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COMPARISON OF SAFETY AND EFFICACY BETWEEN SURGICAL PROCEDURES WITH APONEUROTIC AND TRANSOBTURATORY SLING (SAFYRE? – T) IN PATIENTS WITH STRESS URINARY INCONTINENCE (SUI)

Objectives:
To evaluate efficacy and safety between conventional aponeurotic sling and re-adjustable transobturatory sling (Safyre™-T) in women with stress urinary incontinence (SUI).

Background: Autologous sling has been the standard procedure for surgical treatment of stress urinary incontinence. However, the development of synthetic meshes, in order to restore urethral sustaining, has shown to decrease post-operatory morbidity and intra-operatory complications, such as bladder perforation. Transobturatory slings aroused in 2001 with Delorme's demonstration and have obtained satisfactory results in a median follow-up period.

Methodology:
A retrospective and observational study was designed, totalizing 463 patients. Two hundred and three women realized transobturatory (TOT) sling for SUI confirmed urodinamically between 2003 and 2009. In that same period, 260 patients performed aponeurotic sling. This research was approved by the local Ethics Committee. Preoperative evaluation included detailed history, physical examination, urinalysis and urodynamic study. The urodynamic evaluation was performed with the patient in a sitting position. The test included physiologic serum cystometry, Valsalva Leak Point Pressure (VLPP) assessment. It was analyzed the following variables: age, BMI, success rate (cure and/or improvement), immediate and late surgical complications, and number of patients who underwent re-operations for SUI. After the surgical procedure, patients were evaluated at 7, 40, 90, 180 and 360 days of post-operatory.

Results:
In the aponeurotic sling group, median age was 52(26-91) years old. Thirty-five per cent of the patients were in the menacme period; 26% of women had more than ten years of menopause. Obesity was present in 44.3% of women. Sixty-eight per cent of the patients had a diagnosis of sphincter deficiency and 32% had urethral hypermobility. At presentation, 45% of the patients, in average, had already undergone other gynecological surgeries. Overall success rate was 88%. The intraoperative complications consisted of three bladder lacerations (1.15%) and three urethral lesions (1.15%); chronic urinary retention was present in 10%(n=27) of cases, in which half of them were submitted to urethrolysis; abdominal wound infection or dehiscence were found in 16% of patients. Fifteen (5.7%) patients performed a second surgery for SUI. Mean surgery time was 112 minutes. About TOT sling group, the median age was 54 (29-85) years old, with no statistical differences between aponeurotic sling group regarding reproductive period, BMI and subtype of SUI. Ninety-four per cent of the patients were considered cured or had their SUI decreased. Ten (4.9%) women readjusted TOT sling after primary surgery; half of them became continent. Eight (3.94%) patients had partial tape erosions; seven were surgically corrected and one patient used topic estriol therapy. About immediate complications, there were three bladder lacerations. Chronic morbidities were less prevalent: 4 (1.97%) hematomas, 3 (1.47%) dehiscences of vaginal suture, 6 (2.95%) cases of urinary retention, 3 (1.47%) vaginal wound infections. Mean surgery time was 23 minutes.

Conclusion:
Transobturatory sling has showed less immediate and late surgical complications, probably due to its less invasiveness and similar success rates of treatment of SUI in comparison with aponeurotic sling. It is important to observe a longer follow-up of these patients in order to notice a change in success rates of cure/subjective improvement of SUI.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Comitê de Ética em Pesquisa do Departamento de Ginecologia e Obstetrícia da Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo e Comitê de Ética em Pesquisa do Hospital das Clínicas da FMRP-USP**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**