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Title: Sexual Quality of Life after Treatment of Stress Urinary Incontinence with Adjustable Tension-Free Mesh System in Women Who Were Sexually Active Prior to Surgery

Author: Carla Pérez-Tomás, Luis Gómez-Pérez, Jesús Romero-Maroto, Antonio Palazón-Bru, Felipe Navarro-Cremades, Ernesto Cortés-Castell

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TITLE PAGE:

Title: Sexual quality of life after treatment of stress urinary incontinence with adjustable tension-free mesh system in women who were sexually active prior to surgery.

Short title: Sexual function and urinary incontinence.

Authors: Carla Pérez-Tomás[a], Luis Gómez-Pérez[a], Jesús Romero-Maroto[a], Antonio Palazón-Bru[b], Felipe Navarro-Cremades[b], Ernesto Cortés-Castell[c].

Institutions:

a. Department of Urology, University Hospital of San Juan de Alicante, San Juan de Alicante, Alicante, Spain.

b. Department of Clinical Medicine, Miguel Hernández University, San Juan de Alicante, Alicante, Spain.

c. Department of Pharmacology, Paediatrics and Organic Chemistry, Miguel Hernández University, San Juan de Alicante, Alicante, Spain.

Corresponding author: Prof. Antonio Palazón-Bru, PhD. Department of Clinical Medicine, Miguel Hernández University, Carretera de Valencia - Alicante S/N, 03550, San Juan de Alicante (Spain). Phone number: +34 965919449. Fax number: +34 965919450. E-mail: antonio.pb23@gmail.com.

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ABSTRACT:

Objectives: To assess the sexuality and quality of life of sexually active women with stress or mixed urinary incontinence (SUI/MUI) after surgery with adjustable tension-free suburethral mesh system (TOA/TVA).

Methods: This intervention study with two years of follow-up (visits at three months, one year and two years) involved 60 women with SUI/MUI who underwent surgery using TOA/TVA during 2008-2014 in a Spanish region. The variables of interest measured pre- and post-intervention were the global scores on the following questionnaires: 1) Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire-12 (PISQ-12), the International Consultation on Incontinence Questionnaire (ICIQ-SF) and the Incontinence Quality of Life Questionnaire (I-QOL). Mixed linear models were constructed to determine the effect of the intervention on the outcome variables.

Results: A significant improvement ($p<0.001$) was seen over time in all the questionnaires, although between the one- and two-year visits there was a slight deterioration in all of them.

Conclusions: The technique provided an improved quality of life and sexuality, which was maintained at all the postoperative visits compared to baseline.

INTRODUCTION

Urinary incontinence is a health problem affecting 12-46% of adult women.[1] Types of urinary incontinence include stress (SUI), urgency (UUI), or mixed (MUI). SUI is the involuntary loss of urine associated with physical exertion causing an increase in abdominal pressure.[2] Although this condition is not life-threatening, it can result in reduced quality of life, involving hygiene or social problems that impair psychological, physical and sexual quality.[3-4] In addition, sexual dysfunction is very common in 19-50% of SUI patients.[4]

Treatment of SUI can be conservative or surgical. The treatment of choice for moderate-severe SUI is surgery, with a suburethral mesh being the most effective measure.[5] This improves urinary leakage during intercourse in women with SUI.[3] Nonetheless, mesh placement may worsen sexual aspects such as climax by compromising vascularization or vaginal innervation.[6] This in turn may lead to dyspareunia and a negative emotional response, due to possible tightness of the mesh.

Several articles have examined the quality of life and sexuality of women treated with a nonadjustable suburethral mesh. However, many of these studies use questionnaires that have not been validated,[7,8] and the most recent research with validated questionnaires and statistical significance does not yield the same results. While some conclude that there is improvement in sexual relations after surgical treatment,[9-11] others report no sexual changes after placement of the mesh.[12,13] However, all these authors used nonadjustable suburethral meshes.

