

Obstet Gynecol. Author manuscript; available in PMC 2012 January 5.

Published in final edited form as:

Obstet Gynecol. 2008 August; 112(2 Pt 1): 341-349. doi:10.1097/AOG.0b013e31817cfdde.

OBESITY AND PELVIC FLOOR DISORDERS: A REVIEW OF THE LITERATURE

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Abstract

OBJECTIVE—To review the current literature and <u>summarize the effect of</u> obesity <u>on</u> outcomes of surgical treatment of pelvic floor disorders (PFDs) <u>as well as</u> the effect of weight loss on PFD <u>symptoms</u>.

DATA SOURCES—Relevant sources were identified by a MEDLINE search from 1966 to 2007 (key words: obesity, pelvic floor disorders, urinary incontinence, fecal incontinence, pelvic organ prolapse). References of relevant studies were hand searched.

METHODS OF STUDY SELECTION—Relevant human observational studies, randomized trials, and review articles were included. 246 articles were identified; 20 were used in reporting and analyzing the data. Meta-analyses were performed for topics meeting the appropriate criteria.

TABULATION, INTEGRATION AND RESULTS—There is good evidence that surgery for stress urinary incontinence in obese women is as safe as in their non-obese counterparts, but cure rates may be lower in the obese patient. Meta-analysis revealed cure rates of 81% and 85% for the obese and non-obese groups, respectively [P < 0.001; OR: 0.576 (95% CI: 0.426 - 0.779)] Combined bladder perforation rates were 1.2% in the obese and 6.6% in the non-obese [P = 0.015; OR: 0.277 (95% CI: 0.098 - 0.782)]. There is little evidence on which to base clinical decisions regarding the treatment of fecal incontinence (FI) and pelvic organ prolapse (POP) in obese women, as few comparative studies were identified addressing the outcomes of prolapse surgery in obese patients compared to normal-weight controls. Weight loss studies indicate that both bariatric and non-surgical weight loss lead to significant improvements in PFD symptoms.

CONCLUSION—Surgery for UI in obese women is safe, but <u>more</u> trials are needed to evaluate its long-term effectiveness as well as treatments for both FI and POP. Weight loss, both surgical and non-surgical, should be considered in the treatment of PFDs in the obese woman.

INTRODUCTION

Current data from the Centers for Disease Control and World Health Organization estimate there are 300 million obese adults worldwide, while in the United States 31% of adults are obese and another 33% are overweight (1- 3). This proportion has risen most rapidly in the younger population (18 to 29 years) and especially in women. The impact of obesity on quality of life is broad and multi-faceted, affecting social, behavioral, emotional, and health domains. Obesity is known to contribute to a number of chronic medical conditions. In fact, more than 280,000 deaths annually are attributed to obesity, and greater than 6% of US health care dollars are spent on obesity-related issues. Obesity is second only to tobacco-related disease in both health care costs and preventable deaths (4-6).

Among the medical conditions affected by obesity are pelvic floor disorders (PFDs), including: urinary incontinence (UI), fecal incontinence (FI) and pelvic organ prolapse (POP). Disorders of the pelvic floor are known to affect between 2% and 42% of adult females, depending on the definition of the condition and the study population (7-12). Numerous epidemiological studies have shown an association between obesity and UI (7-9, 13-18) with odds ratios for the presence of UI as high as 1.6 per 5 unit increase in BMI (7). In one clinical study of morbidly obese women presenting for consultation for weight loss surgery, the prevalence of UI symptoms was 67% (13).

The role of obesity in FI is less well defined. The prevalence of FI in the general population is reported to be 2 to 9% (10, 11). However, in morbidly obese patients undergoing evaluation for weight loss surgery, the prevalence of anal incontinence was notable at 32%, while incontinence of liquid stool was 21.1% and solid stool was 8.8% (13).

There is a paucity of evidence on the relationship between obesity and the prevalence of POP, but what little data exist <u>have</u> shown a positive association (19, 20). One study with eleven year follow-up after hysterectomy showed a 4.4% rate of vaginal vault prolapse and obesity as the strongest risk factor for its occurrence (21).

