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CHARACTERISTICS OF OBESE, OVERWEIGHT AND NORMAL (HEALTHY) WEIGHT WOMEN SEEKING SURGICAL TREATMENT FOR STRESS URINARY INCONTINENCE

Hypothesis/aims of study: Obesity is a modifiable risk factor associated with the presence of urinary incontinence (UI); yet little is known about the impact of UI on obese as compared to normal weight women. Additionally little is known about the mechanistic factors that under-lye UI in obese and normal weight women. The aim of this study was to compare baseline characteristics between a large number of normal weight and obese participants in two randomized comparative effectiveness trials for the surgical treatment of stress UI.

Study design, materials and methods: Trial 1 (N=655) was designed to compare the effectiveness of Burch colposuspension and fascial retropubic sling, while Trial 2 (N=597) compared the effectiveness of transobturator versus retropubic synthetic mid-urethral slings. Body mass index [BMI] was characterized as normal (<25 kg/m²), overweight (25kg/m² ≤BMI<30 kg/m²) and obese (BMI≥30 kg/m²). Urodynamic studies were done according to a standardized protocol. Pelvic organ prolapse was measured using the Pelvic Organ Prolapse Quantification System (POP-Q). Other UI severity measures included 24 hour pad weight, incontinence episode frequency on a 3 day diary, Incontinence Impact Questionnaire (IIQ) score, Urogenital Distress Inventory (UDI) total score, UDI urge and stress subscale scores, Medical, Epidemiologic, Social aspects of Aging (MESA) total score and MESA stress and urge subscale scores. Independent BMI groups (3-category obesity measure) and continuous participant variables, were compared using one-way analysis of variance (ANOVA) and cross-classification and Chi square test for categorical measures. Multivariable regression analyses were performed on a measure of subjective and objective UI severity, UDI total score, and incontinence episodes (IE's) by bladder diary, respectively and 2 proposed urodynamic parameters of UI severity (Valsalva Leak Point Pressure, VLPP; Maximal Urethral Closure Pressure, MUCP) controlling for age, race and ethnicity, education, general patient health score, hormone therapy (HT), diabetes and smoking. Analyses were performed using SAS version 9.2 (SAS Institute, Inc. Cary, NC).

Results: In Trial 1, the mean age was 51.9 (SD 10.3) years, and in Trial 2, 52.9 (SD 11.0) years. In Trial 1, 142 (22 %) women were normal weight [Mean BMI (SD), 22.9(1.6)], 218 (34%) overweight [27.5(1.4)], and 290 (45%) obese [35.4(4.8)]. In Trial 2, 137 (23%) were normal weight [22.6(1.7)], 191 (32%) overweight [27.4(1.2)], and 263 (45%) obese [36.5(5.2)]. Overall in both trials, >70% of subjects were white. In both trials, compared to normal weight women, obese women were more likely to have less education and lower occupational scores, and were more likely to smoke, have diabetes and report poorer health. Additionally, obese women in Trial 1 were less likely to be married, use hormone therapy and to have undergone prior surgery for POP. There were no differences among the groups in age, mode of delivery, hysterectomy, prior UI surgery, POPQ stage and fecal incontinence symptoms.

In each trial, obese women had higher pad weights, more incontinent episodes, higher MESA scores (total, stress, urge), greater IIQ total and UDI total scores, and greater UDI urge subscale scores compared to normal weight women. UDI stress subscale scores did not differ between normal weight and obese subjects.