In 2002, Romero designed a new adjustable tension-free (correct tension to achieve urinary continence) mesh system (TOA/TVA). This system consists of suburethral tape

containing two groups of polypropylene strings that allow postoperative tension adjustment. The first group consists of two strings, each one located 1.5 cm from the midline of the mesh on either side. These strings are externalized through the anterior vagina wall and can be used to reduce the tension of the mesh postoperatively by pulling them downwards. The second group consists of three strings in each arm of the mesh, placed at different distances from the midline. These strings are externalized through the same incision through which the mesh is passed and are used to increase the tension by pulling them upwards. Adjustability provides the option of increasing/decreasing the tension (pulling the mesh nearer to/releasing the mesh further from the urethra). The prevention of UUI or persistent incontinence is influenced by various factors, but stress is possibly the most important factor.[14-15]

The placement of TOA/TVA is similar to that of the nonadjustable tension-free suburethral mesh. The published success rates are approximately 90% for both objective healing and satisfaction.[14,15] Although other working groups use TOA/TVA for the treatment of their patients,[16-18] no published studies evaluate the sexuality of sexually active women. Accordingly, we conducted a prospective study assessing this issue in order to provide information concerning the impact on the sexuality of women who have undergone surgery with this type of mesh.

MATERIALS AND METHODS

Study population

The study population comprised women with SUI or stress-dominant MUI undergoing surgery with TOA/TVA at the Urology Department of the University Hospital of San Juan de Alicante (Spain), where we have used these meshes since they became available (Supplementary Material 1). The prevalence of urinary incontinence among women in Alicante is 39.7%.[19] All the patients with SUI or stress-dominant MUI were advised to do pelvic floor exercises, though improvement was generally only seen in those who had mild or moderate SUI. The exercises were undertaken during the period between their visit to the general urologist until they were seen by a pelvic floor specialist who decided whether surgery was required.

Study design and participants

This interventional prospective study with a two-year follow-up assessed the influence of surgery with TOA/TVA on sexual function and quality of life in women with SUI or MUI who did not improve with pelvic floor exercises. For both the diagnosis of this condition and during the follow-up the subjects underwent a gynaecological examination, which included a cough test after bladder filling with 250 mL of saline solution, flowmetry with a post-void residual urine test and a urodynamic study.[20] The follow-up involved assessments prior to the intervention (baseline), and at three months, one year and two years (end of follow-up). Visits after surgery were established by protocol, giving the patient an appointment for postsurgical revision.

The sample consisted of all patients diagnosed with SUI or MUI who failed to improve after conservative treatment and had signed the surgical informed consent at the University Hospital of San Juan de Alicante between January 2008 and August 2014. These

women were operated on by the same surgical team with either the TOA or the TVA technique. For inclusion, participants had to be over 18 years of age and have the physical and mental capacity to understand and complete the self-report questionnaires on sexuality and quality of life assessed in the study. Women were excluded if they had neurogenic bladder, which requires different management from the rest of the general population; prolapse ≥2 on the Baden-Walker scale and surgical correction in the same procedure for other pelvic floor disorders,[21] as this could affect sexual relations regardless of the adjustable mesh; and women who were not sexually active. The choice of technique is made based on the leak point: TOA when this is <60% or when UUI is present.

Procedure

All the women included in the study had a TOA/TVA surgically placed using spinal anaesthesia. Adjustment of the mesh, if necessary, was performed 24 hours after the intervention. Placement of the mesh is performed through a small incision in the anterior surface of the vagina. The mesh placement technique is similar to that of nonadjustable tension-free suburethral meshes. The technique may be ascending (vaginal-suprapubic) or descending (suprapubic-vaginal) as well as a transobturator approach. Adjustments are made by tightening or loosening the strings 24-48h after surgery. Loosening the mesh enables us to avoid UUI if the mesh is too tight, and tightening it prevents persistence of SUI if the mesh is too loose. A photographic description of the technique can be seen in the Supplementary Material 2.

Variables and measurements

For the main variables we used a series of quality of life and sexuality questionnaires, all of which were validated, simple to use, and easy to understand in the Spanish language. These questionnaires were given to the patients before surgery and at all the postoperative visits (at three months, one year and two years). The first was the Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire-12 (PISQ-12).[22] This questionnaire has three domains: behavioural or emotive, physical, and partner-related. The PISQ-12 is derived from the PISQ-31 and evaluates sexuality in women with urinary incontinence and/or bladder prolapse using 12 questions,[23] each with five possible answers. The first four questions pertain to the behavioural or emotive domain, the following five questions refer to the physical domain, the following two questions are part of the partner-related domain, and the last question considers the difference in orgasms after the procedure. All the questions have a Likert-type response (0 to 4 points), the first four being inverse. The final score is calculated by adding all the values for each of the answers. Higher values on the PISQ-12 indicate better sexual function. The second questionnaire used was the International Consultation on Incontinence Questionnaire (ICIQ-SF), which identifies people with urinary incontinence and its impact on their quality of life. This instrument has three Likert-type questions, the results of which are added together and the sum provides the overall test score. A higher score indicates worse quality of life and a null value indicates that the patient does not have urinary incontinence.[24] The third and final questionnaire used was the Incontinence Quality of Life Questionnaire (I-QOL), which is a quality of life instrument that has 22 Likert-type questions (values from 1 to 5) with which one can obtain a minimum score of 22, indicating worse quality of life, and maximum of 110, indicating better quality of life (≥80 is a satisfactory level).[25]