Given the rising obesity epidemic, the purpose of this review was to <u>summarize</u> the current literature <u>regarding the effect of</u> obesity <u>on</u> outcomes of surgical treatment for PFDs and the effect of weight loss on PFD <u>symptoms</u>.

SOURCES AND STUDY SELECTION

Relevant sources were identified by a MEDLINE search from January 1966 to September 2007 (key words: obesity, pelvic floor disorders, UI, FI, POP). References of relevant studies were also hand-searched. All major randomized and observational studies in the English language were included. Of the 246 studies identified, 226 were excluded on the basis of title or abstract, or due to lack of comparative study design. The remaining papers included 7 on use of the tension-free vaginal tape procedure (TVT®, Gynecare, Ethicon) for treatment of stress UI, 4 on non-surgical weight loss and 5 papers on surgical weight loss. Additionally, the results of 2 papers on surgical treatment of FI, as well as 2 papers on treatment for POP, were included.

MOOSE guidelines were followed for meta-analyses. We analyzed data from studies reporting outcomes of TVT® for the treatment of stress UI, performing meta-analyses for cure rates and complications (bladder perforation) between the obese and non-obese groups. We used the random-effects model to estimate and compare the odds ratios via the z-statistic and assessed heterogeneity among studies using the Cochran Q statistic, which was not significant for both TVT® cure rates and bladder perforations. Funnel plots were run for both meta analyses, and there was no publication bias by Egger's test (p> 0.05 for both meta

analyses). Sensitivity analyses were not run, as our samples were too small. All analyses were performed using Comprehensive Meta Analysis version 2.2.027.

RESULTS

Obesity and Surgical Treatment of Urinary Incontinence

The role of UI surgery in the obese population has been debated due to concerns about higher rates of failure and surgical complications (22-25). However, concerns about the safety and feasibility of UI surgery in the obese patient have not been supported by the literature. Combined data from the 7 studies comparing complications of the TVT® included a total of 251 obese and 700 non-obese patients. Regarding surgical and perioperative complications, bladder injury during the procedure was the only complication reported consistently enough across 6 of the 7 studies to warrant meta analysis. Mukherjee et al did not report on bladder perforations (26). The overall perforation rates were 1.2% in the obese and 6.6% in the non-obese [P = 0.015; OR: 0.277 (95% CI: 0.098 – 0.782)].

In the only study that found a difference in TVT® complications, Skriapas et al compared morbidly obese women (BMI \geq 40) to non-obese controls (BMI < 30). They reported a higher early postoperative complication rate in the obese patients (48.4% vs. 38.5%,) (Table 1); however, their numbers were small and the only complications occurring in the obese patients and not seen in the non-obese were: DVT (n = 2), minor wound hematoma (n = 2), new onset arrhythmia (n = 1) and pneumonia (n = 1). No differences were noted in other perioperative complications, including surgical time, blood loss, length of hospital stay, prolonged catheterization or de novo urge symptoms (27).

While incontinence procedures in obese patients may be more difficult due to body habitus, several studies have noted the safety of these procedures in terms of estimated blood loss, operative time, incidence of visceral injuries, and length of hospital stay, when compared with the same procedures in non-obese patients (28-34). In a recent study of 79 obese females (BMI \geq 30) and 171 non-obese controls undergoing TVT®, Rogers et al noted a longer operative time by 15 minutes and higher estimated blood loss in the obese group. However, obese patients experienced a smaller drop in postoperative hematocrit, and there was no difference in the length of hospital stay or major operative complications (34).

The development of de novo urge UI is a recognized problem after incontinence surgery. Rafii et al reported a higher rate of persistent urge UI of 18% in their obese population, compared with 6.4% in overweight and 3.4% in normal weight patients (P = 0.02) (31). However, a difference in de novo urge UI was not observed in this or other studies (26-28, 32, 33). Given the existing data and the minimally invasive nature of current techniques, surgery appears to be a feasible and safe option for treatment of stress UI in the obese woman.

In addition to determining the safety of UI surgery in obese women, we examined whether there is similar effectiveness. Early studies evaluating the Burch colposuspension and needle suspensions of the bladder neck showed mixed results. While some of these studies revealed an association between obesity and poorer surgical outcomes (25, 35, 36), others showed no difference in continence rates among BMI sub-groups (37).

