GYNECOLOGY

The effect of body mass index on retropubic midurethral slings

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BACKGROUND: Analyzing surgical databases uses "real-life" outcomes rather than highly selected cases from randomized controlled trials. Retropubic midurethral slings are a highly effective surgical treatment for stress urinary incontinence; however, if modifiable patient characteristics alter outcomes, thereby rendering treatments less effective, patients should be informed and given the opportunity to change that characteristic.

OBJECTIVE: The aim of this study was to evaluate the effect of body mass index on patient-reported outcome measures by analyzing midurethral slings from the British Society of Urogynaecology database.

MATERIALS AND METHODS: The British Society of Urogynaecology approved analysis of 11,859 anonymized midurethral slings from 2007 to 2016. The primary outcome of this retrospective cohort study was to assess how body mass index affects patient-reported outcome measures. Outcomes were assessed at 6 weeks, 3 months, 6 months, or 12 months after surgery, depending on local arrangements. Outcomes were compared by body mass index groups using χ^2 tests.

RESULTS: As BMI increased, Patient Global Impression of Improvement (PGI-I) scores declined. Women with a normal body mass index (18 to <25) reported feeling better in 91.6% of cases compared to lower rates in BMI groups >30 (87.7−72%) ($P < .001$). Patient-reported outcome measures for stress urinary incontinence inversely correlated with body mass index, with 97% of women with normal body mass index stating that they were cured/improved compared to women in higher body mass index groups (84−94%) reporting lower rates ($P < .005$). Patient-reported outcome measures for overactive bladder show that as body mass index increases, patients reported higher rates of worsening symptoms ($P < .05$). There were higher rates of perforation at the low and high extremes of body mass index.

CONCLUSION: Our results suggest increased body mass index is associated with poorer outcomes after midurethral sling surgery, and that patients should be given the opportunity to change their body mass index. These data could help to develop a model to predict personalized success and complication rates, which may improve shared decision making and give an impetus to modify characteristics to improve outcomes.

Key Words: bladder perforation, BMI, midurethral sling, obesity, patient-reported outcomes, stress urinary incontinence

In the past 2 decades (1993−2014), in England, the prevalence of obesity in adults has risen from 14.9% to 25.6%, and continues to increase.[1] The association between stress urinary incontinence (SUI) and increasing body mass index (BMI) is well recognized.[2−4] Studies have shown that weight loss improves SUI and may render surgery unnecessary.[5] Obesity is a modifiable patient characteristic, so it is vital that clinicians are able to inform patients about its impact on SUI surgery, providing appropriate information and thus encouraging and empowering lifestyle change.

Midurethral slings (MUS) are a highly effective surgical treatment for SUI.[6] Surgical complications exist for all procedures; however the risk of failure to improve symptoms or to cause additional bothersome symptoms is particularly pertinent for reconstructive surgery, for which the functional outcome is of paramount importance. Recent controversy regarding the use of synthetic materials in pelvic floor surgery means that not only do patients expect to be better informed of these risks, and indeed alternative treatments, but medico-legally (in the United Kingdom), the Montgomery ruling has cemented the importance of this discussion as part of the consent process.[7] Of relevance, and often cited in litigation, is the argument that had the patients been informed of the risks, they would not have agreed to undergo surgery, and it has been shown that if patients receive detailed counseling, they are likely to opt for less invasive treatments.[8]

A BMI of >40 or >35 in combination with comorbidities such as cardiac, respiratory, or metabolic diseases is associated with increased surgical morbidity such as infection, thromboembolism, bleeding, organ damage, surgical difficulty, or even the requirement to abandon surgery. Anesthetic difficulties include cannulation, airway and ventilation, analgesia, nausea and vomiting, and moving patients.[9] Indeed some surgical centers have developed guidelines, which restrict surgical intervention for non−life-threatening conditions in patients with morbid obesity.[10] This may be driven in part by commissioners rejecting referrals[11] for surgery in patients with high BMI. If surgery is to be offered to these high-risk groups, the additional risks must be highlighted.

The British Society of Urogynaecology (BSUG) database is a secure database available to BSUG members through an NHS (N3 compliant) computer and is increasingly popular with urogynecologists. Preoperative patient characteristics are collected including age, BMI, and urodynamic diagnosis. The operation is recorded including intraoperative complications. Follow-up is then entered at a later date, which includes any postoperative complications and the

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AJOG at a Glance

Why was this study conducted?

