

Full Length Research Paper

# Comparative outcome of medical and surgical Management of urodynamically-proven mixed urinary incontinence

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This double armed clinical trial aimed to compare the outcome of medical versus surgical management of patients with urodynamically-proven mixed incontinence and to identify risk factors for success of each. 138 patients with mixed urinary incontinence (MUI) were studied. 78 patients with urge predominant were allocated medical treatment, 60 patients were classified as stress predominant and allocated surgical treatment. The primary outcome (Patient Global Impression Index of Improvement (PGI-I)) was analyzed in 129 (93.4%) patients. 63.3% of patients in the surgical group showed improvement of their stress component with 43.3% showing improvement in both stress and urgency components. 51.2% of patients in the medical group showed improvement in their urgency component with 33.3% showing improvement in both stress and urgency components. Maximal detrusor pressure and maximal urethral closure pressure were the only independent predictors of failure of medical treatment while the Valsalva leak point pressure was the only independent predictor of failure of surgical treatment. A prediction regression model can predict the outcome of the medical or surgical route.

**Keywords:** Incontinence surgery, Mixed urinary incontinence (MUI), Medical management of MUI, Predictors of failure, Prediction regression model, Urodynamic studies.

## INTRODUCTION

Urinary incontinence is a widespread and high burden condition affecting 15–50% of women of all ages, compromising the quality of their lives (QOL) (Nygaard et al., 2008). Mixed Urinary Incontinence (MUI) is defined as the “complaint of involuntary loss of urine associated with urgency and also with effort or physical exertion or on sneezing or coughing” (Haylen et al., 2010). The incidence of MUI is highly variable and estimated to be between 29% and 61% of incontinent women (Brubaker

et al., 2009). The subset of patients in this group reporting severe incontinence is significantly higher, QOL is worse with higher risk of depression than those reporting severe incontinence in the stress or urgency groups (Minassian et al., 2008; Frick et al., 2009; Papanicolaou et al., 2005; Melville et al., 2005).

However, optimal treatment for those women is not known. A working subcommittee from the International Urogynecological Association (IUGA) Research and Development (R&D) Committee concluded that the treatment of MUI requires “an individualized approach based on the patient’s symptom components and their effect on her QOL, examination, and findings on urody-

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dynamic investigation when performed” (Kammerer-Doak et al., 2014).

Stress incontinence procedures might be considered for patients with mixed incontinence with a significant stress incontinence component (Jain et al., 2011). Proponents of the initial surgical approach suggest that patients with MUI should be treated with surgery first and then if urgency symptoms persist, treatment with medical therapy should follow. Other studies indicate that urgency incontinence is a major cause of post-surgical dissatisfaction in patients following stress incontinence surgery or prolapse repairs (Mahajan et al., 2006; Elkady et al., 2003). The authors of the MIMOSA trial suggested that in some cases, the severity of the urgency symptoms could be debilitating enough to warrant a revision or reversal of the continence procedure (Brubaker et al., 2009). On the same approach, in cases of urgency predominant MUI the American Urological Association (AUA) overactive bladder (OAB) guideline states that the urgency component should be initially treated with medication with or without the addition of pelvic floor therapy and behavioral modification. If the stress component persists, it should then be managed surgically (Dmochowski et al., 2010).

Most of the previous studies addressing MUI concentrated on patients with mixed symptoms of stress and urgency. It is clear that many patients with mixed symptoms do not exhibit both conditions of detrusor overactivity (DO) and urodynamic stress incontinence (USUI) when undergoing diagnostic testing. In fact, Lee et al. (2011) identified that coexistent detrusor over-activity is a risk factor for persistent urgency after surgery in women with MUI. Methodologically sound trials are needed specifically for that specific group of women with urodynamically-proven mixed incontinence.

This study attempts to fill a gap in the current literature and compare medical versus surgical management of patients with urodynamically-proven mixed incontinence and also, attempts to identify risk factors for success or failure of each route in this specific category of patients to support informed counselling.

## METHODS

The current study is a non-randomized clinical trial conducted at the Specialized Urogynecological unit in Ain Shams University Maternity Hospital. The study was conducted during the period from January 2014 to December 2014. (Figure 1).

All patients presenting with the complaint of mixed incontinence symptoms were evaluated by detailed history and examination to evaluate their condition. Women were excluded from the study if they had neurological symptoms, previous incontinence surgery, pelvic organ prolapse quantification (POP-Q) system

stage 2 or greater on examination, known contraindication to anticholinergic therapy or had incontinence attributed to pelvic fistulas or malignancy.

