Surgical treatment of stress urinary incontinence with a Mini Sling (OPHIRA™) – a pilot study

Tratamento cirúrgico da Incontinência Urinária de Esforço com o minisling OPHIRA – um estudo piloto

Joana Espagiari Marra[1], Guilherme P. Mendes[1], Rafael M. Moroni[2], Pedro S. Magnani[3], Heitor L. P. Rodrigues[3], Francisco Jose Candido-dos-Reis[4], Luiz Gustavo O. Brito[5]

ABSTRACT

Design of the study: Cross-sectional. **Objectives**: To evaluate the efficacy of minisling (Ophyra ™) in women with stress urinary incontinence (SUI). **Methods**: A prospective, observational study comprised 13 patients who underwent minisling surgery from 2010 to 2011. It was analyzed the following variables: age, subjective success rate (cure and/or improvement), immediate and late surgical complications. Quality of life (QoL) parameters (King's Health Questionnaire - KHQ) were analyzed before and after one year of surgery. **Results**: Thirteen per cent (3/13) of women had their SUI relapsed, with 87.5% of subjective success after one year of follow-up. After 12 months of follow-up, women who were considered subjectively cured had improvement in all domains of KHQ QoL scores, except for personal relationships and sleep/energy domains. Four patients had irritative symptoms after surgery and two patients evolved with chronic urinary retention. **Conclusion**: Minisling Ophira was effective to improve SUI and to promote better QoL on women with SUI. A larger sampling is needed to further compare these patients with women who underwent to classic retropubic techniques.

Keywords: Mini Sling. Urinary Incontinence, Stress. Quality of Life. Kings Health Questionnaire.

Introduction

The surgical treatment of stress urinary incontinence (SUI) has been evolving to a minimal, less traumatic invasivity. Synthetic grafts have been replacing traditional procedures, such as Burch colposuspension or autologous slings, and efficacy has been maintained. More than one hundred surgeries were

1. Medical Student. Ribeirão Preto School of Medicine, University of São Paulo (FMRP-USP), Ribeirão Preto, Brazil
2. Post-Graduation Student, Department of Gynecology and Obstetrics, FMRP-USP
3. Attending Physician, Department of Gynecology and Obstetrics, FMRP-USP
4. Associate Professor, Department of Gynecology and Obstetrics, FMRP-USP
5. Attending Physician, Post-Graduation Professor, Department of Gynecology and Obstetrics, FMRP-USP

Address for correspondence:
Luiz Gustavo O. Brito
Department of Gynecology and Obstetrics, FMRP-USP
Avenida Bandeirantes, 3900 – 8th floor – Monte Alegre
Zipcode 14049-900 – Ribeirão Preto – SP – Brazil

Artigo recebido em 30/10/2013
Aprovado para publicação em 26/02/2014

 DOI: http://dx.doi.org/10.11606/issn.2176-7262.v47i4p394-398

created and we do not have an ideal condition to correct this disease, prevalent in 30%-50% of women older than 60 years.[1]

Synthethic retropubic slings were performed by Petros and Ulmsten[2], initiating the placement of free tension vaginal tapes; a second-generation mid-urethral sling (MUS) group was developed, with transobturator *out-in* approach described by Delorme in 2001[3] and DeLeval performed it in a opposite way (*in-out*)[4], reducing intraoperative complications and causing similar objective and subjective cure rates. However, they are still seen, p.ex. bladder and/or urethral injuries, vascular hemorrhage.

Single-incision mini slings (SIMS) are the third generation MUS group and were created with the concept of using a shorter sling, avoiding the risk of muscle perforations and minimizing the intra-operative risks. There are at least four types of SIMS: TVT-Secur ™ (Ethicon, Edinburgh, UK), MiniArc ™ (American Medical Systems, Minnetonka, MN, USA) Ajust ™ (C.R. Bard, Murray Hill, NJ, USA) and Ophira ™ (Promedon, Cordoba, Argentina).

