladder neck mobility using the method described by Schaer et al. [17]. Images were taken at rest and during Valsalva manoeuvre (standardised with patients blowing in a modified sphygmomanometer to 30 mmHg as described by King and Freeman) [18]. Pelvic floor muscle strength assessment was performed using perineometry and Oxford score.

As tests were performed by different members of the team, consistency in the methods of measurement was

checked at the outset of the study (by repeating measures under the supervision of the lead investigator, WA). Perineal ultrasound, Oxford score and perineometry have previously been shown to be reproducible methods of assessment [17, 19]. Investigators could not be blinded, as all patients returning for assessment by definition had lost weight.

The study obtained Local Research Ethics Committee (LREC) approval including an amendment when the design was changed from RCT. Funding was from the Urogynaecology Research Fund at our hospital. No funding was received from the Rosemary Conley organisation or any pharmaceutical company. However, Rosemary Conley supplied an employee free of charge who undertook the exercise classes.

## Weight assessment and weight loss programme

All participants had their height and weight measured (without shoes) to determine BMI. Body weight was measured in kilograms, wearing indoor light clothes, using a Salter type E1210 electronic scale with digital readout, accurate to 0.1 g (Todd Scales, Unit 4, Studlands Park Industrial Estate, Newmarket, Suffolk, UK). Scales were regularly calibrated. Height was measured (without shoes) to the nearest 0.5 cm using a wall-mounted stadiometer (Holtain Ltd., Crosswell, Crymch, Dyfed, Wales SA41 3UF, UK). Waist circumference was measured to the nearest 0.5 cm, at minimal respiration, with the participant standing and with the tape placed in a horizontal plane at the point where the iliac crest meets the mid-axillary line. Body composition analysis was performed using a hand-held BIA unit (Bodystat 1500, Bodystat Ltd, Isle of Man, UK). Impedance was measured between the right wrist and the right ankle using a tetrapolar electrode method. Bodystat was used to objectively demonstrate that patients were losing weight through reduction in their body fat component (as opposed to muscle) and to determine the daily calorific requirements.

Participants were expected to lose 1 to 2 lb (0.45 or 0.90 kg) per week to achieve a goal of 5–10% reduction in body weight over a period of about 6 months. Women were assessed at monthly intervals (or earlier if necessary); body weight and fat percentage were checked at each visit to assess progress and provide feedback. Participants had direct access to the investigators (by phone) to discuss any problems with diet, exercise or drug therapy (as regular contacts with a practitioner during a weight loss programme have been found to help patients to reach their target weight) [20]. Furthermore, patients on Orlistat were advised to register with the motivation, advice and pro-active (MAP) programme (this is a free phone support line provided by the manufacturer).

The diet was low calorie with approximately 30% fat content. It aimed to create an energy deficit of 500–1,000 kcal per day. Women were advised to reduce the use of high-calorie ingredients and to aim for no more than 5 g of fat per 100 g of food. Booklets and leaflets, which included a wide variety of menu suggestions as well as information on how to calculate the percentage of fat content and number of calories, were provided.

The exercise programme was designed for individuals who did not work out regularly and allowed participants to work at their own level. Fitness level was assessed at recruitment using the Chester step test. This test has been validated and is easy to perform within the out-patient clinic [21]. The programme did not include any attempt to exercise the pelvic floor.

Weekly exercise classes at the hospital gym were offered to all participants supervised by a qualified instructor. Brisk walking was recommended for those who were unable to attend the exercise classes. Women were advised on ways to increase physical activity (e.g. using the stairs rather than the lift/elevator). Compliance was assessed by diet and activity record sheets, which were provided to all participants.

Orlistat (Xenical®) was offered to women who failed to achieve weight loss goals through diet and exercise alone (120 mg before meals three times daily). Participants received verbal and written instructions on its use and possible side effects. Women who developed gastrointestinal complications had their eating habits reassessed and were advised on ways to monitor (and reduce) their daily intake of fat.

#### Outcome measures

The primary outcome measures were the 24-h pad test and QoL scores (on the KHQ), as recommended by the third ICI [13]. The measure of severity of urinary leakage was based on a recent quantification system of the 24-h pad test results: continent (<1.3 g/24 h), mild (1.3–20 g/24 h), moderate (21–74 g/24 h) and severe ( $\geq 75$  g/24 h) [22].