The study was conducted because we wanted to establish the effect of body mass index on patient-reported outcomes of midurethral slings and because the use of slings in the severely obese population has not been studied on a large scale.

Key findings

Patients who are severely obese have poorer overall outcomes following midurethral slings. They are also more likely to develop symptoms of overactive bladder, which may explain the poorer global impression of improvement.

What does this add to what is known?

Other studies were limited by the numbers of patients in the severely obese categories and so are not relevant to the Western populations of today.

patient-reported outcome. Use of the database is recommended by several bodies, including National Institute for Health and Care Excellence and National Health Service England[12–14] and is a tool to measure "real-life" success rates and complication rates rather than using highly selected cases from randomized controlled trials and meta-analyses. Analysis of the data entered may assist not only with patient counseling and individual risk assessments but also with resource use, procurement, and best practice evaluation. Information can also be used at a personal level in appraisals or at a national level to identify benchmarks for appropriate practice.

The aim of this study was to use the BSUG database to examine the impact of BMI on patient-reported outcome measures (PROMs) and complication rates following an MUS.

Materials and Methods

Ethical approval for this study was not required, because individual centers using the database are required to be compliant with UK Caldicott Guardian (data protection) regulations. Patients give consent to their anonymized data being used for analysis.

TABLE 1
Participant characteristics, by BMI group

BMI	18 to <25	25 to <30	30 to <35	35 to <40	40 to <45	45 to <50
Age at operation, y (n = 11,572)						
18 to <50	1648 57%	2075 48%	1306 47%	589 50%	159 48%	41 45%
50 to <75	1137 39%	2045 47%	1345 49%	553 47%	163 49%	49 53%
75 to 100	103 4%	191 4%	119 4%	39 3%	8 2%	2 2%
Total	2888	4311	2770	1181	330	92
Preoperative urodynamic diagnosis (n =10,959)						
USI	2245 82.1%	3263 80.1%	2021 76.8%	825 73.8%	230 73.0%	62 72.1%
USI and voiding dysfunction	63 2.3%	106 2.6%	69 2.6%	30 2.7%	6 1.9%	4 4.7%
Mixed	292 10.7%	547 13.4%	438 16.6%	235 21.0%	70 22.2%	18 20.9%
Mixed and voiding dysfunction	10 0.4%	14 0.3%	19 0.7%	5 0.4%	4 1.3%	0 0.0%
DOA	11 0.4%	22 0.5%	13 0.5%	7 0.6%	1 0.3%	1 1.2%
Normal	111 4.1%	118 2.9%	70 2.7%	16 1.4%	4 1.3%	1 1.2%
Voiding dysfunction	2 0.1%	3 0.1%	3 0.1%	0 0.0%	0 0.0%	0 0.0%
Total	2734	4073	2633	1118	315	86
Grade of operator (n = 11,725)						

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TABLE 1
Participant characteristics, by BMI group *(continued)*

BMI	18 to <25	25 to <30	30 to <35	35 to <40	40 to <45	45 to <50
Consultant	2298 78.8%	3376 77.3%	2135 75.9%	915 76.3%	273 81.7%	77 83.7%
Associate Specialist	5 0.2%	21 0.5%	18 0.6%	9 0.8%	1 0.3%	0 0.0%
Subspecialty Trainee (SST)	187 6.4%	299 6.8%	192 6.8%	86 7.2%	16 4.8%	3 3.3%
Staff grade	37 1.3%	48 1.1%	43 1.5%	13 1.1%	6 1.8%	1 1.1%
Speciality Trainee (ST)	357 12.2%	564 12.9%	399 14.2%	160 13.3%	36 10.8%	10 10.9%
FTSTA	1 0.0%	1 0.0%	1 0.0%	0 0.0%	1 0.3%	0 0.0%
Other	33 1.1%	58 1.3%	26 0.9%	17 1.4%	1 0.3%	1 1.1%
Total	2918	4367	2814	1200	334	92

BMI, body mass index; *DOA,* detrusor overactivity; *FTSTA,* fixed-term specialty training appointment; *SST,* subspecialty trainee; *ST,* specialty trainee; *USI,* urodynamic stress incontinence.
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Authorization was requested from BSUG to analyze data for patients who underwent the procedures with Mid-urethral Sling-Tension Free Vaginal Tape (MUS-TVT) (Ethicon Gynaecare, Somerville, NJ) or Advantage and Advantage Fit (Boston Scientific, Boston, MA) from January 1, 2007, until January 27, 2016. The application was approved in a 2-stage process initially by the BSUG Research Committee and was subsequently ratified by the BSUG Database Committee. Individual patients, doctors, and surgical centers cannot be identified due to anonymization of all data at source prior to release to the requesting team.