TVT-Secur presents an absorbable material in its distal shaft; MiniArc has a self-anchor shaft; Ajust has one fixed and other adjustable anchors; Ophira has two fixed anchors. Initially all SIMS was thought to be as low efficacy; however, studies are showing similar cure rates than synthetic MUS.

Experimentally, Ophira has shown the best fixation after seven days of surgery among other SIMS.[5] Quality of life is another parameter of greater importance that should be included in post-operative assessment. However, we do not have larger prospective trials published in medical literature about this specific mini sling. In this pilot study, we are aiming to analyze the efficacy of a SIMS (Ophira™) inserted in women with SUI after one year of treatment.

Methods

Participants and study design

A prospective, pilot study was carried out at the "Hospital das Clínicas de Ribeirão Preto da USP" with all female patients with SUI confirmed by urodynamics with mild to moderate symptoms (uretral hypermobility subtype). They were about to be submitted to surgical treatment and after signing informed consent they filled out Kings Health Questionnaire translated and validated to Portuguese language [6] about their urinary symptoms. Answers were classified according to Likert scale, where 0 was the absence of complaints and 100 the worst complaint at the question.

All patients who refused surgery and did not want to participate in this research were forwarded to pelvic muscle treatment. It was excluded patients with previous surgery for SUI, grade III obesity (BMI higher 40 kg/m^2), with uncontrolled comorbidities (hypertension, diabetes), normal urodynamics, genital prolapse POP-Q equal or higher than grade 2.

Surgery

All patients were operated with regional anesthesia. A vertical 3-cm incision was made, with a 1.5 cm distance from urethral meatus. A polipropilene type 1 tape was positioned at a U distance, without perforation of the obturatory membrane. Anterior vaginal wall was closed with poliglecaprone 25 4.0 with continuous suture. Women were assessed at immediate post-operative period, with 3, 6 and 12 months after procedure. KHQ was applied after twelve months of treatment. Subjective cure rate was defined as a partial/total improvement after surgery when asked the patients.

Statistics

Data was analyzed at SPSS statistical package (Version 10.0 for Windows, SPSS, Chicago, IL, USA). Data are presented as mean ± standard deviations and percentages. About KHQ analysis, paired t-test was utilized to assess if there was improvement of SUI symptoms. A p value of 0.05 was considered as statistically significant.

Results

Thirteen patients were evaluated in this research. Mean age was 52.75±12.02 years (range 32-72), and half of them had obesity grade I. Most prevalent complaints were: stress urinary incontinence and urgency incontinence. Irritative symptoms were found in half of the patients. One quarter of women presented objective urine loss and a large percentage had associated genital prolapse (Table 1).

When analyzing KHQ, it was found an improvement statistically significant on these women in

all domains, except in social limitations, personal relationships and sleep/energy domains (Table 2). After one year, women referred a subjective improvement of 87.5% in SUI, with three relapses after this period. As complications, four patients had irritative symptoms after surgery and two patients with urinary chronic retention. None of the patients had tape erosions.

Discussion

In this pilot study, we have verified that minisling Ophira had improved life quality in patients with SUI, with a great improvement in general score in most of them and causing a better life quality. The greatest impact was noticed in incontinence score, with reinforces its importance as anti-incontinence

Table 1: Urogynecological symptoms and physical findings before and after one year of surgery.

Variables	N (%) - before	N (%) - after
Stress urinary incontinence	13 (100%)	3 (12.5%)
Urgency incontinence	7 (53.8%)	3 (12.5%)
Urgency	6 (46.2%)	4 (30.8%)
Nocturia	6 (46.2%)	0
Increased daytime urinary frequence	5 (38.5%)	0
Nocturnal enuresis	4 (30.8%)	Ignored
Incomplete bladder emptiness	4 (30.8%)	Ignored
Urine insensible loss	4 (30.8%)	Ignored
Coital incontinence	1 (7.7%)	Ignored
Dysuria	1 (7.7%)	Ignored
Necessity of effort maneuvers to end micturition	1 (7.7%)	0
Distal defect	8 (61.5%)	Not applied
Anterior defect – all grade I	5 (38.5%)	35 (38.5%)
Apical defect	4 (30.8%)	Not applied
Objective urine loss	3 (23.1%)	0

Table 2. – Preoperative and postoperative Kings Health Questionnaire (KHQ) data in 13 women undergoing Ophira for SUI.