To determine the mechanism by which weight loss might improve UI, the following were measured (before and after weight loss): bladder neck mobility, pelvic floor muscle strength and waist circumference.

#### Statistical methods

Unpublished data of 13 subjects in the initial study design (i.e. RCT) showed an initial mean pad weight of 55.0 g and the standard deviation (SD) of the difference in pad weights before and after weight loss of 40.0 g. Allowing for a 50% reduction in incontinence, a sample size of 30 was required

for a power of 90% on the paired comparison (using a paired *t* test) before and after, with a significance level of 0.05. It was decided to recruit double this number in case of drop-outs.

The analysis looked at changes in incontinence measures (pad test and QoL) after 5% or more weight loss from baseline.

As data were not normally distributed, they were presented as median and interquartile ranges (IQR). Comparison of primary and secondary outcomes before and after weight loss was calculated by Wilcoxon's signed rank test. These changes are shown as median differences with a 95% confidence interval. These represent an extension of the Wilcoxon test and have been calculated as described by Armitage and Berry [23]. The relationship between various outcomes was tested using Spearman correlation.

Data were entered on an Excel database, and statistical analysis was performed using SPSS version 15 statistical software. Results were considered significant at the 5% level (i.e.  $p < 0.05$ ). Methods, definitions and units conform to the standards recommended by the ICS.

#### Results

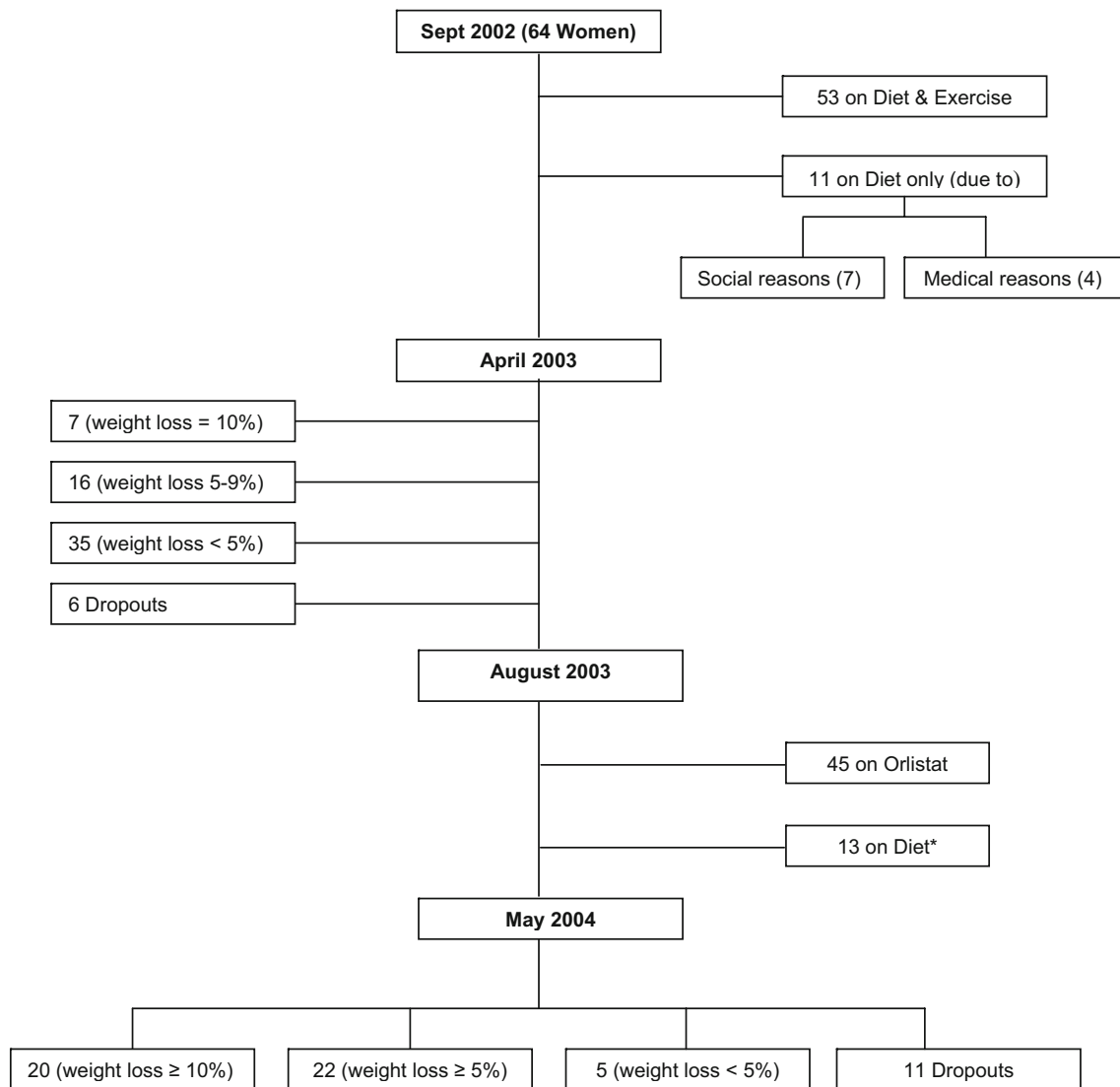
Sixty-four women consented to participate in the study. Flow of the participants throughout the study is shown in Fig. 1.