The primary outcome measure was to assess the effect of BMI on Patient Global Impression of Improvement (PGI-I) for incontinence. Secondary measures were SUI symptoms, OAB symptoms, bladder perforation, and short-term complications.

Follow-up of patients varied between 6 weeks and 12 months, depending on individual unit practice. A variety of methods are used to gather the specific patient-reported outcome measures, including outpatient clinics, postal questionnaires, telephone appointment, online questionnaires, with general practitioners or other individual preference according to custom at the place of surgery.

Overall outcome was measured in a standardized fashion using the patient-reported measure of PGI-I as a validated tool.[15] This is a 7-point scale of "Very Much Better, Much Better, A Little Better, No Change, A Little Worse, Much Worse, or Very Much Worse," and patients are asked to give their assessment of overall impression. For analysis, success was defined as "Very Much Better + Much Better.". Assessment of change in SUI and overactive bladder (OAB) were recorded at follow-up, and patients were questioned as to whether the symptoms

TABLE 2
Timing of postoperative assessment by body mass index (BMI) groups after midurethral sling surgery (n = 7778)

BMI	6 wk	3 mo	6 mo	12 mo
18 to <25	27%	37%	33%	4%
25 to <30	24%	39%	33%	4%
30 to <35	23%	39%	34%	4%
35 to <40	24%	36%	37%	3%
40 to <45	27%	30%	40%	4%
45 to <50	22%	21%	48%	9%

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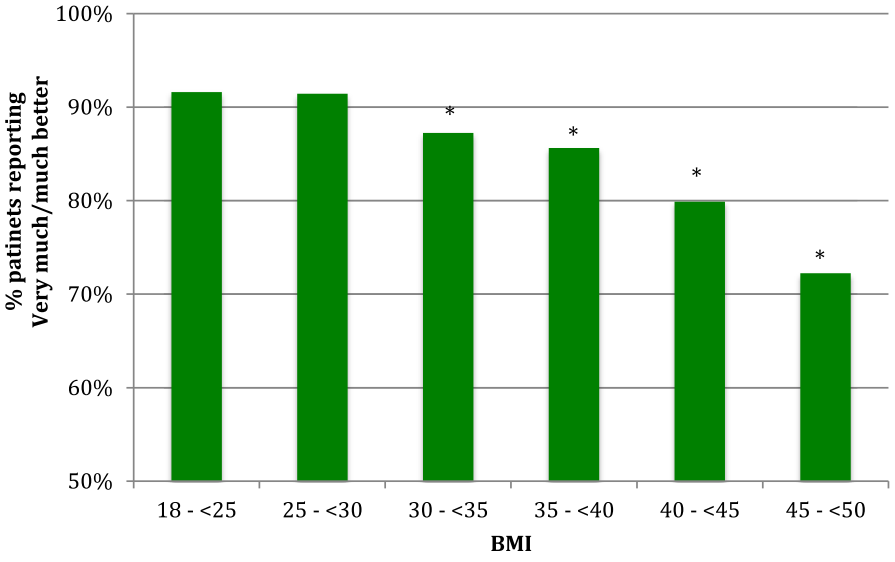
FIGURE 1
Body mass index (BMI) and Patient Global Impression of Improvement (PGI-I) for incontinence (n = 7429). Percentage of patients reporting very much or much better outcomes, by BMI group. *$P < .05$ compared to normal BMI group (18 to <25)



