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ORIGINAL ARTICLE

Is the adjustable TVA mesh effective for the long-term treatment of female stress incontinence?☆

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KEYWORDS
Stress urinary incontinence;
Adjustable suburethral mesh;
Surgical complications;
Results

Abstract

Objectives: To assess the long-term safety and efficacy of the adjustable TVA mesh in treating stress urinary incontinence.

Material and methods: Pseudoexperimental study, before and after, conducted in a university urology department.

Eighty-two patients were invited to participate from January 2002 to March 2005. Thirty-two patients agreed to participate and were implanted an adjustable TVA mesh. The preoperative study included a medical history review, physical examination with full bladder, flowmetry, residue study, complete urodynamic study and the self-administered questionnaires I-QoL and ICIQ-SF.

In the postoperative assessment, the PGI-I questionnaire was added, but a complete urodynamic study was not performed.

Results: Twenty-nine (90.6%) and 28 (87.5%) patients were continent in the stress test at 1 and 10 years, respectively. Twenty (62.5%) and 16 (50%) patients had no urine escape at 1 and 10 years, respectively. Twenty-eight (87.5%) and 25 (78%) patients were satisfied 1 and 10 years after the surgery, respectively. Twenty-eight (87.5%) and 21 (62.5%) patients had a good quality of life at 1 year and at 10 years, respectively. There were no significant complications at the end of the study period.

Conclusions: Treatment of stress urinary incontinence with the TVA mesh presented a high degree of objective healing and satisfaction at 10 years, with no severe adverse effects. The

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study showed that satisfaction does not always mean total continence but rather it reflects the improvement of symptoms and consequent quality of life.

PALABRAS CLAVE
Incontinencia urinaria de esfuerzo;
Malla suburetral ajustable;
Complicaciones quirúrgicas;
Resultados

¿Es eficaz a largo plazo la malla ajustable TVA en el tratamiento de la incontinencia de esfuerzo femenina?

Resumen

Objetivos: Valorar a largo plazo la eficacia y seguridad de la malla ajustable TVA en el tratamiento de la incontinencia urinaria de esfuerzo.

Material y métodos: Estudio seudoexperimental, antes y después, realizado en un servicio universitario de urología.

Ochenta y dos pacientes fueron invitadas a participar desde enero de 2002 a marzo de 2005. Treinta y dos accedieron a participar y se les implantó una malla ajustable TVA. El estudio preoperatorio incluyó historia médica, examen físico con vejiga llena, flujometría, residuo, estudio urodinámico completo y los cuestionarios autoadministrados I-QoL, ICIQ-SF.

En la evaluación postoperatoria se añadió el cuestionario PGI-I, no realizándose el estudio urodinámico completo.

Resultados: Veintinueve pacientes (90,6%) eran continentes en la prueba de esfuerzo al año. Veintiocho (87,5%) a los diez años. Veinte pacientes (62,5%) nunca tenían escape al año. Dieciséis (50%) a los diez años. Veintiocho pacientes (87,5%) estaban satisfechos al año de la cirugía. Veinticinco (78%) a los diez años. Veintiocho (87,5%) tenían buena calidad de vida al año y veintiuno (62,5%) a los diez años. No hubo complicaciones importantes al final del periodo de estudio.

Conclusiones: El tratamiento de la incontinencia urinaria de esfuerzo con malla TVA presenta un alto grado de cura objetiva y satisfacción a los diez años, sin efectos adversos graves. El estudio muestra que la satisfacción no siempre significa continencia total sino que expresa la mejoría de los síntomas y la consiguiente calidad de vida.

Introduction

Suburethral meshes are considered the current standard in the treatment of female stress urinary incontinence.[1] They solve a large number of cases but approximately 15% of patients continue with some incontinence, others suffering postoperative obstructive voiding dysfunction.[2]

Suburethral adjustable meshes TVA and TOA (AMI GmbH, Austria)[3] were developed in order to improve the results of conventional meshes, allowing for adjustment of the tension several days after surgery, thus correcting the possible incontinence or postoperative obstruction.

Excellent short- and medium-term results have been published with this technique.[3–7] However, there is no long-term study of adjustable meshes, those published with conventional meshes being very few.[8–12] By increasing life expectancy and a greater number of women being treated, younger and younger, with suburethral meshes, it is important and necessary to know the results and long-term complications.

The purpose of this study is to investigate the short- and long-term results of treatment with adjustable TVA mesh in women with stress incontinence, analyzing its effectiveness in terms of objective and subjective success, quality of life and satisfaction, also assessing their safety.

Material and methods

Pseudoexperimental study, before and after, carried out in a single department of urology.

Eighty-two women diagnosed in our department with stress incontinence from January 2002 to November 2005 were invited to participate in the study. Thirty-five who met the inclusion criteria accepted the invitation and were operated, implanting an adjustable transvaginal mesh (AMI TVA). The Ethics Committee approved it and all women signed an informed consent.

Inclusion criteria

Women with pure or mixed stress urinary incontinence with predominance of the stress component.

Exclusion criteria

Age lower than 18; neurological disease; having been treated with radiotherapy; more than one surgery for stress incontinence or suffering from genital prolapse higher than grade I (Baden-Walker).

Methods

The preoperative study included medical history, vaginal examination, cough stress test (full bladder with saline 250 ml), free flowmetry, residual urine, pressures/full flow study, and self-realized I-QoL and ICIQ-SF questionnaires. The degree of incontinence was established according to the classification of Ingelman-Sundberg.

The surgical technique has been previously described.[3,4] The day after surgery, continence and micturition were evaluated by cough stress test (full bladder, 250 ml of saline), and free flowmetry and urinary residue respectively, correcting the tension of the mesh if necessary. A maximum flow under 10 ml/s and/or a urinary residue above 150 ml were considered obstruction.[3]

All patients were assessed the first, sixth and twelfth month after surgery during the first year and annually thereafter. Medical history, vaginal examination, cough stress test (full bladder, 250 ml saline), flowmetry and residual urine were performed, and I-QoL, ICIQ-SF and PGI-I questionnaires were self-completed. Evaluation 1 year after surgery has been chosen as short-term result.

Variables

The primary dependent variable is the objective success. Secondary dependent variables are subjective criteria: completely continent, quality of life, and satisfaction. TVA mesh surgery is the independent variable.

The objective success was defined as the absence of urine leak in the stress test with cough. Completely continent was considered when the response in the ICIQ-SF questionnaire was 'never' to the question 'how often do you leak urine?'. It was also analyzed whether the lack of continence was due to stress, urge, or mixed incontinence. The type of incontinence was defined according to the item 6 of the ICIQ-SF questionnaire: 'When do you leak urine: when coughing/exercising, before reaching the toilet, or in both situations?'

The quality of life was evaluated according to the total score of the I-QoL questionnaire. A score greater than or equal to 80 is considered good quality of life.[13] Satisfaction was established according to the PGI-I questionnaire. The surgery was considered satisfactory when the answer was feeling much or somewhat better after surgery.

Complications were divided into early and late intraoperative/postoperative. The Clavien-Dindo classification has been used.

The methods, definitions, and measures are in line with those recommended by the joint committee of the International Association of Urogynecology and the International Society of Continence.[14]

Statistical study

The descriptive analysis was performed using the arithmetic mean and standard deviation or median, along with the interquartile range, for quantitative variables, depending on whether its distribution was normal or not normal. Regarding qualitative variables, they were expressed as relative frequencies and percentages.

The association between qualitative variables was established by means of the Chi-square test or Fisher's exact test. The results of the questionnaires at 12 months and at the end of the study (paired data) were compared using the Student's *t* test and McNemar test for related samples. A α significance level of 0.05 with two tails was established, using the SPSS 15.0 for Windows (SPSS Inc, Chicago). The Kaplan–Meier estimator was used to analyze the survival of the mesh.

Results

This study follows the recommendations of the IUGA/ICS regarding the publication of variables for surgery of pelvic organ prolapse.

Thirty-five women were evaluated a year after the surgery. Three did not do the evaluation after 10 years and were eliminated from the study to be able to conduct a correct comparative study.

Three surgeons performed the thirty-five operations; one of them, trained in Urogynecology, participated in all of them. The mean follow-up was 10 years.[9–12]

Table 1 shows the clinical characteristics. Table 2 shows the different questionnaires before surgery, a year and 10 years after it.

Table 1 Sample characteristics.

Characteristics	Values
Age	
Median (CI)	58.0 (18.0)
Body mass index	
Median (CI)	28.5 (5.3)
Years with incontinence	
Mean (SD)	6.9 (5.5)
Previous surgery N (%)	
Histerectomy	6 (17.14%)
Prolapse	0 (0.0%)
Incontinence	5 (15.6%)
Degree of incontinence N (%)	
Severe	23 (71.9%)
Moderate	8 (25.0%)
Mild	1 (3.1%)
Urgency N (%)	22 (68.8%)
Urge incontinence N (%)	16 (50.0%)
Absorbents (N/day)	
Mean (SD)	3.77 (3.0)
Maximum cystomanometry capacity (ml)	
Mean (SD)	264.3 (68.1)
Peak flow (ml/s)	
Mean (SD)	27.9 (11.5)
Residual volume (ml)	
VLPP (cm H_2O)	No PVR (<20 ml)
Mean (SD)	44.64 (19.6)
Qmax detp (cm H_2O)	
Mean (SD)	26.36 (14.1)
Overactive detrusor N (%)	5 (15.62%)

Pdet Qmáx, detrusor pressure at maximum flow; VLPP, Valsalva leak point pressure.

Table 2 Results of surgery at 1 and 10 years according to questionnaires.

Questionnaire	Item	Pre	1 year	10 years
ICIQ-SF	*3, Frequency*[a]			
	Never	0	20 (62.5%)	16 (50%)
	≤1 week	0	4 (12.5%)	5 (15.62%)
	2–3 weeks	0	2 (6.25%)	1 (3.1%)
	Once a day	0	3 (9.36%)	2 (6.25%)
	Several times a day	24 (75%)	3 (9.36%)	5 (15.62%)
	All the time	8 (25%)	0	3 (9.36%)
	4, Amount[b]			
	Nothing	0	19 (59.3%)	14 (43.8%)
	Small amount	0	12 (37.5%)	11 (34.4%)
	Moderate amount	18 (56%)	1 (3.1%)	5 (15.6%)
	Large amount	14 (44%)	0	2 (6.3%)
	Type of urinary incontinence based on definition item 6			
	Continence	0	20 (62.5%)	16 (50%)
	Stress incontinence	16 (50%)	2 (6.2%)	2 (6.3%)
	Mixed incontinence	14 (44%)	3 (9.3%)	6 (18.7%)
	Urge incontinence	2 (6%)	7 (21.8%)	8 (25%)
I-QOL	*22 items*	29 (5–80)[c]	106 (93–108)[c]	98.5 (64–105)[c]
PGI-I[c]	*Much better*		25 (78.1%)	22 (68.8%)
	Quite better		3 (9.3%)	3 (9.4%)
	A little better		1 (2.86%)	4 (12.5%)
	No change		1 (2.86%)	1 (3.1%)
	A little worse		2 (5.71%)	0
	Quite worse		0	1 (3.1%)
	Much worse		0	1 (3.1%)

[a] Frequency of urine leak.
[b] Amount of urine leak.
[c] Median (range).

Twenty-six (81%) patients were continent immediately after surgery. Six (19%) were incontinent and the tension of the mesh was increased. Three (9%) with a maximum flow lower than 7 ml/s and/or urinary residue that exceeds 150 ml were considered obstructed and the mesh tension was reduced.

All patients were discharged continent and without residual urine. There was no statistical significant difference between the preoperative peak flow (26 ± 11 ml/sg) and the maximum flow at a year (23 ± 10 ml/s) ($p > 0.5$), nor with that obtained at 10 years (22 ± 7 ml/s) ($p > 0.05$).

29 out of 32 patients (90.6%) were completely continent after 1 year during cough stress test, 3 (9.4%) showed a small leak and they did not consider a new surgery. 28 out of 32 (87.5%) were at 10 years, and 4 (12.5%) with slight leak did not consider it enough for another intervention. There is no significant difference between the two results ($p = 1$). The Kaplan–Meier survival curve shows that continence decreases to 22 months remaining stable thereafter (Fig. 1).

20 patients out of 32 (62.5%) did not leak urine after a year in any circumstances. 16 (50%) were in the same situation at 10 years (Table 2). There is no statistically significant difference between both results ($p = 0.219$).

Urgency is the most common cause of this decline in continent patients. According to the ICIQ-SF questionnaire, 31% of patients suffered from urge incontinence at 1 year and 43.7% did at 10 years ($p = 0.63$).

The amount of urine lost decreases significantly after surgery. Thirty-one patients (97%) lost nothing or very little a year after surgery. At 10 years, this number decreased

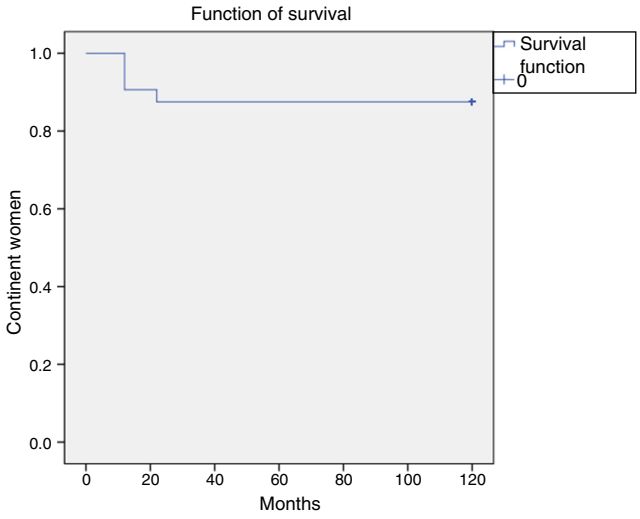

Figure 1 Kaplan Meyer curve expressing percentage of continent patients after surgery.

Table 3 Variables associated to results (univariate analysis *p* value).

Variables	Objective success	Subjective success	Quality of life	Satisfaction
Age >65	0.128	0.029	0.450	0.671
Deliveries ≥2	0.205	0.562	0.286	0.590
Presurgery overactive detrusor	1	0.639	0.290	0.285
Presurgery urge incontinence	1	0.157	0.009	1
Urge incontinence after surgery	0.602	0.000	0.000	0.000
Leak after surgery (>small amount)[a]	0.000	0.000	0.003	0.002
Frequency of leak (>once a day)[b]	0.104	0.000	0.003	0.008

[a] Amount of leak in the ICIQ-SF questionnaire.
[b] Frequency of leak in the ICIQ-SF questionnaire.

significantly to 25 (78%) ($p = 0.031$) (Table 2, ICIQ-SF, item 4).

The frequency of urine leak decreases, also after surgery. Twenty-six patients (81%) never leak urine or they do, at most, two or three times a week a year later. At 10 years, this number drops to 22 (68%) ($p = 0.063$) (Table 2, ICIQ-SF questionnaire, item 3).

28 patients (87.5%) had good quality of life 1 year after surgery and 25 (78%) at 10 years ($p = 0.453$).

28 patients (87.5%) were satisfied a year after surgery and 25 (78%) at 10 years ($p = 0.453$). Ten percent of the patients saw their quality of life and satisfaction at 10 years diminish.

The urgency, assessed with clinical history, disappeared at the end of the study in 8 cases out of the 22 (36%) where it previously existed. It improved in 4 (18%), there was no change in 6 (27%), and worsened in 4 (18%). De novo urgency appeared in one (10%) of the 10 cases where it did not exist before surgery.

Table 3 shows, in the bivariate study, the influence of different variables intervening on the result at 10 years. Table 4 shows the complications that occurred, divided into two groups, intraoperative and early postoperative, and those that occurred late. The two bladder perforations that occurred were identified during surgery and the mesh was removed and repositioned correctly at that moment.

Table 4 Complications.

Intraoperative complications and in immediate postoperative	
Bladder perforation	2 (5.71%)
Vaginal erosion	1 (2.86%)
Urethral injury	–
Intestinal injury	–
Vascular injury	–
Severe bleeding	–
Voiding dysfunction	–
Postoperative obstruction before the adjustment (residual volume > 50 ml; peak flow < 7 ml/s)	3 (9%)
Need for probing	–
Late postoperative complications	
Vaginal mesh extrusion	1 (2.86%)
Pain >3 months	–
Repeated urinary infections	–
Postoperative infections	–
Subjective voiding difficulty	–

The two extrusions of the mesh (Clavien-Dindo III-A) occurred 1 month and 1 year after surgery respectively. They were located in the middle part of the anterior vaginal wall in both cases and excision of the portion protruded and subsequent closure to obtain healing was enough.

Six patients out of ten presenting urge incontinence after surgery agreed to undergo a complete urodynamic study. The average maximum bladder capacity was 280 ml (250–400), the mean detrusor pressure at peak flow 31 cm H_2O (15–44), the average peak flow 22 ml/s (16–35), and none presented urinary residue above 25 ml. Two of them with overactive detrusor before surgery continued showing it in this study. The other four did not show hyperactivity before or after surgery.

Discussion

This study analyzes our long-term results with adjustable mesh TVA in the treatment of female stress incontinence in objective and subjective terms. The variables were chosen following the recommendations of the ICS regarding objective and subjective criteria.[15] Specific questionnaires for incontinence, validated in Spanish, were chosen with recommendation grade A, which adjusted to the objectives of this study.

The implementation of the retropubic mesh TVA has been an effective and safe procedure over time, with an 87.5% objective success at 10 years, showing no significant difference with the result at 1 year (90.6%). The small percentage of incontinent patients occurred in the first 22 months of the postoperative, continence remaining stable thereafter. Costantini et al.[16] find the same situation, and postoperative incontinence originates in patients treated with TVT before 25 months, stabilizing the mesh thereafter. However, the reduced sample in both series prevents definitive conclusions.

Total, subjective continence, established by the ICIQ-SF questionnaire, is clearly lower than objective continence, both at 1 and 10 years after surgery and decreases in this period from 62.5 to 50%. Although the difference is not significant, it is doubtful that it was with a larger sample. Quality of life and satisfaction decrease both also at 10 years compared to the first year after surgery, 87 versus 78%.

Urgency, either as urge incontinence or as a component of mixed urinary incontinence, is the main cause of the difference between objective and subjective continence. Likewise, urgency has conditioned a greater amount of urine leak and increased frequency of leaks at 10 years after surgery compared to the first year in our patients. Both variables clearly affect the quality of life and satisfaction and, in this sense, and despite not having performed multivariate study due to the high number of possible intervening variables of risk regarding the number of patients, it appears to have been the most important cause in our study on the decline in both at 10 years. The urgency was the only variable affecting the quality of life of our patients in a multivariate study.[3] Svenningsen et al. found that their very satisfied patients after surgery had an average rate of urgency lower than those less satisfied.[10] Aigmuller et al. found that patients who worsened after surgery was due to bladder overactivity or mixed incontinence.[17]

However, both the amount of urine lost and the frequency with which this loss occurs, after a year and 10 years, are much lower than those existing prior to surgery. This explains the high rate of satisfaction after surgery despite maintaining some degree of incontinence and it also explains the worsening at 10 years, by increasing the amount lost and frequency. Kulseng-Hanssen et al.[18] published the same experience, although only 28% of patients never suffered from stress or urgency incontinence, 78% were satisfied with the surgery. Robinson et al.[19] found that what most of their patients wanted was an improvement enough to make their symptoms not interfere with their lives. Tincello et al.[20] found that the improvement of symptoms and consequent improvement in quality of life could be the most important variables of treatment for patients.

The long-term studies published with suburethral meshes are very scarce.[8–12] The comparison of ours with them is difficult, first due to the different criteria used in the assessment and second because the patients included in most of these studies[8,9,11,12] suffered only pure stress incontinence. Our sample is more complex because it is representative of daily clinical practice, in which a considerable proportion of patients show symptoms of bladder overactivity.[21] Our work provides, this way, information on the long-term evolution of these unselected patients, who are the usual practice.

Our goal, however and despite the differences, is comparable and even superior to that of published studies, ranging from 83[12] to 93%.[11] The retropubic suburethral meshes appear to be quite effective in the long term correcting the stress component of female incontinences.

The subjective success is difficult to compare because of the different definitions of it. The subjective success is not defined by a single variable but by several interrelated that give us a true picture of the situation and will depend, in turn, on the expectations of patients.[13] The personal perception of complete continence, established by validated questionnaire, represents the most strict criterion of success,[22] matches the situation that happens in a woman without pathology, and shows the need to differentiate the terms dryness and healing. We think that it objectively represents the actual subjective success regarding the treatment of incontinence. A subjective success defined by a questionnaire with three situations, cure, improvement, or failure, may have more to do with the satisfaction obtained by reducing symptoms and perceived improvement in quality of life than with continence as such.[19,20]

When satisfaction is considered, our results are comparable to those published, Olsson[9] gets 74% and Svenningsen[10] 83%, although it is necessary to emphasize that the evaluation of a not inconsiderable proportion of these patients was made by phone or by mail.

Subjective variables seem to worsen over time. In line with our experience, Svenningsen[10] reported a significant progressive decrease of women answering being very satisfied and Liapis[12] found 12.3% of urgency after a year and 19.6% at 7 years. Serati, however, finds a stable situation in his patients.[12] The role that the aging process or the possible obstruction plays in this decline of subjective success is difficult to establish.[21,23,24] In our case, the urodynamic studies carried out in six of our urge incontinence patients showed no obstruction criterion.

As in the rest of the papers published, there were no major late complications or erosions or infections in the long term. Regarding the TVA mesh, external threads, and tension adjusters, they did not increase the risk of infection.

Despite giving a minimum tension to the mesh, nine percent of our patients had obstruction on the day after surgery. This was solved by pulling the lower threads, resulting in reduced tension. All patients were discharged continent and none required catheterizations or section of the mesh; none had subjective signs of obstructive voiding dysfunction or experienced more than three urinary tract infections in 6 months either.

Unlike our cases, all long-term studies show a certain percentage of patients with signs or symptoms of voiding dysfunction, urinary retention after surgery,[8–10] urinary difficulty,[11,12] urethrotomy, urethral dilation, or section of the mesh.[17] The possibility of adjusting the tension of the mesh postoperatively appears to prevent the occurrence of obstructive voiding dysfunction.

The implantation of an adjustable mesh theoretically has certain advantages, makes it possible to correct the possible persistence of postoperative incontinence or obstruction. The only existing comparative study, non-randomized, between adjustable and non-adjustable mesh was conducted by Youn et al.[7] with the transobturator mesh. Healing and satisfaction were 90% and 95% with the TOA mesh versus 85 and 85% with TOT. One patient required increasing tension and four decrease it in the TOA group. Eight patients showed obstruction in the TOT group and three of them needed a urethrolysis. The urine residue was significantly lower in the TOA group. Despite these results, there is no quality evidence to point its superiority.

The factors that give strength to this study are[1] the exclusion of surgical procedures concomitant to the implantation of the suburethral mesh[2]; the evaluation of objective and subjective parameters with validated tools[3]; being a representative sample of daily practice where a significant proportion of patients suffering from mixed urinary incontinence[4] and being the same patients among whom the comparison is established after a year and at 10 years, without loss of any of them. Limiting the same is the sample size, which can decrease the statistical significance, although it makes it possible to establish trends clearly shown in the variables.

Conflict of interest

Dr. J. Romero Maroto developed the TVA mesh and is AMI GMBH Consultant, Austria. The other authors have no conflict of interest.

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