Forty-two (65%) achieved a weight loss of  $\geq 5\%$  and constitute the main focus of this study. The demographics of this cohort are presented in Table 1. They are comparable to those of the whole population ( $n=64$ ) in terms of age, parity, BMI, pelvic organ prolapse quantification, hysterectomy, menopausal status and urodynamic diagnosis. Of the remaining participants ( $n=22$ ), five continued their participation in the study but lost <5% of baseline weight and 17 dropped out. Reasons for dropping-out were that patients were not satisfied with the degree of weight loss ( $n=9$ ), social reasons ( $n=3$ ) and unspecified reasons ( $n=5$ ). No adverse effects were reported as a consequence of weight loss.

At the beginning of the study, all participants had BMI  $> 30$  kg/m<sup>2</sup>. Twenty women (31%) lost  $\geq 10\%$  of initial weight, 22 (34%) lost 5–9% and five (8%) lost <5%. At the end of the study, 14 (22%) women had BMI between 27.2 and 29.9 kg/m<sup>2</sup> (i.e. overweight) and none had a normal BMI (i.e.  $< 25$  kg/m<sup>2</sup>).

The average weight loss by women who completed the study ( $n=47$ ) was 8.8 kg (SD=5.5). The greatest individual weight loss was 26 kg (21%), and the least amount of weight loss was actually an increase of 11 kg (9%).

Women who lost  $\geq 5\%$  of baseline weight had a reduction of BMI from a median of 36.2 (IQR, 34.1–39.1) to 31.9



\* Women offered Orlistat but opted not to use it (n=1 lost <5%, n=2 lost ≥ 5% and n=10 dropouts)

**Fig. 1** Flow of the participants throughout the study

(IQR, 29.4–35.4;  $p < 0.001$ ) and showed a significant reduction in girth and fat percentage as shown in Table 2.

The effect of weight reduction (in those who achieved ≥5% from baseline,  $n=42$ ) on pad test, FVC, pelvic floor strength and bladder neck mobility are shown in Table 2. KHQ domains before and after weight loss are shown in Table 3.

Significant reductions from baseline were found in pad test weight. There were also significant reductions (i.e. improvement) in all nine domains of the KHQ. Nocturia (as reported in the FVC) was significantly reduced (but not frequency).

Using the incontinence severity classification [22], at the beginning of the study, none of the participants was continent. Of the 42 women who lost ≥5% from baseline,

six had mild incontinence, 26 had moderate incontinence and ten had severe incontinence (before weight loss). At the end of the study, two were continent, 21 had mild leakage, 15 had moderate leakage, and only four had severe leakage. This, using Wilcoxon's signed rank test, is significant ( $p < 0.001$ ).

Both patients who became continent had a diagnosis of USI at baseline and normal urodynamics after weight loss. Their weight loss was 21.5 and 10 kg (i.e. 19% and 10% weight reduction, respectively). Both showed improvement in all domains of the KHQ after weight loss.

Figure 2 shows the percentage of participants with a change of ≥5 points in the KHQ domains after weight loss, which is an indication of a clinically meaningful effect that is important to the patient [24].