As secondary variables, only at the descriptive level, all the women underwent a directed clinical history with preoperative data, including age, body mass index, degree of incontinence, number of births, number of sanitary pads used per day, personal history of pelvic floor surgery, and type of intervention and incontinence. The degree of incontinence was defined as mild (when coughing and sneezing), moderate (when running and lifting) and severe (when walking and climbing stairs). This was supplemented with the cough test and the leak point pressure measurement (when available).

Sample size

There was no prior sample size calculation, as the data for all the women who underwent this technique during the study period were included, resulting in a total of 60 women. In order to compare the mean PISQ-12 score before and after the intervention, expecting to find a difference of 2.25, a standard deviation pre-intervention of 0.87 and a standard deviation post-intervention of 1.20,[26] the power of the contrast was close to 100.

Statistical analysis

The qualitative variables were described with absolute and relative frequencies, whilst for the quantitative variables the mean and standard deviations were estimated. To determine the effect of the intervention on the mean values, mixed linear models (repeated measures) were constructed using the number of visits as independent variables (0→baseline, 1→3 months, 2→1 year, 3→2 years) and their second and third powers, and the questionnaires as dependent variables. The model was compared to the null model to determine its goodness of fit. This type of model enables analysis of the data without having all the data for all the visits for each patient. Through the coefficients of the models, the changes in the

scores on the questionnaire over time were represented in Cartesian charts, eliminating the random factor of each patient. Type I error was set at 5% and for each relevant parameter its associated confidence interval (CI) was calculated. The statistical packages used were IBM SPSS Statistics 24 and R 2.13.2.

Ethical considerations

The study was approved by the Ethics Committee of the University Hospital of San Juan de Alicante. Although this was a routine clinical practice study, written informed consent was required for participation in the study and to undergo surgical treatment.

RESULTS

Table 1 shows the descriptive characteristics of the sample, comprising 60 patients who underwent surgery using TOA/TVA. The mean age was 53.3 years, and three out of every five women had severe incontinence.

Table 2 shows the coefficients of the mixed models, which were highly significant. However, given the difficulty of its interpretation, the change in the mean scores on the questionnaires analysed was represented graphically, eliminating the variability of the individual (Figure 1). An improvement over time was seen in sexual function on all the questionnaires, although between the follow-up visits at one and two years there was a slight worsening on all of them. Nonetheless, there was a marked improvement from baseline. Finally, the following surgical complications were noted: urinary infection resolved with antibiotics, 2; mesh erosion/extrusion resolved using vaginal oestrogens, 3;

vaginal/inguinal pain resolved in three months without intervention, 1; urethral injury, repaired during surgery (the procedure was postponed for six months), 1; loss of sensitivity in the left inguinal area (recovered after one year), 1; and UUI requiring Botox, 1.

The number of patients showing improvement in each questionnaire was as follows: 59 (98.3%) in the I-QOL and ICIQ-SF, and 10 (16.7%) in the PISQ-12. The number of patients who worsened was: 0 (0%) in the I-QOL, 1 (1.7%) in the ICIQ-SF, and 13 (21.7%) in the PISQ-12.

COMMENT

The women in our study showed a statistically and clinically significant improvement in both quality of life and sexuality after treatment of SUI and stress-dominant MUI with TOA/TVA. This improvement was maintained throughout the three postoperative visits, although between the one-year and two-year postoperative follow-up visits a slight worsening was noted.

Although our objective was to have an overall view of sexuality after surgery, (question #6 of the PISQ-12), we also analysed coital incontinence: 1) always/frequently: pre-intervention (23%) and post-intervention (0%); 2) never: 25% and 66.6%, respectively. Regarding another issue of interest on the PISQ-12, coital pain (#5), there were no differences between pre- and post-intervention.

The technique used in our centre allows adjustment of the mesh after surgery, which is not contemplated in the published research examining sexuality with nonadjustable meshes. We are therefore limited when comparing our results with those of others, but we

believe that this technique is of considerable benefit to our patients as it allows mesh adjustment after surgery should it be necessary.