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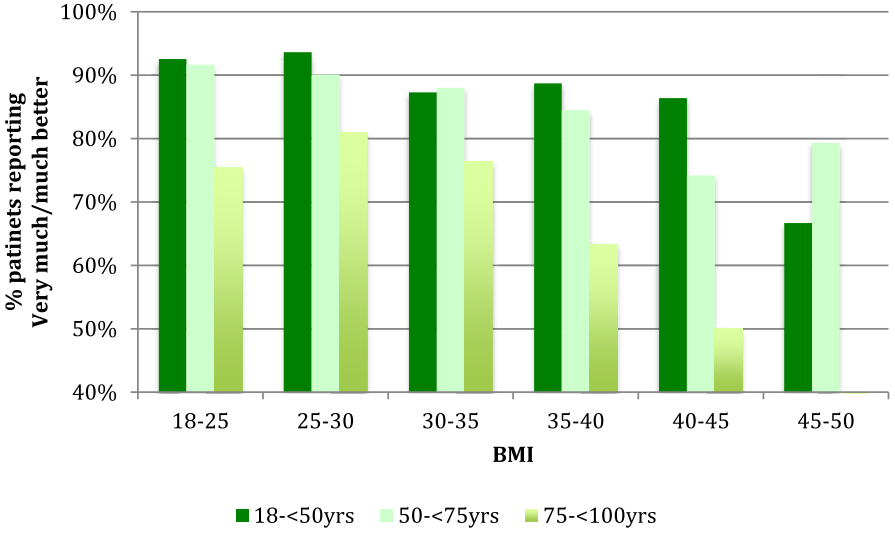
were "Cured, Improved, No change, Worse, New Symptom or Never Present."[16,17] Outcomes were compared by BMI groups overall and stratified by important clinical factors using χ^2 tests. Excel (Microsoft Corp., Redmond, WA) and STATA (StataCorp, College Station, TX) software were used. *P* values <.05 were considered statistically significant.

FIGURE 2
Body mass index (BMI) and Patient Global Impression of Improvement (PGI-I) for incontinence, by age (n = 7267). Percentage of patients reporting very much or much better outcomes by BMI group, split by age



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Results

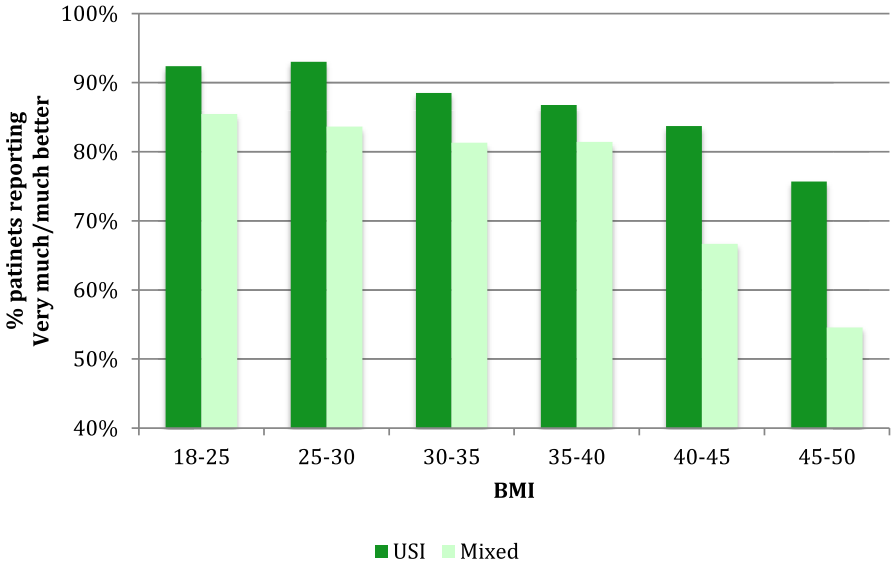
A total of 18,763 primary MUS procedures (of the aforementioned devices) were entered onto the database from 124 centers. The number of MUS entered per center ranged from 1 to 1721, with a median of 39. A total of 11,859 patients had BMI recorded, with the remaining 6904 either without a BMI entered or an invalid entry. BMI groups contained the following numbers of patients: BMI 15 to <18 had 13 patients (0.11%), 18 to <25 had 2943 (24.82%), 25 to <30 has 4401 (37.11%), 30 to <35 had 2838 (23.93%), 35 to <40 had 1209 (10.20%), 40 to <45 had 338 (2.85%), 45 to <50 had 92 (0.78%), and 50 to <65 had 24 (0.20%). Of the 11,859 cases with BMI data, 7436 had PGI-I data, 7398 cases reported PROM, and 11,816 recorded the presence or absence of bladder perforation.

The population data (Table 1) show that, in this group, patients with a lower BMI tended to be younger; that as BMI increased, the percentage of patients with mixed results on urodynamic studies (UDS) increased; and that patients with a higher BMI were more likely to be operated on by a consultant. Follow-up intervals are shown in Table 2.