All women gave written consent for urogynecological assessment and for inclusion in the study. The study was approved by the local hospital ethics committee.

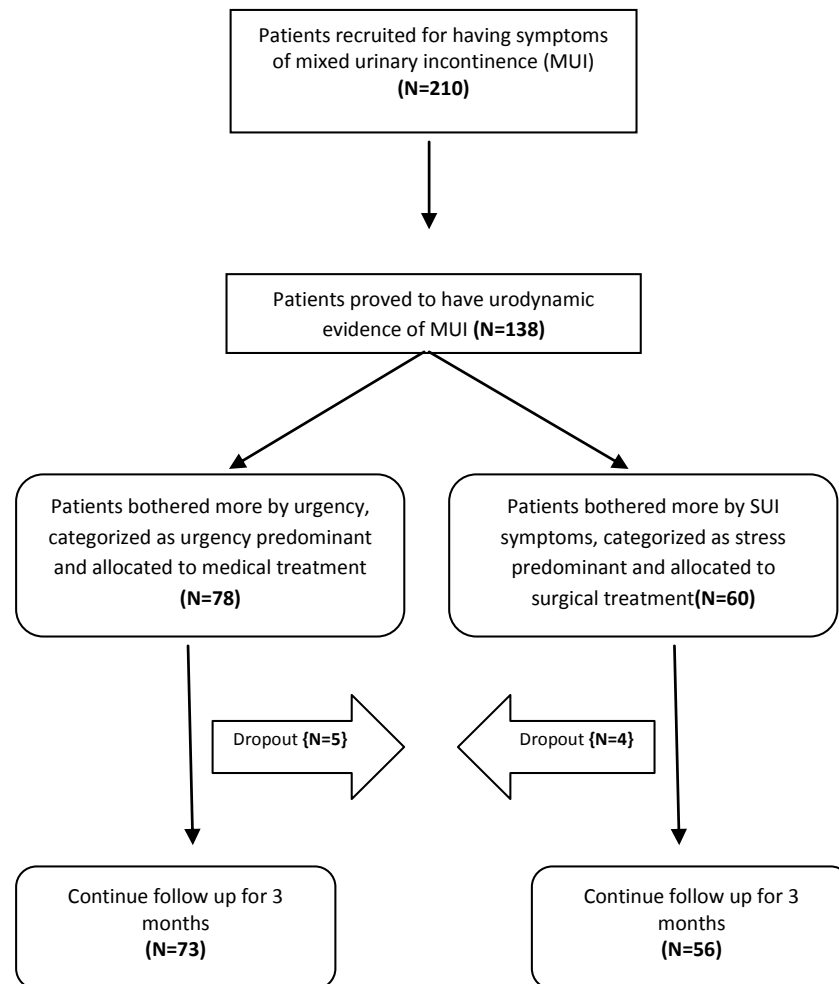
All patients were evaluated by urodynamic studies according to the standard principles described in International Continence Society (ICS) Good Urodynamic Practices and Terminology of Lower Urinary Tract Function publications (Sandvik et al., 1995). Standardized urodynamic studies (UDS) were completed using a Medi-watch (UK Ltd production) machine and a triple-lumen catheter. Patients were enrolled in the study if their UDS data collection included the presence of both idiopathic detrusor over activity with loss of urine in the absence of increased intra abdominal pressure, in association with urine loss seen with increased intra-abdominal pressure, but without increased detrusor pressure (urodynamic stress incontinence (USI)) in the same woman according to the definition described by the IUGA committee (Haylen et al., 2010).

## Sample Size Calculation

The required sample size was estimated using Power Analysis and Sample Size software version 08.0.9 (PASS; NCSS, LLC, Kaysville, Utah). From local institutional data, the failure rate associated with surgical or medical treatment was expected to be approximately 40% or 45%, respectively. So, it was estimated that a sample of 60 patients treated surgically would yield approximately 24 (40%) patients with failed treatment. This sample size would achieve a power of 80% to detect a difference of 0.25 between a c-statistic of 0.5 under the null hypothesis and a c-statistic of 0.75 under the alternative hypothesis. On the other hand, it was estimated that a sample of 75 patients treated medically would yield approximately 34 (45%) patients with failed treatment. This sample size would achieve a power of 91% to detect statistical significance for the same effect size. These calculations used a two-sided z-test at a significance level of 0.01.