Although this is the first study to analyse sexuality and quality of life in women undergoing surgery with TOA/TVA, other studies in the literature on nonadjustable suburethral meshes have also reported statistically significant improvements in sexual function. Durson used the Female Sexual Function Index (FSFI) [27] with follow-up performed only at one postoperative visit at six months, whereas our study included three postoperative visits with follow-up to two years. The study by Filacamo, who used the FSFI questionnaire as a working tool, is unusual in that it included women who were not sexually active. The questionnaire that should have been used in this case was the PISQ-IR, but it was not available at that time.[28] De Souza had a sample of patients similar to ours, but included patients who, in addition to the nonadjustable suburethral meshes, were not excluded if they had had other concomitant surgery.[9] Others, however, concluded that there are no differences in sexual function after placement of the nonadjustable mesh using either the PISQ-12 or the FSFI as a working tool.[12,13] Finally, although some studies have reported a deterioration in sexual function,[7,8] it must be noted that none found statistical significance and none used validated and reliable questionnaires that allow us to measure what is intended to be measured, to reproduce what has been measured and with the capacity to detect treatment effects and clinically significant changes. In summary, we can say that there is great variability in research methodology and the results obtained.

As research implications, a fundamental line of research is proposed. This consists of a clinical trial evaluating the influence of TOA/TVA on sexual function using a control

group. This will allow us to calculate the clinically relevant (reduction in relative and absolute risk, and number needed to treat) and associated (relative risk) parameters.

Regarding the clinical implications of our results, we emphasize that our group is not a sample of selected women, but rather a group of patients that reflects the experience of daily clinical practice. In addition, the women with SUI/MUI who visit our consultations are increasingly younger and therefore more likely to be sexually active. Whichever option we use to resolve this condition should be able to be evaluated from the point of view of the patients, not only regarding the impact on their quality of life but also regarding the implications in terms of sexual relations. More and more patients are requesting the procedure and it is essential to understand its repercussions before offering it. In our study we found a significant improvement in sexual function after surgery with an adjustable suburethral mesh, possibly related to the improvement in incontinence during intercourse.

The main strength of this study is that, to the best of our knowledge, this is the first report to provide data on sexuality and quality of life in women treated surgically using an adjustable suburethral mesh. We found no published articles in our literature search on this subject. Furthermore, we used validated, self-reported and easily understood questionnaires to measure quality of life, allowing us to reliably determine the improvement experienced by our patients after surgery with an adjustable suburethral mesh. In addition, we point out that the use of a mathematical model with repeated measures enables us to better establish an effect than with the classic application in this type of study, where the means of the parameters of interest are compared before and after the intervention. Finally, it should be noted that the entire group of women treated came from the same hospital, and the surgeries were performed by the same team of three expert surgeons. The surgical technique is

simple enough to be performed by any urologist, and this is what is taking place in other centres. However, as a greater number of surgeons become involved, fewer procedures are performed by each one, increasing the probability of complications. In our case the probability of failure using this technique decreases as regards the urologist.

As a limitation, we note that the PISQ-12 questionnaire needs to be completed by sexually active women (selection bias), so there may be bias by not including women who at the time of the study were sexually inactive precisely because of their incontinence. Including these women might have improved the results. A new questionnaire, the PISQ-IUGA Revised (PISQ-IR), is available and could include this type of women.[29] However, its validation in the Spanish language had not been carried out at the time of data collection.[30] To minimize information bias the data were collected in person, through a direct interview by the urologist, systematic physical examination, and completion of the validated questionnaires by the patient, both at the preoperative visit and at three months, one year and two years. In addition, although the questions on the questionnaire were closed, any of them could be discussed for clarification. Finally, it is clear that our study design is interventional, but with a single group (no control group was randomized). Thus, to understand the impact on sexuality using our surgical technique much more accurately, a randomized clinical trial should be conducted comparing the adjustable suburethral mesh with the nonadjustable suburethral mesh. In view of the results obtained and since not many sexually active women undergo surgery for SUI/MUI with an adjustable suburethral mesh, multicentre studies are needed to assess this issue.

CONCLUSIONS

A statistically and clinically significant improvement in quality of life and sexuality was seen in our group of patients who underwent surgery with TOA/TVA that was sustained throughout all the postoperative visits.

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FIGURE LEGEDS

Figure 1: Changes in the mean scores of our patients after the surgical treatment with adjustable tension-free mesh.

International Consultation on Incontinence Questionnaire (ICIQ-SF).

Incontinence Quality of Life Questionnaire (I-QOL).

Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire-12 (PISQ-12).