Domains of KHQ	Mean before	Mean after	p value*
General health	56.25	21.88	0.052
Incontinence Impact	100.00	25.00	0.008
Role limitations	59.38	12.82	0.024
Physical limitations	55.63	10.62	0.042
Social limitations	44.37	41.75	NS
Personal relationships	51.76	49.80	NS
Emotions	60.23	51.80	NS
Sleep/energy	42.13	39.34	NS
Severity measures	48.20	29.11	0.058

* paired t-test

device. Morbid obesity was an exclusion criteria because we still do not know if in this group of patients a smaller graft would be a risk factor for relapsing SUI. So, we preferred to include patients without this physical characteristic.

Minislings are being compared with traditional methods such as transobturator and retropubic slings. A study comparing Miniarc with Monarc (transobturator sling) found no differences in the treatment of patients with SUI.[7] The same minisling had a prospective, non-comparative study with 119 patients followed after 12 months of surgery, and 80% were cured and 11% showed improvement. A recent RCT comparing Ajust (SIMS) with TVT-O (MUS) showed similar patient-reported and objective cure rates (85.5% versus 91.2%; 90% versus 97%, respectively), with shorter stay and earlier return to normal activities and work for SIMS group.[9] A long-term postoperative trial (5 years) comparing TOT sling and a tissue-fixation system (TFS) showed a better efficacy for TFS system (83% vs 75%) than TOT slings.[10]

All SIMS present differences regarding their structure and anchoring systems, which makes the task to compare them a difficult one. Furthermore, literature does not have enough research with this type of synthetic material. The first RCT data on a minisling was from a study from Basu et al. [11] when they compared TVT with MiniArc and they have found that SIMS had a lower efficacy rate; however, follow-up was only of 6 months. However, newer researches were presented [9,10], and showed a higher efficacy, but we still do not know what is the best indication for these tapes. A non-inferiority trial comparing minisling with TVT on 263 patients showed similar subjective cure rates in both groups with greater postoperative incontinence severity with the minisling than the TVT.[12] Another research with TVT-Secur in office with local anesthesia showed a success of 80%.[13]

Recently, an abstract published shown at IUGA Congress about Ophira in a multicentre trial, showed that from 124 patients who were operated, using the pad test as an objective cure pattern, 85.3% of patients were dry[14], with no cases of sexual dysfunction, severe bleeding, infection. Four patients had urinary retention. They also evaluated quality of life with ICIQ-SF and UDI-6, with improvement on SUI scores.

About postoperative complications, almost a third of the group presented overactive bladder symptoms, which was seen in previous studies[8,9,10]; also, a recent multicenter study showed 7.3% of *de novo* urgency.[14] We did not have any tape erosions, probably due to small sampling.

This research showed that Ophira mini sling had an efficacy rate in a short time, with similar efficacy rates of traditional sling in SUI. It is not known if relapse may occur in a longer period. One hypothesis is that multipoint fixation arms provide stable fixation of the sling for a long period. We hope to increase the number of followed patients and see if these results maintain.

Acknowledgments

We would like to thank FAEPA (Fundação de Apoio ao Ensino, Pesquisa e Assistência do HCFMRP-USP) and PIBIC-CNPq/FMRP-USP for the scientific initiation scholarship for the students.