Women were asked, preoperatively, to decide what their predominant bothering symptom according to the incontinence component they wished to improve most after treatment. Participants and clinicians were not blinded to the treatment assignment.

All participants were offered pelvic floor muscle physiotherapy and strategies to suppress urgency and stress incontinence (Dumoulin et al., 2010). According to the recent European Association Urology (EAU) guidelines in 2013, women with a predominant symptom of urgency incontinence were offered treatment with bladder training and an FDA approved anticholinergic



**N:** Number

**Figure (1).** Flow chart of the patients included in the study

drug. Participants were invited to adjust their medication dose at 1-month follow-up visit. Medication adherence was assessed through pill counts at that visit. On the other hand, patients with predominant stress components were offered surgical treatment in the form of Transobturator tape (TOT). All women had a TOT operation (outside In) (Dynamesh Germany) performed under regional anesthesia by one of the urogynecologists in the unit. They were all assessed for residual urine postoperatively. If this exceeded 100 ml in more than one occasion, intermittent catheterization was started. It was agreed to assess participant-reported outcomes at 3 months, when peak improvements from both treatment approaches would be evident, as agreed before in the MIMOSA trial (Lee et al., 2011).

### Outcome Measurements

The primary outcome measure used was the Patient Global Impression Index of Improvement (PGI-I). The PGI-I is a global, patient-oriented outcome measure that assesses components of both Stress Urinary Incontinence (SUI) and Urgency Urinary Incontinence (UII). The PGI-I asks subjects to best describe how one's urinary tract condition (bladder) at follow up, compared to how it was before treatment for urinary leakage, with 7 options to choose. The patient-reported success rate was defined by very much better/much better on PGI-I, with all other responses classified as failures.

Secondary outcomes included objective Cure of SUI de-

**Table 1.** Characteristics of urgency predominant and stress predominant patients.

Variable	Urgency Predominant (n=78)	Stress Predominant (n=60)	P value
Age (years)	48 (37-52)	48 (45-56)	0.259*
Parity			0.103**
P1	11 (14.1%)	2 (3.3%)	
P2	17 (21.8%)	12 (20.0%)	
P3	21 (26.9%)	21 (35.0%)	
P4 or higher	29 (37.2%)	25 (41.7%)	
Maximal detrusor pressure (cmH2O)	12 (9 to 17)	11 (7.5-16)	0.346*
Valsalva leak point pressure (cmH2O)	114.5 (100-144)	116 (79.5-129)	0.249*
Urethral stress closure pressure(cmH2O)	-20.5 (-46 to -2)	-26.5 (-63.5 to 1)	0.580*
Maximal flow rate (ml/s)	31 (22.6-46.7)	29 (19-38.5)	0.114*

Data are presented as median (interquartile range) or number (%).

\* Mann-Whitney test.

\*\* Chi-squared test for trend.

defined as a negative cough stress test in the second postoperative visit or the last recorded follow-up visit. Postoperatively, urgency and UUI was defined as a cure based on improvement in the 3-day bladder diary.

Persistent or de novo urgency was identified in patients who needed to continue or initiate anticholinergic medications after surgery, as well as those reporting symptoms of urgency/frequency or UUI in their postoperative bladder diaries.

Adverse events of medical treatment involving dry mouth, constipation, drowsiness, tachycardia, urinary hesitancy or retention were classified as “potentially associated with anticholinergic therapy”. Adverse events of surgery included those related directly to surgery or anesthesia.

Data was analyzed using MedCalc© version 14 (MedCalc© Software BVBA, Ostend, Belgium). Owing to the marked skewness of their distribution, numerical variables were presented as median (interquartile range), and intergroup differences were compared non-parametrically using the Mann-Whitney test. Categorical variables were presented as number (%), and the chi-squared test for the trend was used for comparison of ordinal data. Multivariable binary logistic regression analysis was used to identify predictors of failure of treatment in medically treated or surgically treated patients. A two-sided p-value < 0.05 was considered statistically significant.

## RESULTS

The baseline clinical data of both groups is shown in Table-1. The primary outcome was analyzed in 129 (93.4%) patients. 4 patients in the surgical group and 5 patients in the medical group were lost from follow up and were considered as failures. (Figure 2)

Table-2 and Table-3 show the results of multivariable binary logistic regression analysis for predictors of failure of treatment in medically treated or surgically treated patients.

Maximal detrusor pressure and maximal urethral closure pressure were the only independent predictors of failure of medical treatment while the Valsalva leak point pressure (VLPP) was the only independent predictor of failure of surgical treatment.