Visits were defined as: baseline (*visit=0*), 3 months (*visit=1*), 1 year (*visit=2*) and 2 years (*visit=3*).

SUPPLEMENTARY MATERIAL

Supplementary material 1: Suburethral mesh procedures.

Supplementary material 2: Photographic description of the adjustable tension-free mesh system.

Table 1: Baseline characteristics of the patients who underwent surgery.

Variable	n=60 n(%)/x±s
Age (years)	53.3±8.5
Personal history of pelvic floor surgery	6(10.0)
Trans-obturator technique	54(90.0)
Urinary incontinence: Stress Urgency* Mixed	 35(58.3) 0(0) 25(41.7)
Degree: Mild Moderate Severe	 9(15.0) 15(25.0) 36(60.0)
BMI (kg/m^2)	29.1±6.0
Number of deliveries	2.1±1.0
Number of sanitary pads	3.4±2.6

Abbreviations: n(%), absolute frequency (relative frequency); x±s, mean ± standard deviation.

*Urgent urinary incontinence is not treated by surgery.

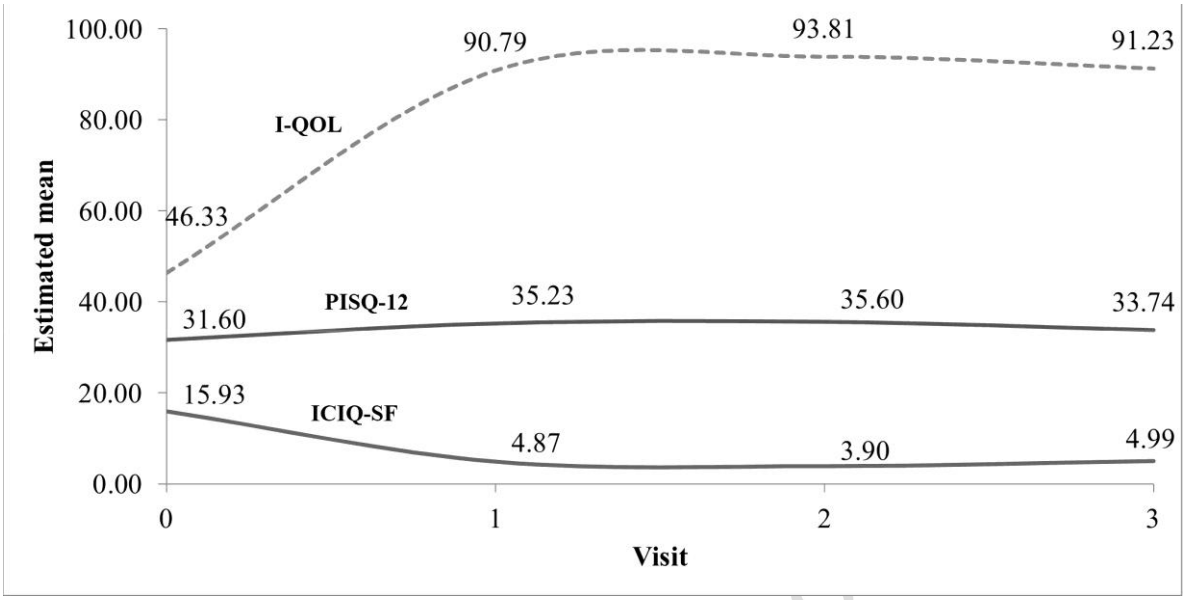
Table 2: Linear Mixed-Effects Models for the quantitative outcomes in our study.

Parameter	I-QOL		ICIQ-SF		PISQ-12	
	B	p-value	B	p-value	B	p-value
Intercept	46.33	<0.001	15.93	<0.001	31.60	<0.001
Visit	77.13	<0.001	-18.80	<0.001	5.61	0.058
$Visit^2$	-38.64	<0.001	9.07	<0.001	-2.16	0.416
$Visit^3$	5.97	<0.001	-1.34	<0.001	0.17	0.766
Standard deviation	11.41	N/A	2.32	N/A	6.73	N/A

Abbreviations: I-QOL, Urinary Incontinence Quality of Life Scale; ICIQ-SF, International Consultation on Incontinence Questionnaire Short-Form; N/A, not applicable; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire.

Likelihood ratio test to compare with the model without taking into account the visits (only with the intercept): I-QOL, p<0.001; ICIQ-SF, p<0.001; PISQ-12, p<0.001.

Visit is defined as: 0→Base-line, 1→3 months, 2→1 year and 3→2 years.



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