Global Impression of Improvement

A decline in PGI-I is seen with rising BMI, with a significantly greater success rate in the group of patients with a normal BMI (18 to <25) compared to the groups of patients with BMI >30 ($P < .001$) (Figure 1, n = 7429). As previously mentioned, when studying the patient characteristics, patients with a BMI of 18−25 tend to be younger, so the population was divided into age groups; and the difference with BMI still remained (Figure 2, n = 7267). Also, because there is potentially a difference with UDS because of patients with a higher BMI being more likely to have a diagnosis of mixed urinary incontinence, the data were split to look at urodynamic stress incontinence (USI) and mixed difference in outcomes of

FIGURE 3
Body mass index (BMI) and Patient Global Impression of Improvement (PGI-I) for incontinence, by urodynamic studies (UDS) (n = 6530). Percentage of patients reporting very much/much better outcomes by BMI group split by urodynamic diagnosis



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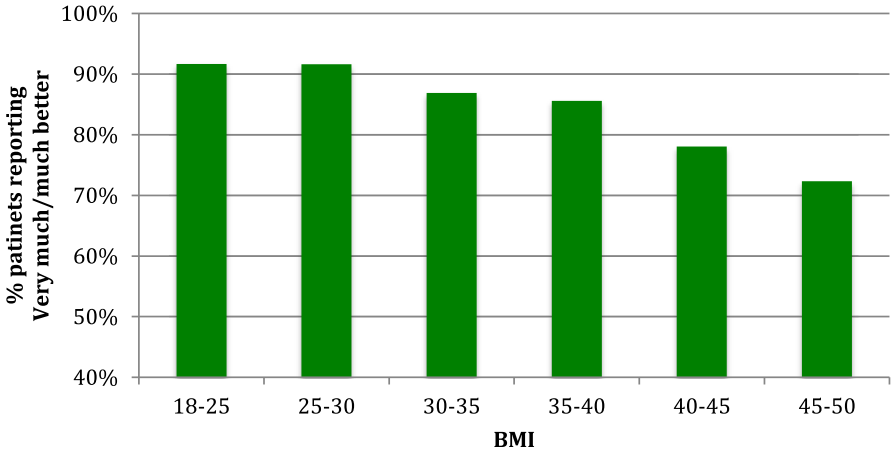
different BMIs. The differences still remained (Figure 3, n = 6530). Because of the relative lack of trainees operating on patients with higher BMI, the data were analyzed again only for consultants performing the operations. The difference still remained (Figure 4, n = 5793).

Change in SUI Symptoms

The percentage of patients reporting cure or improvement of SUI symptoms correlated inversely with rising BMI. A significantly lower proportion of women in the BMI groups >35 stated that they were cured or improved compared to patients with a normal BMI (35−40, $P = .004$; 40−45, $P = .005$; and 45−50, $P < .001$) (Figure 5, n = 7176).

FIGURE 4
Body mass index (BMI) and Patient Global Impression of Improvement PGI-I for incontinence, for procedures performed by consultants (n = 5793). Percentage of patients reporting very much/much better, by BMI, for procedures performed only by consultants



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Change in OAB Symptoms

Our analysis agrees that OAB symptoms are more common in women with increasing BMI[18] (Table 1) and the falling percentage of patients reporting "OAB symptoms never present" with increasing BMI in our series (Figure 6, n = 7123).

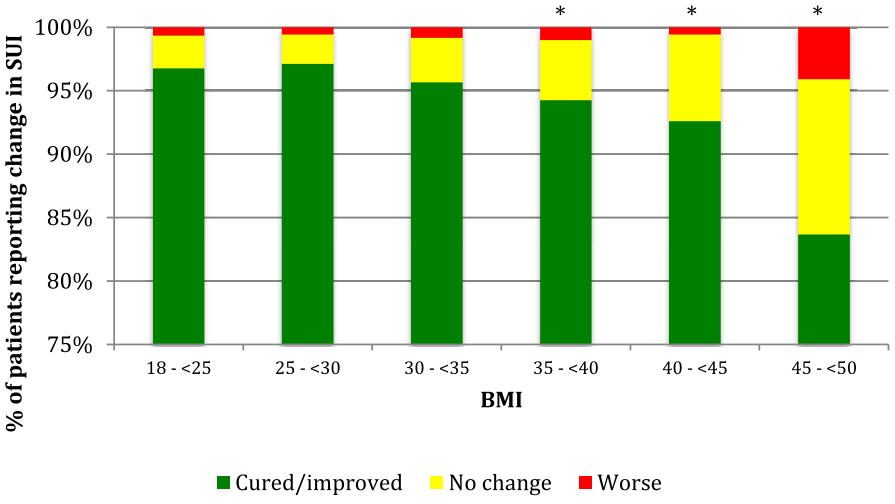
PROMs for change in OAB symptoms showed that, as BMI increased, a higher proportion of patients reported worsening symptoms (Figure 7, n = 4187). For the group with BMI of 18−25, 8.45% become worse vs 65.8% being cured or improved, compared to the group with BMI of 45−50, of whom 21.9% became worse vs 53.7% being cured or improved. Thus, although overall patients are likely to see an improvement in OAB symptoms following an MUS, the ratio of improvement to worsening is poorer with higher BMI. To state it another way, with a BMI of 18−25, a patient's OAB symptoms are nearly 8 (7.8) times more likely to be cured or improved than to deteriorate, whereas with a BMI of 45−50 a patient's symptoms are only 2.5 times more likely to be cured or to improve compared to worsening.