Candidate predictors were forced into the regression model using the simultaneous (enter) method. A prediction rule was developed based on the estimates of the regression model.

For cases of urgency predominant managed by medical treatment, the model (Table 2) had a correct classification rate of 69.2% with an area under the operating characteristic ROC curve (AUC) curve of 0.775 (95% CI, 0.666 to 0.862; p-value <0.0001). The best cut-off value was a predicted probability of >0.656. This had a sensitivity of 47.4% (95% CI, 31.0% to 64.2%), a specificity of 95.0% (95% CI, 83.1% to 99.4%), a positive

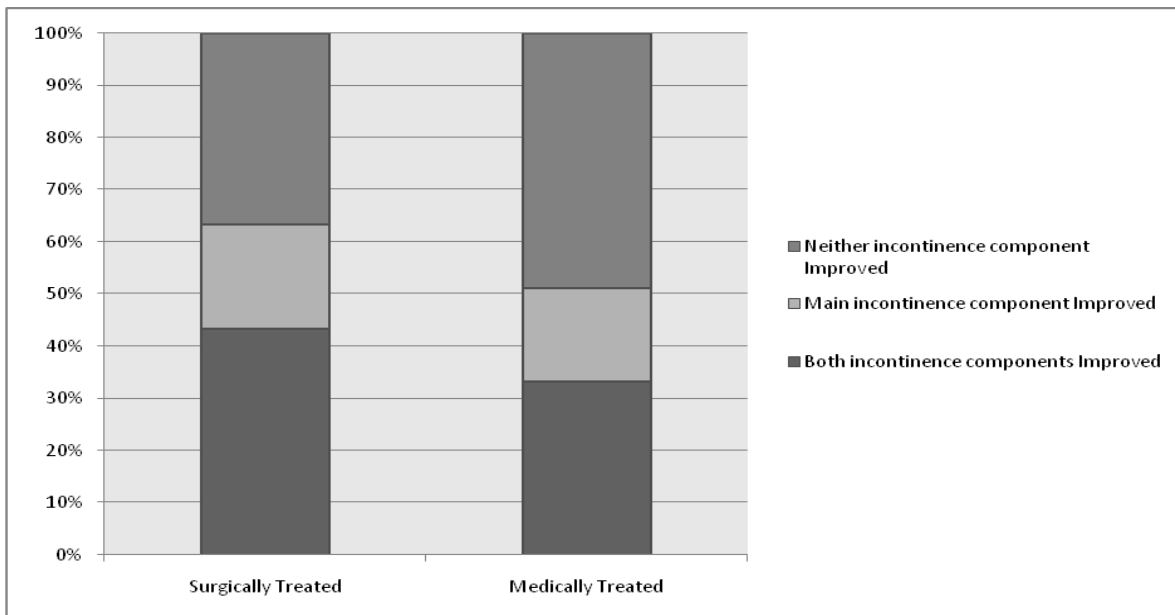


Figure 2. Outcome of treatment in medically treated or surgically treated patients.

Table 2. Multivariable binary logistic regression analysis for predictors of failure of treatment in medically treated patients.

Variable	B	SE for B	p-value	OR (95% CI)
Age (years)	-0.03	0.03	0.355	0.97 (0.91-1.04)
Parity				
P2 (=1)†	0.64	0.95	0.499	1.90 (0.30-12.18)
P3 (=1)†	0.76	0.95	0.427	2.13 (0.33-13.83)
P4 or higher (=1)†	1.61	0.97	0.095	5.02 (0.75-33.42)
<b>Maximal detrusor pressure (cmH2O)</b>	<b>0.09</b>	<b>0.04</b>	<b>0.018</b>	<b>1.09 (1.01-1.17)</b>
Valsalva leak point pressure (cmH2O)	0.01	0.01	0.125	1.01 (0.997-1.02)
<b>Maximal Urethral stress closure pressure (cmH2O)</b>	<b>-0.03</b>	<b>0.01</b>	<b>0.006</b>	<b>0.97 (0.95-0.99)</b>
Maximal flow rate (ml/s)	-0.02	0.02	0.464	0.98 (0.94-1.03)
Constant	-2.17			

B: Regression coefficient; SE: Standard error; OR: Odds ratio; 95% CI: 95% confidence interval.

† Referenced to P1 (=0).

Predicted probability (p) =  $1/(1+e^{-z})$ , where e is the base of natural logarithm and z is logit(p).