**Table 1** General characteristics of the 42 women who lost  $\geq 5\%$  of initial weight

	<i>N</i> (%)	Median	IQR
Age (years)		52.5	44–62.8
Parity		2	2–3
Weight (kg)		94.1	87.4–100.3
BMI (kg/ m <sup>2</sup> )		36.2	34.1–39.1
Hysterectomy	6 (14.3)		
Menopausal status			
Pre	20 (48)		
Post	22 (52)		
HRT	3 (13.6) <sup>a</sup>		
Urodynamic diagnosis			
USI	21 (50)		
Mixed	13 (31)		
DOI	8 (19)		

USI Urodynamic stress incontinence, DOI detrusor overactivity incontinence, Mixed mixed incontinence IQR interquartile range

<sup>a</sup> Of the 22 postmenopausal patients

A modest (non-significant) improvement in the strength of vaginal contraction was observed using perineometry (Table 2). The small difference in Oxford score after weight loss was however statistically significant. The changes in pelvic floor strength were correlated to the improvements in pad testing using Spearman's correlation coefficient (to explore the possibility that there might be an association). No statistically significant association was found between pad test improvement and changes in perineometry ( $r=0.086$ ,  $p=0.593$ ) and Oxford score ( $r=0.192$ ,  $p=0.224$ ).

Thirty-six women (86% of those who lost 5% or more) had repeat urodynamics after weight loss. Their initial diagnoses were USI ( $n=20$ ), detrusor overactivity incontinence (DOI;  $n=8$ ) and mixed UI ( $n=8$ ). Six patients declined to have a repeat test (no reasons were given). Eight women (40%) with an initial diagnosis of USI were found to have resolved their urodynamic abnormality after weight loss. Of the women with mixed UI initially, one had

USI alone and one DOI alone on repeat testing. Patients initially diagnosed as DOI remained in the same category.

The results were also analysed according to the baseline urodynamic diagnosis (Table 4). Bladder neck mobility and urine loss on pad test were significantly lower after weight reduction in all three groups (i.e. USI, DOI and mixed incontinence) Changes in nocturia were significant in the women with USI and mixed incontinence only. Changes in other outcome measures were not statistically significant.

A weak but statistically significant correlation was seen between pad test improvement and reductions in abdominal girth ( $r=0.357$ ,  $p=0.020$ ) and between pad test improvement and bladder neck mobility ( $r=0.357$ ,  $p=0.024$ ). There was however no correlation between reduction in BMI and improvement in the pad test ( $r=0.192$ ,  $p=0.223$ ). Furthermore, reduction in bladder neck mobility showed no correlation to reduction in abdominal girth ( $r=0.089$ ,  $p=0.586$ ).

Only five women did not achieve the target weight loss. A summary analysis was done and showed that the differences between baseline and end of study measures of urine loss (pad test) and QoL measures (KHQ) were all non-significant.

## Discussion

Until recently, the only data on the effects of weight loss on incontinent women was derived from surgical series of obese women who had undergone bariatric surgery. Bump et al. [5] demonstrated significant improvements in UI in 12 women (mean pre-operative BMI of 49.9 kg/m<sup>2</sup>) 1 year after surgically induced weight loss. In addition, Dietel et al. [6] reported significantly less stress incontinence (using a non-validated questionnaire) in women who lost 50% or more of their excess body weight after bariatric surgery. Recently, Burgio et al. [9] reported a significant reduction in the prevalence and severity of UI symptoms (using QoL questionnaires) 6 and 12 months after laparoscopic bariatric

**Table 2** Effects of weight reduction in women with  $\geq 5\%$  weight loss

	Baseline Median (25–75% IQR)	Post weight reduction Median (25–75% IQR)	Median difference (95% CI)	<i>p</i> value
Body fat (%)	45.35 (37.60–54.20)	40.00 (26.80–49.80)	4.70 (4.05–5.55)	<0.001
Girth	107.50 (85.50–132.00)	103.50 (83.10–127.00)	4.00 (3.00–4.75)	<0.001
Pad weight (g)	38.75 (27.00–69.00)	18.50 (8.63–34.88)	19.00 (13.00–28.00)	<0.001
Frequency	7.33 (6.58–8.08)	7.33 (7.00–8.00)		0.60
Nocturia	1.00 (.58–1.42)	0.67 (0.33–1.00)	0.50 (0.33–0.67)	<0.001
Mean voided volume (ml)	177.33 (147.92–240.67)	193.17 (168.92–218.92)		0.44
Perineometry (cm H <sub>2</sub> O)	16.50 (11.25–29.00)	20.00 (13.50–25.25)		0.34
Oxford Score (grade)	3 (1–3)	3 (2–3)		0.02
Bladder neck mobility (mm)	7.71 (5.43–11.82)	5.65 (3.51–10.51)	2.44 (1.66–3.34)	<0.001