When only patients with no preoperative OAB symptoms were studied, the rate of patient-reported "new OAB" cases increased with increasing BMI (Figure 8, n = 2936). There were no new cases of OAB in the group with BMI 45−50, which does not fit with the pattern; however, this may be because there were only 10 cases for analysis in this group, as the majority of patients (n = 41) had pre-existing symptoms that excluded them from this subanalysis.

Perforation

There were higher rates of perforation at the low and high extremes of BMI. There were significantly fewer perforations

FIGURE 5
Body mass index (BMI) and change in stress urinary incontinence (SUI) symptoms (n = 7176). Percentage of patients reporting different outcomes of SUI symptoms by BMI group. *$P < .05$ compared to normal group with normal BMI (18 to <25)



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with the groups with BMI 25 to <30 ($P = .032$), 30 to <35 ($P < .001$), and 35 to <40 ($P < .001$) compared to 18 to <25, although it is noteworthy that this difference was not observed in the groups with BMI of 40–45 ($P = .057$) or 45–50 ($P = .54$) (Figure 9, n = 11,816). This difference is borne out when consultants and trainees were separated, although the effect with trainees was much greater (Table 3).

Comment

Although the overall percentage of patients who report on PGI-I that they are "better" following an MUS is high (95.8%),[19] women with a greater BMI are less likely to report a PGI-I of "very much better/much better" and cure/improvement of SUI symptoms. In addition, not only does a higher BMI suggest a higher preoperative rate of OAB and mixed UDS, there is a greater chance that OAB symptoms will develop or worsen postoperatively. These outcomes may all be interrelated with the presence or worsening of OAB symptoms, leading to poorer results with respect to PGI-I and SUI PROM. Ultimately, there is a complex construct of different symptom combinations, which will vary from patient to patient.

A recent paper using data from the DUGAbase[20] found that there was no difference in subjective outcome between the different BMI group; however, the highest BMI category in that study was ">35," whereas the data in this study were divided into 35–40, 40–45, and 45–50, meaning that differences can be identified in the much-higher BMI groups. Interestingly, researchers in the other study did find that there was a nonsignificant higher risk of reoperation in patients with a BMI of >35. Other studies also have similar limitations and therefore did not examine the higher BMI categories.[21–23] This means that our study findings may be more relevant to the current Western, including American, populations in view of rising BMI in these populations.[24]

The bladder perforation rate graph is interesting and may be explained on the basis that as the BMI increases, there is an optimal amount of protective fat around the bladder, thereby reducing the rate of injury. Once the BMI becomes very high, however, the anatomical landmarks become distorted, and it may become more difficult to negotiate a fixed curved needle behind the symphysis pubis. The comparative data for perforation at different BMI groups between consultants and trainees is very interesting, with a dampening of the effect of BMI on perforation with experience. Again, a previous paper did not find this to be the case; however the highest group in this paper was patients with a BMI of 30.[21]

FIGURE 6
Overactive bladder (OAB) symptoms "never present," by body mass index (BMI) (n = 7123). Percentage of patients reporting that they had never had OAB symptoms, by BMI