$z = b_0 + b_1 * \text{age in years} + b_2 * \text{parity} + b_3 * \text{maximal detrusor pressure in cmH2O} + b_4 * \text{Valsalva leak point pressure in cmH2O} + b_5 * \text{maximal flow rate in ml/s}$ , where  $b_0$  = value of the constant in the regression, and  $b_1$  to  $b_5$  are the regression coefficients for the corresponding variables.

**Table 3.** Multivariable binary logistic regression analysis for predictors of failure of treatment in surgically treated patients.

Variable	B	SE for B	p-value	OR (95% CI)
Age (years)	0.004	0.04	0.909	1.00 (0.94-1.08)
Parity				
P2 (=1)†	-0.25	1.65	0.878	0.78 (0.03-19.64)
P3 (=1)†	0.19	1.61	0.905	1.21 (0.05-28.44)
P4 or higher (=1)†	0.68	1.64	0.681	1.96 (0.09-49.07)
Maximal detrusor pressure (cmH2O)	-0.03	0.05	0.555	0.97(0.89-1.07)
<b>Valsalva leak point pressure (cmH2O)</b>	<b>0.02</b>	<b>0.01</b>	<b>0.041</b>	<b>1.02 (1.01-1.04)</b>
Maximal Urethral stress closure pressure (cmH2O)	-0.01	0.01	0.288	0.99 (0.98-1.01)
Maximal flow rate (ml/s)	0.02	0.03	0.472	1.02 (0.97-1.07)
Constant	-3.76			

**B:** Regression coefficient; **SE:** Standard error; **OR:** Odds ratio; **95% CI:** 95% confidence interval.

† Referenced to P1 (=0).

**Predicted probability (p) = 1/(1+e-z)**, where e is the base of natural logarithm and z is logit(p).

$z = b_0 + b_1 * \text{age in years} + b_2 * \text{parity} + b_3 * \text{maximal detrusor pressure in cmH}_2\text{O} + b_4 * \text{Valsalva leak point pressure in cmH}_2\text{O} + b_5 * \text{maximal flow rate in ml/s}$ , where  $b_0$  = value of the constant in the regression, and  $b_1$  to  $b_5$  are the regression coefficients for the corresponding variables.

predictive value of 90.0% (95% CI, 68.3% to 98.8%), and a negative predictive value of 65.5% (95% CI, 51.9% to 77.5%).

As regards surgically treated patients, the model (Table 3) provided a correct classification rate of 75.0% with an area under the receiver-operating characteristic ROC curve (AUC) of 0.721 (95% CI, 0.590 to 0.829; p-value, 0.002). The best cut-off value was a predicted probability of >0.396. This had a sensitivity of 63.6% (40.7% to 82.8%), a specificity of 79.0% (62.7% to 90.4%), a positive predictive value of 63.6% (40.7% to 82.8%), and a negative predictive value of 78.9% (62.7% to 90.4%).

## DISCUSSION

The main question in MUI is which component to treat first, and literature is sparse on this subject due to lack of universal acceptance of definitions. One attempt of a

randomized controlled trial comparing the initial treatment approach for MUI - medical management of UUI versus surgical management of SUI - was done by Brubaker et al. (2009). Unfortunately, this trial failed to recruit patients willing to randomize to surgical versus medical therapy. A recent working subcommittee from the IUGA R&D Committee found that the IUGA and ICS definition of MUI is quite limiting, especially with regard to evaluation of treatment outcomes and advised that categorization based on objective urodynamic tests rather than symptoms should be adopted (Kammerer-Doak et al., 2014). This is true since symptomatology is often inconsistent with urodynamic findings as demonstrated in studies by Sandvik et al. (1995) who found that only half of the patients with MUI symptoms had an identifiable mixed condition. The current study is one of the very few studies that focused on women with urodynamically evident MUI and their optimum management.

The findings of the current study confirmed those of previous speculations and studies. Surgical correction

lead to resolution of urgency incontinence and urgency in a majority of patients with stress predominant MUI. This finding agrees with the meta-analysis conducted in 2011 by Jain et al. (2011). A more recent study in 2014 by Abdel Fattah et al. (2014) found that transobturator tape procedures are associated with a good (73.8 %) patient reported success rate at a minimum of 3 years of follow up in the surgical management of MUI in women with predominant SUI symptoms and nearly half of the women reported a cure of their urgency and UUI (Dumoulin et al., 2010).