**Table 3** KHQ domains before and after weight reduction in women with  $\geq 5\%$  weight loss

Domains	Baseline Median (25%–75% IQR)	Post weight reduction Median (25%–75% IQR)	Median difference (95% CI)	p value
General health perception	37.50 (25.00–50.00)	25.00 (25.00–50.00)	25.00 (0.00–25.00)	0.003
Incontinence impact	66.67 (66.67–100.00)	33.33 (33.33–66.67)	33.33 (33.33–33.33)	<0.001
Role limitations	50.00 (33.33–66.67)	33.33 (12.50–50.00)	25.00 (16.67–33.33)	<0.001
Physical limitations	66.67 (33.33–83.33)	33.33 (16.67–54.17)	25.00 (16.67–33.33)	<0.001
Social limitations	44.44 (11.11–66.67)	22.22 (11.11–44.44)	16.67 (11.11–27.78)	<0.001
Personal relationships	66.67 (33.33–100.00)	50.00 (33.33–75.00)	25.00 (8.33–33.33)	0.013
Emotions	66.67 (33.33–88.89)	33.33 (11.11–66.67)	27.78 (22.22–33.33)	<0.001
Sleep/energy	50.00 (33.33–83.33)	33.33 (16.67–66.67)	16.67 (16.67–33.33)	<0.001
Severity measures	70.00 (60.00–80.00)	53.33 (33.33–73.33)	16.67 (13.33–23.33)	<0.001

surgery, in a surgical series of 101 obese women with a mean pre-operative BMI of 48.8 kg/m<sup>2</sup>. The prevalence of UI decreased from 66.7% before surgery to 41% at 6 months and 37% at 12 months. The reduction in the prevalence of UI was proportional to the magnitude of weight loss. These encouraging results raised the question of whether moderately obese incontinent women could improve their continence by non-surgical weight reduction.

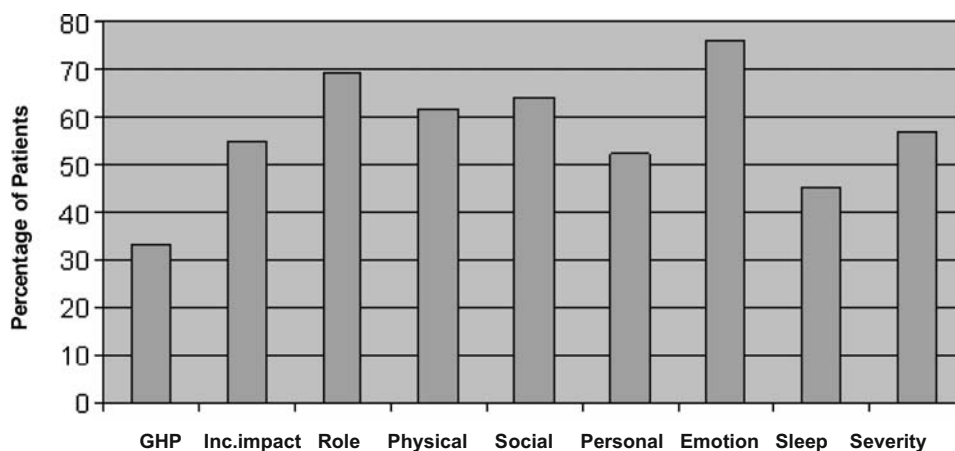
While this investigation was in progress, two studies (from the same group) were published addressing this point [7, 8]. The first (a pilot observational study of ten women) showed a greater than 50% reduction in incontinence episodes per week in women who lost  $\geq 5\%$  of their body weight [7]. The second (RCT of 40 women) confirmed an improved continence ( $>50\%$  reduction in weekly incontinence episodes) in women who lost  $\geq 5\%$  of initial weight and  $\geq 3\%$  of abdominal girth [8]. The populations investigated in these studies were not strictly defined in terms of weight and urodynamic diagnosis. Overweight women (i.e. BMI of less than 30 kg/m<sup>2</sup>) were included, as well as women with gross obesity (i.e. BMI  $\geq 40$  kg/m<sup>2</sup>). Furthermore, both studies included subjects that did not undergo urodynamic investigations [7], and in those who did, some were included who had no urodynamic abnormality before weight loss [8].