RESUMO

Desenho do estudo: Transversal. **Objetivos:** Avaliar a eficácia do minisling Ophyra ™ em mulheres com incontinência urinária de esforço (IUE). **Métodos:** Estudo prospectivo, observacional, que abrangeu 13 pacientes que realizaram cirurgia de minisling entre 2010 e 2011. As seguintes variáveis foram analisadas: idade, taxa subjetiva de sucesso (cura e /ou melhora), complicações cirúrgicas imediatas e tardias. Os parâmetros de qualidade de vida (King's Health Questionnaire - KHQ) foram analisados antes e depois de um ano de cirurgia. **Resultados:** Treze (3/13) por cento das mulheres recidivaram a IUE, com 87,5% de sucesso subjetivo depois de um ano de seguimento. Depois de 12 meses de seguimento, as mulheres foram consideradas subjetivamente curadas em todos os domínios dos questionários de qualidade de vida KHQ, exceto por relações pessoais e domínio de sono/energia. Quatro pacientes tiveram sintomas irritativos depois da cirurgia e duas pacientes com retenção urinária crônica. **Conclusão:** O minisling Ophira foi efetivo para melhorar a IUE e promover melhor qualidade de vida em mulheres com IUE. Maior amostragem é necessária para posteriormente comparar essas pacientes com mulheres que foram submetidas a técnicas retropúbicas clássicas.

Palavras-chave: Mini Sling; Incontinência Urinária de Esforço. Qualidade de Vida. Kings Health Questionnaire.

References

1. Thomas TM, Plymat KR, Blannin J, Meade TW. Prevalence of urinary incontinence. Br Med J. 1980; 281:1243-5.

2. Petros P, Ulmsten U. An integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephrol. 1993;153:1-93.

3. Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of urinary stress incontinence in women. Prog Urol. 2001;1:1306-13.

4. De Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. Eur Urol. 2003; 44:724-30.

5. Palma P, Siniscalchi RT, Maciel LC, Bigozzi MA, Fabbro ID, Riccetto C. Primary fixation of mini slings: a comparative biomechanical study in vivo. Int Braz J Urol. 2012;38:258-66.

6. Tamanini JT, D'Ancona CA, Botega NJ, Rodrigues Netto N Jr. Validation of the Portuguese version of the King's Health Questionnaire for urinary incontinent women. Rev Saúde Publica. 2003;37:203-11.

7. De Ridder D, Berkers J, Deprest J, Verguts J, Ost D, Hamid D, Van der Aa F. Single incision mini-sling versus a transobturator sling: a comparative study on MiniArc and Monarc slings. Int Urogynecol J. 2010; 21:773-8.

8. Oliveira R, Botelho F, Silva P, Resende A, Silva C, Dinis P, Cruz F. Single-incision sling system as primary treatment of female stress urinary incontinence: prospective 12 months data from a single institution. BJU Int. 2011;108:1616-21.

9. Mostafa A, Agur W, Abdel-All M, Guerrero K, Lim C, Allam M, et al. A multicentre prospective randomized study of single-incision mini-sling (Ajust) versus tension-free vaginal tape-obturator (TVT-O) in the management of female stress urinary incontinence: pain profile and short-term outcomes. Eur J Obstet Gynecol Reprod Biol. 2012 Aug 20 Epub ahead of print].

10. Sivasloglu AA, Unlubilgin E, Avdogmus S, Keskin L, Dolen I. A prospective randomized controlled trial of the transobturator tape and tissue fixation mini-sling in patients with stress urinary incontinence: 5-year results. J Urol. 2012;188:194-9.

11. Basu M, Duckett J. A randomized trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence. BJOG 2010;117:730-5.

12. Barber MD, Weldner AC, Sokol AI, Amundsen CL, Jelovsek JE, Karram MM, Ellerkmann M, Rardin CR, Iglesia CB, Toglia M. Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol. 2012;119:3 28-37.

13. Khandwala S, Jayachandran C. TVT-Secur in office sling procedure under local anesthesia: a prospective 2-year analysis. Female Pelvic Med Reconstr Surg. 2012;18:233-8.

14. Palma P, Riccetto C, Bronzatto E, Hermann V, Dalphorno F, Castro R, Altum S. Efficacy of Ophira Minisling System for stress urinary incontinence: midterm follow up of 124 patients in a multicentre international clinical trial. Int Urogynecol J 2012;23(Suppl.20):S212.