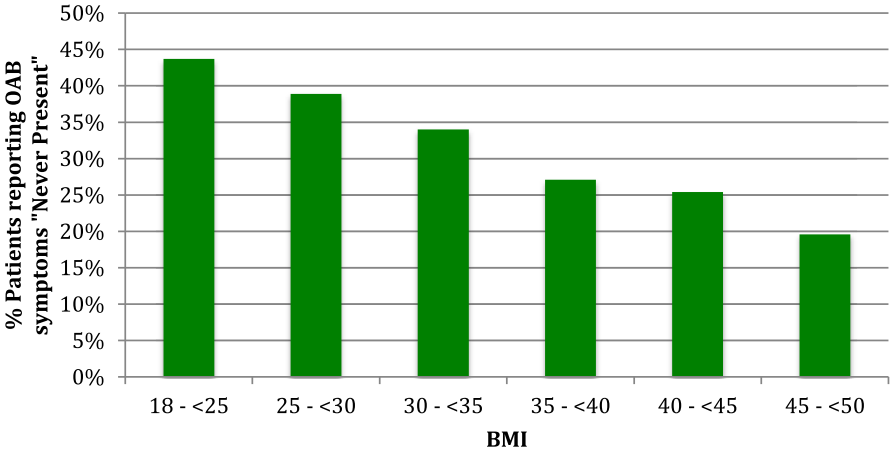

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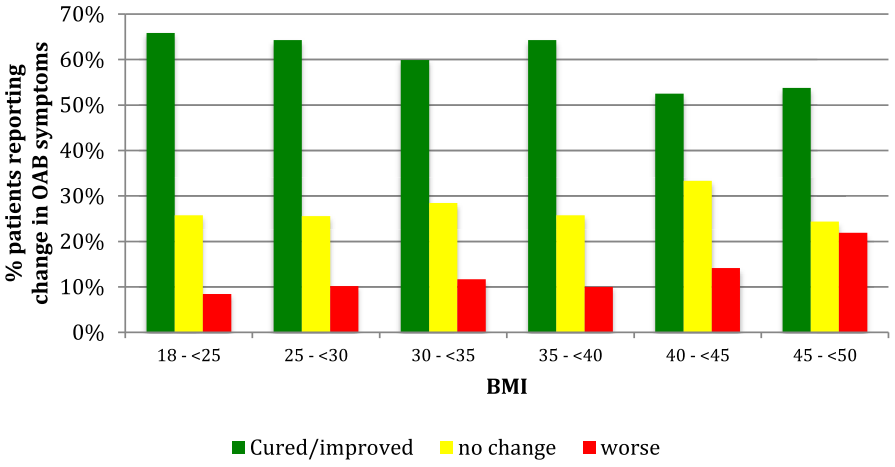
FIGURE 7
Body mass index (BMI) and change in preoperative overactive bladder (OAB) symptoms (n = 4187). Percentage of patients experiencing change in their OAB symptoms, by BMI



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Study Strengths

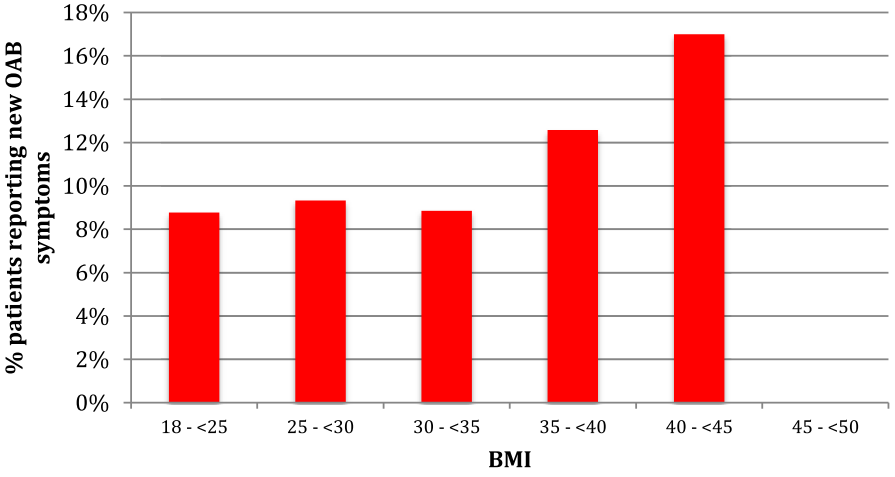
The major strength of this established database and this study is the large number of "real-life" outcomes from a wide range of different centers and surgeons, rather than the more restrictive patient groups included in randomized controlled trials. The comparison to the other papers highlights the huge benefit of a population-based database, as the numbers are so large that the "smaller" groups of patients still contain large amounts of patients.