In the present study, only moderately obese women (BMI 30–39.9 kg/m<sup>2</sup>) were included [25]. Pre-treatment urodynamic tests were performed in an attempt to clearly identify sub-populations and diagnostic groups where weight loss might be more beneficial. Pad tests were performed to objectively measure improvement and to correlate improvement to variables that might explain why improvement occurs (such as the amount of intra-abdominal fat, bladder neck mobility and pelvic floor strength).

The method used to induce weight loss was deliberately pragmatic. Low-calorie diet, exercise and drug therapy are practical, low-cost and well-established interventions [26]. This method achieved a weight loss of  $\geq 5\%$  in 65% of recruited women, although most participants required Orlistat to achieve this effect (Fig. 1). This is lower than the 90% achieved by Subak et al. [8] when using a very low-calorie diet (i.e.  $\leq 800$  kcal per day). However, it is quite similar to the National Institute for Health and Clinical Excellence (NICE) report on the review of trials comparing Orlistat to placebo. A weight loss of  $\geq 5\%$  at 12 months was achieved by 54% (33–73%) of people taking Orlistat and 32% (13–50%) of those taking placebo [26].

The results shown by Subak et al. [8] are confirmed in this investigation. A weight loss of 5% or greater was

**Fig. 2** Women with a change of  $\geq 5$  points in the KHQ domains after weight loss (i.e. clinically meaningful change). *GHP* General health perception, *Inc. impact* incontinence impact



**Table 4** Significance of changes in the outcome measures (before weight loss–after weight loss) according to baseline urodynamic diagnosis

	Pad test	Frequency	Nocturia	Mean void vol.	Perineometry	Oxford score	BN mobility
SUI	<0.001	0.613	0.006	0.254	0.307	0.063	0.009
DOI	0.008	0.313	0.063	0.250	0.742	0.625	0.039
Mixed	<0.001	0.273	0.004	0.554	0.486	0.750	0.002

Values in each cell represent *p* value.

BN Bladder neck

associated with a significant improvement in UI measures. The objective improvement shown by pad testing was mirrored by the improvements seen in the KHQ. It is interesting that similar improvements using the same questionnaire have been shown after colposuspension [27]. While a 10% reduction is necessary to confer clinically important reductions in the metabolic and cardiovascular risks associated with obesity [28], it is encouraging to see that a 5% reduction is enough to significantly improve UI.

Equally significant improvements were seen for all types of incontinence, although it is difficult to draw firm conclusions due to the relatively small number of women with mixed UI ( $n=13$ ) and DOI ( $n=8$ ).

It is not clear why obesity should be associated with UI. The increase in intravesical pressure created by accumulation of abdominal fat has been proposed as a likely causative factor. In previous studies, it has been suggested that UI improvement after weight loss was likely to be due to the reduction in intravesical pressure [5, 8]. However, a direct cause and effect relationship was not established as measures of intravesical pressure were not correlated to measures of UI.

In this study, the waist circumference has been used as a measure of intra-abdominal fat. Studies using computed tomography have shown that waist circumference measures accurately the amount of abdominal fat [15]. Furthermore, waist circumference has been found to be associated with intravesical pressure [29]. The association seen in this study between improved urinary leakage (on pad test) and reduced waist circumference supports the hypothesis that improvement in UI after weight loss is due to a reduction in the amount of abdominal fat and intravesical pressure.

It is interesting that, while the reduction in girth significantly correlated with improvement in pad test measures, no such correlation was found for changes in BMI. This suggests that the distribution of fat might be important. Women with increased waist-to-hip ratios (so called apples) might benefit from weight reduction more than women where fat is deposited mostly below the waist (so called pears).