More recently, numerous studies have been conducted evaluating the efficacy of the new minimally invasive procedures for stress UI in obese compared to non-obese women (26-28, 30-33) (Table 1). Hellberg et al reported a significantly lower cure rate after the TVT® in patients with BMI > 35 (52%; defined as an answer of "almost completely cured" or "cured" by questionnaire) compared with that found in normal weight subjects (81%) (30).

Interestingly, when using a BMI cutoff of 30 for comparing obese and non-obese patients in this study, the cure rates are 66% and 77%, respectively. This is more in keeping with cure rates found in other studies, the majority of which have found no significant difference in overall cure rates, which approach 90%, with follow-up of up to 24 months (26-28, 31-33).

Despite the findings of these individual studies, meta-analysis did reveal a significant difference in cure rates between the two groups. Combined data on outcomes of TVT® from these 7 studies include 453 obese and 1186 non-obese patients, with cure rates being 81% and 85%, respectively [P < 0.001; OR: 0.576 (95% CI: 0.426 – 0.779)].

Obesity and Surgical Treatment of Fecal Incontinence

Early studies of anal sphincteroplasty for FI reported success rates of 62 to 94% in the general population (38-44), although a more recent study with long-term follow-up of 77 months showed a 50% success rate (45). A recent Cochrane Database review concluded that there is not enough evidence to recommend surgical versus behavioral treatment, or one surgical procedure over another for the treatment of FI (46).

Only two studies were found that investigated surgical outcomes for FI in obese patients. Korsgen et al evaluated 57 women who had undergone total pelvic floor repair (i.e., post-anal repair with anterior levatorplasty and external anal sphincter plication) for post-obstetric neuropathic FI (47). Those with a localized sphincter injury were excluded. With an average follow-up of 36 months (range 18-78), improvements in incontinence scores were seen in 72% of patients, but obesity was found to be associated with poor outcomes (P < 0.05). The details of these poorer outcomes were not provided (47).

Nikiteas et al reported results of 32 women who underwent sphincter repair; 6 for fistula-related injuries and 26 for third-degree obstetric injuries. While all of the women with fistula-related injuries regained continence, only 15 of 26 obstetric injuries (57%) were continent after surgery. In evaluating obesity together with either age > 50 years or the presence of perineal descent, 64% of surgical failures had two of these factors compared with only 7% of patients with successful surgeries (P = 0.003) (48). Thus, the role of surgery for obese patients with FI remains unclear.

Obesity and Surgical Treatment of Pelvic Organ Prolapse

While there are several studies showing an association between obesity and POP (19-21, 49-51), as well as the effects of PFDs on prolapse symptoms and quality of life (52), the data are scarce on the outcomes of surgery for POP in the obese woman. One of the few prospective trials to examine the effect of obesity on outcomes was an observational study by Clark et al, who followed 376 women after surgery for POP and/or UI. Over a 5 year follow-up period, 36 women underwent 40 re-operations. No association was found with BMI in these surgical failures (53). Additionally, a study by Auwad et al prospectively evaluated the development of POP in 77 patients who underwent Burch colposuspension. After 8 years of follow-up, 38% had developed symptomatic prolapse and another 38% had asymptomatic prolapse. Again, BMI was not found to have a significant association with surgical failure (54).

More recently, Bradley et al reported the results of a secondary analysis of the Colpopexy And Urinary Reduction Efforts (CARE) trial, which examined the effects of abdominal sacrocolpopexy in stress continent women (55). Seventy-four obese (BMI \geq 30 kg/m²), 122 overweight (BMI 25 – 29.9 kg/m²), and 125 healthy-weight (BMI 18.5 – 24.9 kg/m²) women were evaluated preoperatively and 2 years postoperatively by physical examination including Pelvic Organ Prolapse Quantification (POP-Q) (56), as well as validated measures of symptoms and patient satisfaction. Obese women were found to have significantly longer

operative times than healthy weight women (189 vs. 169 minutes, P = 0.02), but no differences were found in stress incontinence, prolapse symptoms, and patient satisfaction outcomes. There was an improvement in colorectal symptoms after surgery in both the healthy-weight and obese groups, but the obese group reported more colorectal symptoms and related functional impact. A comparison of subscale scores on the Colorectal, Anal Distress Inventory (CRADI) revealed that the difference seen in overall colorectal symptoms was explained by more painful and irritative colorectal symptoms and more bowel incontinence in the obese group (p=0.0006 and 0.002, respectively) POP-Q points were similar in obese and healthy-weight women, except for POP-Q point Bp (posterior vaginal descent, cm), which was lower (more prolapsed) in obese women compared to healthy-weight women (-2.0 [-3.0, -1.0] versus -3.0 [3.0, -2.0], p=0.003) (55).