The current study showed a typical clinical outcome in MUI patients on anticholinergic therapy which is the resolution of the urgency component in more than 50% of patients with mild improvement (33.3%) in the stress component, as shown in earlier studies (Smith Karen et al., 2008). There have been several reports suggesting that the efficacy of anticholinergics is not affected by the stress component in MUI (Michel et al., 2004).

The effect of urodynamic parameters on the outcome of surgical intervention for MUI has previously been evaluated. In the largest prospective cohort study to date with a mean follow-up period of 50 months, coexistent idiopathic detrusor over activity (IDO) increased by two-fold the risk of both persistent urgency and UUI following different mid-urethral sling procedures in women with MUI in multivariate analysis (Sandvik et al., 1995). In a similar study, the specific pre-operative urodynamic predictors of persistent post-operative IDO in this group of women using logistic regression were low maximum cystometric capacity, IDO volume, Maximal Urethral stress closure pressure (MUCP) and maximum urinary flow rate (Gamble et al., 2008). The SISTER trial reported that having a lower quartile VLPP or MUCP confers almost two-fold increase in odds of objective failure (Nager et al., 2008). Gurette et al. (2008) used incremental values of the preoperative MUCP & VLPP as cut-off points. They found that a combined cut-off value of MUCP  $\leq 40$  cm H<sub>2</sub>O and VLPP  $\leq 60$  cm H<sub>2</sub>O was most predictive of surgical failure, with a sensitivity of 83% (95% CI, 0.55–0.99) and specificity of 79% (95% CI, 0.67–0.88). Similar results were obtained by Hsiao et al. (2009). On the other hand, Costantini et al. (2009) noted no increased relative risk of surgical failure when comparing transobturator or retropubic MUS based on VLPP or MUCP findings. Another meta-analysis confirmed that urethral function did not predict the outcome of MUS (Latthe et al., 2007). A preoperative urodynamic diagnosis of mixed incontinence was not found to be an independent predictor for failure in the ETOT study (Abdel-Fattah et al., 2010) and SISTER study (Nager et al., 2008), despite the fact that increased urgency symptoms and increased urgency bother were associated with surgical failure in both trials. This may reflect the small number of patients with DO in both these studies.

The value of urodynamic evaluation in women with MUI who will not be treated by surgery is less clear. In previous large community-based studies, urodynamic parameters were not predictive of the outcome of either pharmacological therapy or behavioural treatment of MUI (Burgio et al., 2003). In the current study high Maximal detrusor pressure and low maximal urethral closure pressure were independent predictors of failure of medical treatment.

The strength of this study lies in its prospective nature and the specific cohort of patients with definite urodynamic evidence of mixed incontinence and to the first time a complete model for the probability of success of treatment was introduced. In the current study we agreed with the authors of the MIMOSA trial who believed that it was appropriate to assess participant-reported outcomes at 3 months, because peak improvements from both treatment approaches should be evident at that time (Brubaker et al., 2009). Also, in assessing the outcomes of this complex condition, a woman's subjective assessment of her continence status would be more meaningful to both clinicians and the general population than objective tests (a trend recently adopted by the Food and Drug Administration (FDA)). The authors recognize that the current body of evidence supports use of conservative treatment, including non-surgical, non-pharmaceutical therapy as an initial treatment of MUI. The main stays of conservative therapy are behavioural and lifestyle modifications which both require patient compliance, and this could be a limiting factor for long-term success. The IUGA review recognized the fact that the realistic feasibility of the treatment and the patient's willingness to engage in such therapy should be taken into account before counseling women for such approach.

In the current study all the stress predominant cases were treated by a TOT procedure. It has been suggested that patients with poor urethral function have better success rates with retropubic than transobturator MUS because the vector forces provided by a retropubic sling may be more compressive than that provided by a transobturator sling. However, Nager et al. (2011) found that the increased risk of failure with lower VLPP or MUCP values was not significantly more for the transobturator procedure compared to the retropubic procedure. Botros et al. (2007) found that more patients undergoing the retropubic approach had worsening UUI (14 % versus 6 %). It is conceivable that the retropubic midurethral slings profile is tighter, which may contribute to the higher rate of persistent OAB after surgery. This is consistent with results from the meta-analysis of Lee et al. (2011).

We are aware of the limitations of this study as being non-randomized, non-blind study, but this is acknowledged given previous studies failed to randomize women to different treatment options.

The effect of previous anti-incontinence surgery and the coexistent prolapse were not addressed in this study and might be interesting points of future research in this subgroup.

## CONFLICT OF INTEREST

The authors declare that they have no conflict of interest or financial disclosure.

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