Excessive bladder neck mobility is associated with stress incontinence, and most surgical methods of treatment for

stress incontinence aim to support the urethra and reduce mobility. In this study, there was a weak but statistically significant correlation between reduction in bladder neck mobility and pad test improvement. This is difficult to explain, as we found no correlation between reduction in waist circumference and reduction in bladder neck mobility. Furthermore, the reduced bladder neck mobility cannot be explained by improved pelvic floor function, as this was found to be inconsistent (only a modest improvement was observed in the Oxford scores, and there was no effect on perineometry). Further research is needed to explore the association between obesity and UI and to fully understand why women who lose weight experience improved continence.

The lack of a randomised controlled design is the study's main limitation. The difficulties experienced (after randomisation) could be overcome only by changing the design. In our original RCT, similar degrees of weight reduction were achieved by both study and control groups. This was probably due to 'randomisation resentment' by some women in the control group (since finding help with weight reduction was as important to them as the treatment of incontinence). Alternatively, weight loss of some women in the control group could be explained by 'compensatory equalisation'. This observation occurs when participants in the control group change their behaviour to compensate for the fact that they are not in the treatment group [30]. It could also be due to the 'Hawthorne effect', which causes alteration of study subject's behaviour as a result of their awareness of being under observation [14]. As a result of the difficulty to keep the two groups separate, an early decision was made to change the design to a prospective cohort study.

Another limitation of the study was the lack of 'blinding' (researchers were aware of the weight loss during the assessments) and the use of multiple observers for some measures. This was due to practical difficulties and care was taken to ensure the consistency of the measures. It was also felt that pad testing is an objective and accurate measure where it is very difficult to introduce bias. Health questionnaires were completed by the participants without input from the researchers.

Despite the limitations of the study, we believe that the observed association between weight loss (and reduction of

the abdominal girth) and improved continence is real and unlikely to be due to chance or other factors. This is because the observed improvements in UI and QoL were not consistent with spontaneous remission rates reported in epidemiological studies [3]. Women in the study were not encouraged to perform pelvic floor exercises, and the minor and inconsistent improvement in pelvic floor strength was not associated with improvements on pad testing. Furthermore, the fact that those not losing weight did not show any change in continence provides some evidence to support internal validity of the study.

## Conclusion

This study supports weight loss as a treatment option for obese incontinent women. Our data suggest that weight loss is associated with objective reduction of UI (as measured with pad tests) and with statistically and clinically meaningful enhancement in QoL (using condition-specific questionnaires). This effect is attainable after realistic degrees of weight reduction (i.e. 5–10% of baseline weight).

The mechanism of improvement is multifactorial and not yet clear. It is likely to be due to a decrease in abdominal and vesical pressures (as a result of loss of abdominal fat) and also to a reduction in bladder neck mobility.

Given the high prevalence of both UI and obesity in women, promoting weight reduction as a treatment for UI might improve its initial management in the primary care. In addition, knowing that UI improvement might motivate obese women to lose weight. Further studies are needed to investigate the long-term effects of such a strategy on UI.