Effects of Weight Loss on Pelvic Floor Disorders

Because pelvic floor disorders are associated with obesity, studies of weight loss have examined its effects and explored the pathophysiologic mechanisms of improvement in PFDs. Most clinical studies have focused on the hypothesis that chronically increased abdominal pressure (\underline{P}_{abd}) is a mechanism through which obesity increases the development of PFDs (57-62). Theoretically, increased \underline{P}_{abd} "stresses" the pelvic floor, leading to overt structural damage or neurologic dysfunction predisposing to prolapse and incontinence.

Canine studies that evaluated urethral sphincter incompetence have noted an association between obesity and UI, in addition to other anatomic findings, including shorter urethras and reduced urethral tone (63-65). Human studies by both Sugerman and Noblett have noted elevated $\underline{P}_{\underline{a}\underline{b}\underline{d}}$ and intravesical pressures ($\underline{P}_{\underline{v}\underline{e}\underline{s}}$) in patients with increased sagittal abdominal diameter and elevated BMI (57, 58). Studies of patients undergoing significant weight loss have shown improvements in stress UI, with decreases in $\underline{P}_{\underline{v}\underline{e}\underline{s}}$, cough pressure transmission, and urethral mobility, supporting the theory of increased abdominal pressure (66, 67).

While the association between sagittal abdominal diameter, high BMI, $\underline{P_{abd}}$ and $\underline{P_{ves}}$, and PFDs is strong, other pathophysiologic explanations may exist. For example, a study of 429 workers determined that obesity was a risk factor for median nerve conduction delays; the risk for abnormal median nerve conduction was 3.5-fold greater in obese workers (68). Additionally, Heliovaara reported a higher incidence of lumbar disk herniation in obese men compared to normal weight controls (69). These studies suggest that neurogenic disease caused by obesity might lead to dysfunction of the pelvic floor and urethra, potentially placing obese women at a greater risk for prolapse and incontinence (63).

Several studies have examined the effects of weight loss achieved by dieting and lifestyle changes on UI (Table 2). One prospective cohort study demonstrated a 50% decrease in incontinence frequency on bladder diaries of 10 patients who lost 5% or more of their body weight via programs including low-calorie diets, exercise and behavioral modification (70). Additionally, randomized controlled trials by Brown and Subak have shown a lower prevalence of stress UI in association with lifestyle intervention, as well as significant reductions in weekly incontinence episodes among patients losing more than 5% of their body weight through participation in weight loss programs (71-73) (Table2).

An NIH consensus panel has recommended that for morbidly obese patients (BMI \geq 40 kg/m²), the use of bariatric surgery should be considered (74). As the number of morbidly obese patients undergoing bariatric surgery has increased (61), so has our understanding of the effects of massive weight loss on overall health, as well as PFDs. Sugerman et al reported on 15 severely obese gastric bypass patients followed prospectively for one year, with an average weight loss of 69% of excess body weight. Significant changes were seen in

sagittal abdominal diameter (32 to 20 cm, P < 0.0001) and \underline{P}_{ves} (17 to 10 cmH₂O, P < 0.001) (75) (Table 3).

A number of observational studies have now documented improvements in UI after weight loss surgery (Table 3) (59, 66, 67, 74-77). One of the earliest studies reported on 138 mostly reproductive-aged females who lost greater than 50% of their excess body weight. Obstetric-related conditions (infertility, hypertension/ preeclampsia, diabetes, and DVT) and other comorbidities essentially resolved, including a reduction in stress UI from 61 to 11.6% (P < 0.001) (66). Bump et al reported similar improvement in both subjective and urodynamic prevalence of UI, as well as certain other urodynamic parameters (67) (Table 3).