Study Limitations

The BSUG database contains a variety of timescales and methods of follow-up based on individual preference, and to mandate a change to this would be inappropriate.

Missing data comprise an important limitation. Use of the database is mandatory only for those centers who are accredited by BSUG, but many other, nonaccredited centers do use it. There may be individual data, patients, or whole units that are not included, either because clinicians or patients do not want to be involved, are too busy, or are not inclined to report complications.[25] Missing data are common in large registries, and analyses of PGI-I and PROM data were performed in ~40% of the patient cases in the registry.

FIGURE 8
Body mass index (BMI) and new overactive bladder (OAB) symptoms (n = 2936). Percentage of patients experiencing new OAB symptoms, by BMI



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Future Work

With the current uncertainty about the future of the MUS, it will be interesting to run this analysis on the alternatives, as it is likely that the complications will be far greater in the obese population and that, if the MUS is unavailable, the viable management options for USI in the obese population will therefore be dramatically reduced.

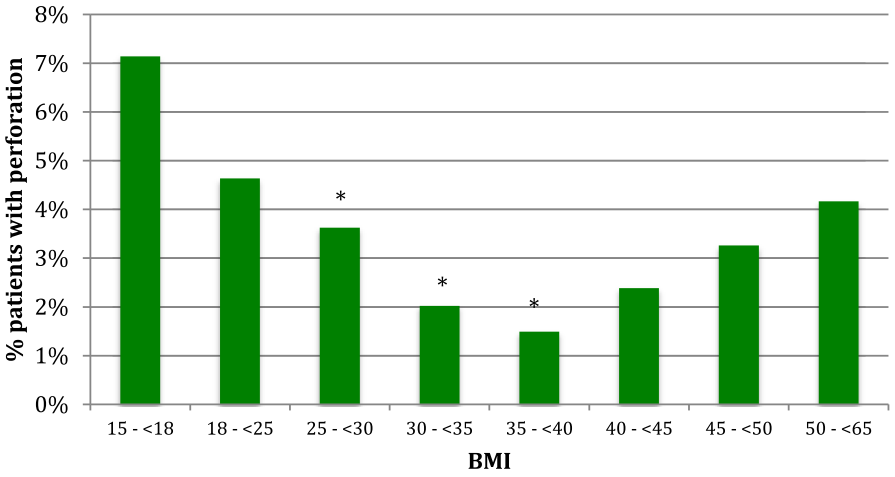
Identification of modifiable characteristics that have an impact on the likelihood of success and the risk of complications from MUS and all surgeries for USI[26] could be combined to create a computerized algorithm to allow patients to make an informed choice as to whether or not to proceed with surgery, or to defer intervention while undertaking lifestyle changes. The database can also be developed to be used for benchmarking for individual clinicians or centers.

Final Comments

This study highlights the value of recording demographics, procedural data, and patient outcomes on a national database and how this could be used to aid decision making in the future. Subsequent analysis—in this case, the effect of BMI—can inform a broad range of health care professionals in respect to the extent of risk of an intervention, which can then be translated into meaningful, individualized assessment. Incorporation of such data into the shared decision-making process is likely to result in greater patient satisfaction, through improved understanding and awareness of risk.

FIGURE 9

Body mass index (BMI) and perforation rate (n = 11,816). Percentage of patients who experienced a bladder perforation, by BMI. *$P < .05$ compared to group with normal BMI (18 to <25)



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The information in this analysis should not preclude patients with high BMI from receiving interventions; however, we would reinforce that individualized patient counseling is of vital importance prior to an MUS, and that overweight patients should be made aware of the possibility of a lower success rate. They should also be advised that rates of pre-existing SUI and OAB are higher in patients with higher BMI.[18,27] BMI is modifiable and, if reduced, surgery may be rendered unnecessary; if it is still required, then logically the outcome should be more successful. However, patients must be informed of the individual risks, and, in the context of informed consent, these lifestyle alternatives should also be personalized to comply with the Montgomery ruling.[28]

TABLE 3

Percentage of bladder perforation by surgeon type (consultants, n = 9049; trainees, n = 2301)

BMI	Consultant	Trainee
18 to <25	3.3%	10.1%
25 to <30	2.0%	9.9%
30 to <35	1.5%	4.1%
35 to <40	1.2%	1.6%
40 to <45	2.2%	0.0% (n=0)
45 to <50	1.3%	15.4%

BMI, body mass index.

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