**Conflicts of interest** None.

## References

- Department of Health (2002) Health Survey for England
- Flegal KM, Carroll MD, Ogden CL, Johnson CL (2002) Prevalence and trends in obesity among US adults, 1999–2000. *JAMA* 288:1723–1727
- Hunskar S, Burgio K, Clark A, Lapita MC, Nelson R, Sillen U et al (2005) Epidemiology of Urinary and faecal incontinence and pelvic organ prolapse. In: Abrams P, Cardozo L, Khoury S, Wein A (eds) *Incontinence. Third International Consultation on Incontinence*, 3rd edn., pp 255–312
- Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL (1997) Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 89:501–506
- Bump RC, Sugeran HJ, Fantl JA, McClish DK (1992) Obesity and lower urinary tract function in women: effect of surgically induced weight loss. *Am J Obstet Gynecol* 167:392–397
- Deitel M, Stone E, Kassam HA, Wilk EJ, Sutherland DJ (1988) Gynecologic-obstetric changes after loss of massive excess weight following bariatric surgery. *J Am Coll Nutr* 7:147–153
- Subak L, Johnson CL, Whitcomb D, Boban J, Brown JS (2002) Does weight loss improve incontinence in moderately obese women? *Int Urogynecol J* 13:40–43
- Subak LL, Whitcomb E, Shen H, Saxton J, Vittinghoff E, Brown JS (2005) Weight loss: a novel and effective treatment for urinary incontinence. *J Urol* 174:190–195
- Burgio KL, Richter HE, Clements RH, Redden DT, Goode PS (2007) Changes in urinary and fecal incontinence symptoms with weight loss surgery in morbidly obese women. *Obstet Gynecol* 110:1034–40
- Brieger G, Korda A (1992) The effect of obesity on the outcome of successful surgery for genuine stress incontinence. *Aust N Z J Obstet Gynaecol* 32:71–72
- Wilson PD, Berghmans B, Hagen S, Hay-Smith J, Moorre K, Nygaard I et al (2005) Adult Conservative Management. In: Abrams P, Cardozo L, Khoury S, Wein A (eds) *Incontinence. Third International Consultation on Incontinence*, 3rd edn., pp 855–964
- Lose G, Fantl JA, Victor A, Walter S, Wells TL, Wyman J, Mattiasson A (2001) Outcome measures for research in adult women with symptoms of lower urinary tract dysfunction Standardization Committee of the International Continence Society. *Acta Obstet Gynecol Scand* 80:981–985
- Abrams P, Andersson KE, Brubaker L, Cardozo L, Cottenden A, Denis L et al (2005) Evaluation and treatment of urinary incontinence, pelvic organ prolapse and faecal incontinence. In: Abrams P, Cardozo L, Khoury S, Wein A (eds) *Incontinence. Third International Consultation on Incontinence*, 3rd edn., pp 1589–1630
- Roethlisberger F (1941) The Hawthorne experiments. In: *Classics of organizational behaviour*. Interstate printers, Danville, IL
- Lord J, Thomas R, Fox B, Acharya U, Wilkin T (2006) The effect of metformin on fat distribution and the metabolic syndrome in women with polycystic ovary syndrome—a randomised, double-blind, placebo-controlled trial. *BJOG* 113:817–824
- Lukaski HC (1987) Methods for assessment of human body composition: traditional and new. *Am J Clin Nutrition* 46:537–556
- Schaer GN, Koechli OR, Schuessler B, Haller U (1996) Perineal ultrasound: determination of reliable examination procedures. *Ultrasound Obstet Gynecol* 7:347–352
- King JK, Freeman RM (1998) Is antenatal bladder neck mobility a risk factor for postpartum stress incontinence? *BJOG* 105:1300–1307
- Isherwood PJ, Rane A (2000) Comparative assessment of pelvic floor strength using a perineometer and digital examination. *BJOG* 107:1007–1011
- Foreyt JP, Goodrick GK (1991) Factors common to successful therapy for the obese patient. *Med Sci Sports Exerc* 23:292–297
- Stevens N, Sykes K (1996) Aerobic fitness testing: an update. *Occup Health (Lond)* 48:436–438
- O’Sullivan R, Karantanis E, Stevermuer TL, Allen W, Moore KH (2004) Definition of mild, moderate and severe incontinence on the 24-hour pad test. *BJOG* 111:859–862
- Armitage P, Berry G (1994) *Statistical methods in medical research*. Blackwell Science, London
- Kelleher CJ, Pleil AM, Reese PR, Burgess SM, Brodish PH (2004) How much is enough and who says so? *BJOG* 111:605–612
- World Health Organization (1997) *Consultation on Obesity: preventing and managing the global epidemic*. WHO Technical Report Series 894
- National Institute for Health and Clinical Excellence (2006) *Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children*. Clinical guideline 43



27. Bidmead J, Cardozo L, McLellan A, Khullar V, Kelleher C (2001) A comparison of the objective and subjective outcomes of colposuspension for stress incontinence in women. *BJOG* 108:408–413
28. Pi-Sunyer FX (1996) A review of long-term studies evaluating the efficacy of weight loss in ameliorating disorders associated with obesity. *Clin Ther* 18:1006–1035
29. Lambert DM, Marceau S, Forse RA (2005) Intra-abdominal pressure in the morbidly obese. *Obes Surg* 15:1225–1232
30. Lam J, Hartwell S, Jekel J (1994) I prayed real hard, so I know I'll get in: living with randomization in social research, critically evaluating the role of the randomized experiments. *New Dir Progr Eval* 63:55–66