More recently, Burgio et al reported on 101 women followed for 12 months after laparoscopic gastric bypass surgery. Weight loss was associated with a 44% decrease in UI prevalence (66.7 to 37%) (78). Furthermore, greater reductions in BMI were associated with greater recovery of continence; among patients who lost more than 18 BMI points, 71% regained urinary continence (Figure 1). In addition to the impact of intervention on prevalence of UI, this study demonstrated a 56% decrease in the prevalence of FI 12 months after surgery (78) (Table 3).

CONCLUSION

For obese patients with UI, mid-urethral sling procedures appear to be as safe as in non-obese patients, but based on combined data from the available studies their long-term effectiveness is unclear. Most studies had limited follow up of only 2 years or less and involved only the use of the TVT®. Longer-term studies are needed to determine whether the chronically increased abdominal pressure experienced by obese women affects the longevity of treatment outcomes. Likewise, the efficacy of the newer mid-urethral slings using the transobturator approach and shorter slings such as the TVT SecurTM needs to be determined in the obese population. Until these data are available, however, the TVT® does appear to be a good mid-urethral sling treatment option for stress UI in obese patients (Table 1) (27, 29, 30).

Regarding the treatment of FI and POP in obese women, there is little evidence on which to base clinical decisions. While an association of obesity with PFDs has been seen, the majority of studies report this as a secondary outcome and are not powered to detect a difference (20, 21). No comparative studies were identified that were designed to address the outcomes of non surgical or surgical therapy in obese women compared to normal weight controls. The relationship between obesity and PFDs, traditional repair of POP, as well as the use of the new mesh kits for POP should be an area of research focus. With respect to FI, it appears that anal sphincteroplasty is less successful in obese patients (48, 49), but these data are from small observational studies. Larger, prospective trials are needed to evaluate treatment of FI in both obese and non-obese patients, including the role of behavioral, medical, and surgical treatments.

Documented improvements in disorders of the pelvic floor following massive weight loss after gastric bypass are encouraging. <u>Additionally</u>, promising reductions in UI have been observed in patients losing only 5-10% of their body weight combined with lifestyle modification (70-73). While the effects of weight loss on PFDs remains an area of need for future research, the known benefits of weight loss on PFDs, as well as overall health benefits, should be shared and discussed with our obese patients.

Acknowledgments

Partially funded by DK068389 to HER

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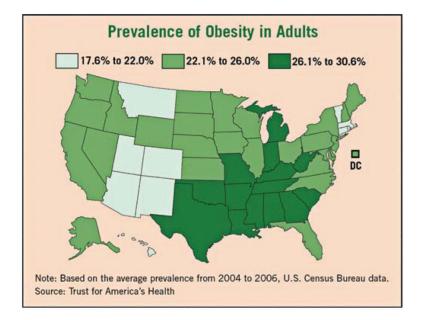


Figure 1. Distribution of obesity in US adults by state. Obesity rises in more than half of states. From Schneider ME. ObGyn News Nov 1, 2007; 42(21):29.

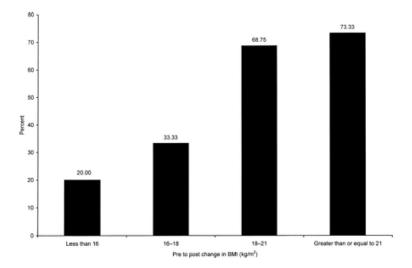


Figure 2.Percentage of women with resolution of urinary incontinence by magnitude of change in body mass index.
From Burgio et al. Changes in Incontinence After Weight Loss. Obstet Gynecol 2007.