Table 1. Characteristics of Incontinence Evaluation by BMI

Variable	Normal wght	Overwght	Obese	Overall	p-value
Trial 1	N=142	N=218	N=290	N=650	
Pad weight	26.9(41.4)	40.3(72.3)	53.2(94.6)	43.5(79.4)	0.005
IIQ total score	132.1(87.0)	170.5(102.5)	191.2(101.1)	171.4(101.3)	<0.0001
UDI total score	138.8(43.7)	146.7(51.4)	160.0(46.4)	151.0(48.6)	<0.0001
UDI urge score	39.6(22.6)	45.7(24.5)	53.3(25.4)	47.8(25.2)	<0.0001
UDI stress score	77.2(19.3)	74.0(24.6)	81.4(20.4)	78.0(21.9)	0.0008
Incontin epis/d	2.2(2.1)	3.3(3.3)	3.6(3.0)	3.2(3.0)	<0.0001
Tot MESA score	23.0(6.7)	25.6(7.3)	27.3(7.5)	25.8(7.4)	<0.0001
Stress score	17.7(4.3)	19.3(4.6)	20.2(4.5)	19.3(4.6)	<0.0001
Variable	Normal wght	Overwght	Obese	Overall	p-value
Urge score	5.3(3.4)	6.3(3.9)	7.2(4.0)	6.5(3.9)	<0.0001
Trial 2	N=137	N=191	N=263	N=591	p-value
Pad weight	26.9(50.9)	27.3(53.9)	46.3(79.6)	35.8(66.6)	0.002
IIQ total score	119.6(78.3)	132.4(90.0)	182.6(102.4)	151.5(97.4)	<0.0001
UDI total score	124.4(40.6)	130.2(44.1)	143.5(47.2)	134.6(45.5)	0.0001
UDI urge score	33.4(21.5)	37.7(25.6)	48.2(25.5)	41.2(25.4)	<0.0001
UDI stress score	75.5(21.8)	74.5(21.5)	73.9(21.5)	74.4(21.5)	0.77
Incontin epis/d	2.9(3.3)	2.8(2.3)	3.9(3.1)	3.3(3.0)	<0.0001
MESA score (total)	23.0(7.5)	24.9(7.1)	27.6(7.4)	25.6(7.5)	<0.0001
Stress score	18.0(4.9)	18.9(4.3)	20.4(4.4)	19.3(4.6)	<0.0001
Urge score	5.0(3.6)	6.0(3.9)	7.2(4.1)	6.3(4.0)	<0.0001

Mean(SD)

Key urodynamic parameters for trial 2 are summarized in Table 2, similar trends were seen in Trial 1, except that MUCP and FUL's were not assessed. In both trials, obese women had higher VLPP, Pves at baseline and at Qmax, Pabd at baseline and at Qmax, and lower time to Qmax compared to normal weight women. Additionally, in Trial 2, obese women had lower mean bladder volumes at first desire, strong desire and maximum cystometric capacity as compared to normal weight subjects. Urethral closure

pressures were only measured in Trial 2. Compared to normal weight women, MUCP was higher in obese women, while functional urethral length did not differ.

Table 2. Urodynamic Parameters by BMI: Trial 2

Variable	Normal wght N=137	Overwght N=191	Obese N=263	Overall N=591	p-value
Trial 2					
VLPP	107.5(35.2)	114.0(39.3)	130.3(46.0)	119.4(42.4)	0.0001
UPP					
MUCP	60.5(26.7)	68.2(34.6)	71.8(33.4)	67.9(32.5)	0.008
FUL	32.0(7.3)	31.7(7.9)	31.5(8.6)	31.7(8.1)	0.84
Pves	32.3(9.2)	35.0(11.2)	39.4(11.9)	36.3(11.4)	<0.0001
Pabd	30.4(9.7)	33.0(11.2)	37.7(11.2)	34.4(11.3)	<0.0001
Bldr vol first des	133.4(85.8)	111.8(85.6)	111.4(73.0)	116.4(80.4)	0.02
Bldr vol strong des	250.3(126.2)	222.7(119.0)	218.6(111.8)	227.0(117.7)	0.03
MCC	370.1(136.6)	350.7(122.7)	341.7(114.3)	351.4(122.6)	0.09
Max Flow (PFS)	21.9(10.6)	21.9(11.2)	22.2(10.5)	22.1(10.8)	0.95
Pves at Qmax	47.5(19.2)	53.8(28.1)	63.9(27.2)	56.4(26.5)	<0.0001
Pabd at Qmax	30.1(21.3)	36.0(28.9)	42.4(26.9)	37.1(26.7)	0.001

Mean(SD)

In Trial 1, multivariable regression analyses showed that increasing BMI category was independently associated with mean increasing total UDI score ($p=0.003$), increasing IE's ($p<0.0001$) and with **higher** VLPP's ($p=0.003$). In Trial 2, increasing BMI classification was not associated with total UDI score ($p=0.19$), but was associated with increasing IE's ($p=0.0004$) and significant increases in VLPP's ($p=0.0004$) and MUCP's ($p=0.01$).

Interpretation of results: In general obese women reported worse UI symptom distress and impact as compared to normal weight women. As anticipated, they also had higher intravesical and intra-abdominal pressures at baseline and maximum flow. Curiously, VLPP's and MUCP's increased with increasing BMI perhaps reflecting a compensatory mechanism of urethral function.

Concluding message: Our findings suggest that obese women presenting for surgical treatment of SUI have more severe UI and are disproportionately impacted by their condition compared to normal weight women thereby representing a unique population for targeted therapies. Surprisingly, despite subjective and objectively worse UI severity, obese women have better urethral function as measured by urodynamic parameters, suggesting that factors other than urethral failure may contribute to UI in obese women.

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Is this study registered in a public clinical trials registry?	Yes
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What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Institutional Review Board
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes