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Prognostic value of urethral mobility and valsalva leak point pressure for female transobturator sling procedure

Luis Gustavo Morato de Toledo, Pedro Henrique Oliveira Cabral, Mário Luís Casella, Gabriel Elias Politi, Sandro Nasser Cardoso, Luiz Figueiredo Mello, Sidney Glina

Department of Urology, Section of Urogynecology, Ipiranga Hospital, São Paulo, SP, Brazil

ABSTRACT

Purpose: To analyze the influence of urethral mobility and Valsalva leak point pressure on postoperative outcomes of transobturator sling (TOT) for female stress urinary incontinence.

Materials and Methods: A prospective cohort was conducted including 66 patients submitted to TOT from March 2006 to May 2009. Urethral hypermobility was defined as mobility ≥ 30º on Q-tip test, and Valsalva leak point pressure (VLPP) was classified as greater than 60 cmH_2O or 60 and less on preoperative urodynamics. These parameters were compared through well defined postoperative objective and subjective success criteria. Intensity of urinary leakage and quality of life was analysed by ICIQ-SF. Statistical analysis was accomplished and the results rendered significant if $p < 0.05$.

Results: Mean follow up was 10 months (3 to 28). Mean age was 55 years (33 to 80), 70% were white and 30% African descendent, mean body mass index was 27 (21 to 38), average vaginal and abdominal deliveries were 2.8 and 0.5 respectively. A quarter had prior stress incontinence surgery. Patients with urethral hypermobility had higher objective success rates (98% versus 81.25%, $p = 0.04$). The subjective success rate was also greater in the hypermobility group (84% versus 62.5%), but statistical significance was not reached ($p = 0.07$). VLPP had no influence on either objective or subjective postoperative success rates ($p = 0.17$ and 0.34, respectively). In the subgroup analysis, those with low mobility and high VLPP had worse objective success rates in comparison to the group with hypermobility and low VLPP ($p = 0.04$) and also in relation to the remaining of the studied population. Other possible prognostic factors (previous surgery, mixed incontinence, gestational status) had no influence on success rates.

Conclusions: High urethral mobility, regardless of the sphincteric status indicated by VLPP, is a favorable prognostic factor for tension-free transobturator tape procedure. No relationship was demonstrated between postoperative success rates and VLPP.

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INTRODUCTION

Stress urinary incontinence (SUI) is a significant health problem worldwide, affecting up to 30% of adult women (1). Despite extensive studies in this field, the exact pathogenesis is still imperfectly comprehended. Nonetheless, recent evidence-based theories introduced more realistic insights about the mechanisms responsible for continence and, more importantly, about how to restore it in incontinent women.

The most accepted theory, the "hammock theory", states the urethra is closed during straining as a result of compression against a ham-

mock-like, supporting layer of connective tissue, and not by assuming truly intra-abdominal position, as previously thought (2). Base on this hypothesis, mid-urethral sling procedures were introduced, providing reinforcement of a defective suburethral support rather than correcting hypermobility, leading bladder neck procedures to be virtually abandoned (3). While this is true, it's still debated the prognostic significance of urethral mobility and Valsalva leak point pressure (VLPP), which is a marker of intrinsic sphincter function (4-7). So we decided to study the influence of these two determinants on postoperative outcomes of the transobturator sling procedure. This study aims to analyze independent influence of urethral mobility and Valsalva leak point pressure on postoperative outcomes of transobturator sling (TOT) for female stress urinary incontinence in the same group of patients.

MATERIALS AND METHODS

The study protocol was approved by the Ethics Committee of the Hospital. All the patients understood and signed the informed consent.

From March 2006 to May 2009, 73 consecutive patients with urodynamically proved stress or mixed urinary incontinence submitted to tension-free transobturator tape procedure (TOT) were included into a prospective cohort. The operations followed Delorme's description, using a polypropylene mesh, under spinal anesthesia (3).

Exclusion criteria included neurogenic bladder, concomitant urogenital prolapsed greater than POP-Q (Pelvic Organ Prolapse - Quantification) stage 1, pregnancy and malignancy. Patients who had received previous surgical treatment, either a sling or a colposuspension operation, were not excluded.

Preoperatively, data including age, body mass index (BMI), previous surgeries and parity were collected. Urethral mobility was measured using Q-tip test in the supine position and VLPP (at maximal cystometric capacity) through multichannel urodynamics following International Continence Society (ICS) standardisation (8). Hypermobility was defined as mobility ≥ t^o and VLPP was classified as high when > 60 cmH_2O and low when 60 or less, according to previously established criteria (9-11).

For Q-tip tests, a sterile lubricated cotton swab was placed into the bladder through the meatus and withdrawn until resistance indicated correct positioning at urethrovesical junction. The angle between the cotton swab at rest and after maximal Valsalva maneuver in degrees was defined as the urethral mobility (measurements were taken using a goniometer placed against the patient's perineum).

The sling material used was monofilament polypropylene mesh (Intracorp™, Venkuri, Brazil) through outside-in technique.

On postoperative visits, 3 and 6 months, and after that every 6 months, patients responded questions about their continence status and were classified as total continence, stress incontinence, urgency incontinence or both (mixed incontinence). They also were questioned about the need of using pads and satisfaction with the procedure according to a visual analogic scale from 0 to 10. A full bladder standing Valsalva and cough maneuver completed the evaluation. If the patient did not leak she was asked to repeat the maneuver bending the knees. A post test void of, at least, 200 mL was necessary for the test to be considered valid.

Intensity of urinary leakage and quality of life was assessed before and after surgery using the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF), as validated in the Portuguese language for Brazilian population (12).

Analysis of outcomes

Postoperative objective success was defined as absence of any urinary loss during full bladder standing Valsalva/cough maneuver and no need of pads, while subjective success was achieved when patients considered themselves much better or cured (Question: How do you feel today about your bladder problem comparing to before the surgery? Answers: cured, much better, better, unchanged, worse and much worse), the level of satisfaction was ≥ 8 (visual analogic scale from 0 to 10) and there was no report of

stress incontinence after surgery. Objective and subjective success rates were compared between the groups (high versus low mobility, low VLPP versus high VLPP). To analyze independent outcome influence of the two variables (mobility and VLPP), we also divided the patients into four subgroups: subgroup I, low mobility and high VLPP; subgroup II, low mobility and low VLPP; subgroup III, high mobility and high VLPP; subgroup IV, high mobility and low VLPP.

All terminology followed that proposed by the ICS (13). Statistical analysis was performed by a professional, applying the Student t-test or Mann-Whitney test for continuous variables, according to the distribution (parametric or nonparametric). The Chi-square test, Fisher's exact test or its extension were used for categorical variables. The results rendered significant if $p < 0.05$.

RESULTS

Among the 73 patients submitted to the TOT procedure, seven were excluded due to incomplete preoperative data (VLPP or urethral mobility) and 66 patients were included for analysis. Mean follow-up was 10 months (3 to 28). Mean age was 55 years (33 to 80), 70% were white and 30% African descendent, mean body mass index was 27 (21 to 38), average vaginal and abdominal deliveries were 2.8 and 0.5 respectively. A quarter had prior stress incontinence surgery. Overall, 94% and 79% of our patients were considered as a success according to objective and subjective success criteria, respectively. There were two cases of mesh extrusion to the vaginal wall and one case of erosion to the bladder neck. None of them presented local severe infection and were submitted to the correcting surgery electively. They were all healthy and continent on completion of follow-up.

Baseline characteristics (age, BMI, gestational status, preoperative ICIQ-SF, type of incontinence and previous incontinence surgery) had similar distribution when different groups were compared. These possible prognostic factors were individually analysed and had no influence on postoperative outcomes. Mean preoperative ICIQ-SF was 15.5 and 16.7 in patients with low and high mobility ($p = 0.2$ - Mann-Whitney's test), respectively.

Urethral hypermobility was an important determinant of objective success ($p = 0.04$), as just one patient with mobility $\geq 30^{o}$ failed therapy (Table-1). Subjective success rate was also higher in this group, but the difference did not reach statistical significance ($p = 0.07$). Conversely, VLPP had no role as prognostic factor, either when analysed as categorical variable (Table-2) or when numeric VLPP values were compared. In the objective success analysis, mean VLPP was 77 cmH_20 and 95 cmH_20 in successful and unsuccessful cases, respectively ($p = 0.21$ - Mann-Whitney's test). In the subjective success analysis, patients who failed therapy had mean VLPP similar to those who succeed (79.3 cmH_20 versus 73.6 cmH_20, respectively) ($p = 0.31$ - Mann-Whitney's test).

There was no statistical difference between mean postoperative ICIQ-SF in the presence of high and low mobility (mean 3.7 and 2.8, respectively) ($p = 0.16$).

In the subgroup analysis, patients with concomitant low mobility and high VLPP (subgroup I) had worse objective success rates when

Table 1 - Influence of urethral mobility on postoperative success rates.

Urethral mobility	Objective success - n(%)		p*	Subjective success - n(%)		p*
	Yes	No		Yes	No	
Mobility < 30º	13 (81)	3 (18.7)		10 (62.5)	6 (37.5)	
Mobility ≥ 30º	49 (98)	1 (2)	0.041	42 (84)	8 (16)	0.07
Total	**62 (94)**	**4 (6)**		**52 (78.8)**	**14 (21.2)**	

* Fisher's exact test.

compared to subgroup VI, those with hypermobility and low VLPP (Table-3). The former also presented lower rates of objective (p = 0.01) and subjective (p = 0.04) success in relation to the remaining of the studied population, subgroups II, III and IV (Table-4).

DISCUSSION

This paper reiterates the effectiveness of TOT for the treatment of SUI and has similar results to previously published data (14,15). Notwithstanding, as the number of surgeries per-

Table 2 - Role of Valsalva leak point pressure on postoperative success rates.

Valsalva leak point pressure	Objective success – n(%)		p*	Subjective success – n(%)		p*
	Yes	No		Yes	No	
≤ 60 cmH_20	23 (100)	0 (0)		17 (73.9)	6 (26.1)	
> 60 cmH_20	39 (90.7)	4 (9.3)	0.17	35 (81.4)	8 (18.6)	0.34
Total	**62 (93.9)**	**4 (6.1)**		**52 (78.8)**	**14 (21.2)**	

* Fisher's exact test.

Table 3 - Comparison between specific subgroups.

Subgroups	Objective success – n(%)		p*	Subjective success – n(%)		p*
	Yes	No		Yes	No	
Mobility < 30º and VLPP > 60 cmH_20	8 (72.7)	3 (27.3)		6 (54.5)	5 (45.5)	
Mobility ≥ 30º and VLPP ≤ 60 cmH_20	18 (100)	0 (0)	0.04	13 (72.2)	5 (27.8)	0.28
Total	**26 (89.7)**	**3 (10.3)**		**19 (65.5)**	**10 (34.5)**	

* Fisher's exact test.

Table 4 - Subgroups compared to the remaining of the studied population.

Subgroups	Objective success – n (%)		p*	Subjective success – n (%)		p*
	Yes	No		Yes	No	
Mobility < 30º and VLPP > 60 cmH_20	8 (72.7)	3 (27.3)		6 (54.5)	5 (45.5)	
			0.01			0.04
Other patients	54 (98.2)	1 (1.8)		46 (83.6)	9 (16.4)	
Mobility ≥ 30º and VLPP ≤ 60 cmH_20	18 (100)	0 (0)		13 (72.2)	5 (27.8)	
			0.27			0.31
Other patients	44 (91.7)	4 (8.3)		39 (81.2)	9 (18.8)	

* Fisher's exact test.

formed progressively increases in the contemporary scenario of minimally invasive procedures indicated more indulgently, surgeons frequently faces the difficult situation of a patient, with high expectations, with persisting incontinence after surgery. The need to refine selection criteria for TOT motivated us to conduct a study to shed some light on what are the determinants of postoperative outcomes, considering that they are imperfectly understood for the TOT procedure (introduced in 2001 by Delorme (3)) and that controversy exists about its efficacy in patients with sphincter deficiency. (7,16-19).

There are few prospective series addressing prognostic factors for TOT and results are conflicting (16). Minaglia (6) and Karateke (17) found that low urethral mobility was associated with higher rates of postoperative incontinence, while Paick (20) states the cure rate was not significantly lower in the group without a mobile urethra (< 30º). None of them concomitantly analysed the role of VLPP, although the last showed that mean VLPP was similar in patients with and without hypermobility. Two other studies concluded that VLPP was a prognostic determinant, but urethral mobility was not discussed (18,19).

To more adequately analyze the interaction between urethral mobility and sphincter intrinsic dysfunction (indicated by VLPP ≤ 60 cmH_20), we compared subgroups and demonstrated that high urethral mobility predicts cure, even when VLPP indicates a theoretically more dysfunctional sphincter. Low mobility was a predictor of failure even in women with good intrinsic sphincter function (high VLPP), although cure rates remain acceptable. This type of analysis seeks to circumvent selection bias, as analyzing urethral mobility or VLPP singly. A contemporary Turkish study had a similar conclusion (21).

Current evidence suggests not only that urethral hypermobility is equally common in women with lower urinary tract symptoms and SUI, but also that intrinsic sphincteric deficiency and urethral hypermobility may coexist and do not define discrete classes of patients with SUI (10). Additionally, previous reports demonstrate that correction of hypermobility is not required to obtain continence either for retropubic or transobturator sling procedure (14,22).

For all these reasons, urethral hypermobility should be no more considered an etiology of incontinence as leak of urine always implies some degree of sphincteric insufficiency. This expression was elaborated about half-century ago when suspension procedures were the rule, according to the belief that incontinence resulted from excessive downward movement of the urethra, leaving the abdominal cavity and leading abdominal pressure to be transmitted to the bladder and not to the urethra (23,24). The term itself is incorrect because "hypermobility" implies a mobility that exceeds normal values producing disease and, in reality, theses values are unknown (despite classic textbook teaching) and all evidence suggests high mobility does not cause incontinence. Accordingly, patients with SUI should be characterized by VLPP and urethral mobility, but not classified by them (4,10,16). Nonetheless, a general agreement in this issue has not been reached (11).

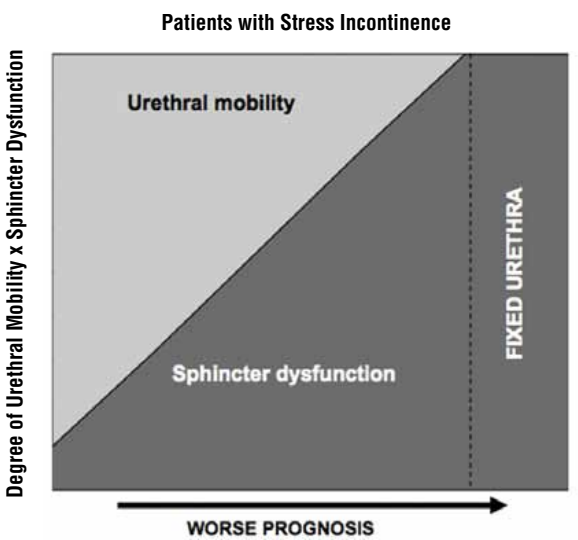
Theoretically, a successful sling procedure restores continence not by increasing resting urethral pressure but by providing a support the holds the mid-urethra in place while the proximal urethra descends under stress, allowing better pressure transmission and, more importantly, a kinking of urethra during straining (16,25). When urethra doesn't move well, this kinking does not occur. That's the advocated mechanism for urethral mobility as a prognostic factor. We propose a graphic to illustrate how sphincter dysfunction and urethral mobility interact to determine prognosis following sling procedure (Figure-1). Similar illustration has been presented in lectures and plenary sessions, but note that in this graphic SUI is not possible without some degree of sphincter deficiency.

This study presents several limitations including the low number of subjects, short follow-up time and lack of multivariable analysis, but it was clearly possible to demonstrate and differentiate prognostic influence of urethral mobility from VLPP.

Finally, this paper also addresses subjective improvement and, interestingly, some of the differences favoring urethral mobility as a prognostic factor were not significant when subjective success rates were compared. Although this may seem discordant initially, subjective success allows a wider

and deeper evaluation of response to treatment as it takes into account patient's satisfaction and opinions. The lower subjective success rates may be explained by diverse patient's expectations that would not be accomplished by the sling procedure. Therefore, subjective success depends on how well patients are informed about the goals of surgical treatment. More cases will probably be needed to render differences, according to subjective success criteria, significant.

Figure 1 - Prognostic interaction between urethral mobility and sphincter dysfunction in women with SUI after sling procedure. Note that some degree of sphincter dysfunction is required for incontinence to occur.



CONCLUSIONS

Urethral mobility was an important prognostic factor for TOT surgery. Low urethral mobility predicts higher failure rates, but it does not preclude surgery as most of these patients are cured following the procedure. No association was found between postoperative outcomes and preoperative VLPP.

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CONFLICT OF INTEREST

None declared.

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Correspondence address:
Dr. Luís Gustavo M. Toledo
Rua Aimberê, 909 / 104
São Paulo, SP, 05018-011, Brazil
Telephone: +55 11 3673-5385
E-mail: luisgtoledo@uol.com.br