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Table 1

Outcomes of the TVT® procedure in the obese

Study	N (Obese / Nonobese)	Follow-up (months)	% Cure (Obese / Nonobese)	P value	Complications
Mukherjee et al (26), 2001	87 / 156	Not given	90 / 91.2	NS	No difference in urinary retention, operative complications
Chung et al (32), 2002	60 / 31	(12 -24)	100 / 100	NS	No difference in length of hospital stay, voiding dysfunction
Rafii et al (31), 2003	39 / 149	27 (6 - 38)	82 / 91.2	0.1	More persistent urge UI in obese (17.9% vs. 4.6%)
Lovatsis et al (28), 2003	35 / 35	(6 – 24)	88.6 / 91.4	NS	- More bladder perforations in nonobese (14 vs. 0%, $P = 0.03$) - Longer operative time in obese (49 vs. 35 min, $P < 0.05$)
Skriapas et al (27), 2005	31 / 52	18.5 (12 – 24)	26 / L8	0.103	More early postoperative complications in obese $(48.4\% \text{ vs. } 38.5\%, P = 0.021)$
Ku et al (33), 2006	45 / 240	10	84.4 / 91.6	0.173	No difference in urinary retention, persistent urgency
Hellberg et al (30), 2006	163 / 570	68.4 (24 – 96)	66.1 / 77.5	*	* Cure rates for BMI < $25 = 81\%$, for BMI > $35 = 52.1\%$ ($P = 0.0005$)

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Table 2

Effect of non-surgical weight loss on UI

Study	N	Design	BMI (or wt) A	Δ in UI episodes	Other Outcomes
Subak et al (70), 2002	10	Weight loss program	BMI down from 38.3 to 33.0 (-5.3 +/- 6.2; P < 0.03)	13 to 8 per week after wt loss ($P < 0.07$)	All pt's losing $\geq 5\%$ body wt (6 of 10) had > 50% reduction in UI freq ($P < 0.03$)
Subak et al (72), 2005	40	Randomized to: 1. Immediate intervention (n = 20) 2. Delayed (3 month) intervention (n = 20)	Wt ∆ by group: 1. −16 kg 2. No change P < 0.0001	Reduction in weekly SUI (%): 1. 60 2. 15 P <0.0005	- Group 2 had 71% reduction in weekly UI after wt loss - Group 1 had significant improvements in IIQ and UDI scores
Brown et al (71), 2006	1957	Randomized to: 1. Lifestyle intervention (n = 660) = 660) (n = 636) 3. Placebo (n = 661)	Wt \triangle by group: 1. -3.4 ± 8.2 kg 2. -1.5 ± 7.6 kg 3. $+0.5 \pm 6.7$ kg P < 0.001	Prevalence of weekly SUI (%): 1.31.3 2.39.7 3.36.7 P = 0.006	Weekly Urge UI was lower in Group 1 (23.7% vs. 28.7 and 25.6), but not significant ($P = 0.12$)
(73), 2007	338	Randomized to: 1. 6 month wt loss program (n = 226) 2. Health information sessions (n = 112)	Wt A by group: 18 kg (8%) 22 kg (2%) P < 0.0001	Reduction in weekly U1 / SUI (%): 1.49 / 59 2.33 / 30 P = 0.01 / < 0.01	A 70% decrease in UI episode frequency was seen in 41% of Group 1 vs. 22% in Group 2 (P < 0.003)

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Table 3

Effects of surgical weight loss on UI

Study	Z	Follow-up (months)	BMI (or wt) A	Δ in prevalence of UI episodes	Other outcomes
Deitel et al (66), 1988	138	i	124 to 79 kg	61.2% to 11.6% $(P < 0.001)$	After wt loss, infertility, menstrual irregularities and obstetric complications improved
(67), 1992	13	12	BMI: 49.4 to 33.1 (131.5 to 88.1 kg)	92.3% to 23.1% (P = 0.004)	Improvements seen in: - vesical pressure - ∆ in vesical pressure with cough - urethral mobility - need for absorptive pads
Sugerman et al (75), 1998	15	12	BMI: 52 to 33 (140 to 87 kg)	46.6% to 0% (P < 0.001)	Significant changes in: - sagittal abdominal diameter (32 to 20 cm, <i>P</i> < 0.0001) - urinary bladder pressure (17 to 10 cmH ₂ O, <i>P</i> < 0.001)
Erigg et al (77), 2004	233	44	Excess wt loss at 4 year follow up was 54%	Of the 26% of all patients with preop SUI, 58% were cured at 2 years follow-up	Improvements also seen in other medical co- morbidities (HTN, DM, GERD, etc)
Burgio et al (78), 2007	101	12	48.9 to 30.2	66.7% to 37% (P < 0.001)	- FI prevalence decreased from 19.4% to 8.6% (<i>P</i> = 0.018) - Decrease in UI was significantly associated with decrease in BMI

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