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A SAFETY AND QUALITY OF LIFE ANALYSIS OF INTRAVAGINAL SLINGPLASTY IN FEMALE STRESS INCONTINENCE: A PROSPECTIVE, OPEN LABEL, MULTICENTER, AND OBSERVATIONAL STUDY

Hypothesis / aims of study

The intravaginal slingplasty (IVS) is a tension-free vaginal tape variant that uses a multifilament polypropylene tape to support the mid urethra for the treatment of female stress incontinence. Although many practitioners prefer to use monofilament mesh because of the mesh pore size, recent data have been reported that the infection and erosion after multifilament mesh sling procedure are almost same as monofilament mesh [1,2]. The purpose of this prospective, open label, multicenter, and observational study was to determine the efficacy, safety, and the impact of this procedure on the current quality of life.

Study design, materials and methods

The IVS procedure was carried out on 103 female patients with stress incontinence. The age range was from 37 to 77, mean age 51 years. All patients underwent assessment including history and physical examination, Incontinence Quality of Life questionnaire (I-QoL), 3-day consecutive frequency-volume chart, stress test, pad test, and multichannel urodynamic study before surgery. If appropriate, surgery for genital prolapse was performed. Post implant evaluation was done at 1, 3, and 12 months. The post operative evaluation consisted of clinical examination, I-QoL, 3-day consecutive frequency-volume chart, free flowmetry, and measurement of post void residual (PVR). At that time, complete cure was defined as the absence of stress incontinence confirmed by both perception of patient and examination of the patient with a full bladder. If the patients reported stress incontinence alone or in combination with either urge incontinence, this was taken as indicative of failure. I-QoL was analyzed with total and three subscale scores (avoidance and limiting behaviors, psychosocial impacts, and social embarrassment).

Results

83 patients have completed 12 months follow up and are included in this interim analysis. Mean abdominal leak point pressure was 99.7±34.0cmH_2O (range 28-135cmH_2O). Patient assessment of continence revealed 86.7% (72/83) cure rate (completely dry). During follow up period, one patient (1.2%) has presented with vaginal erosion of the sling material. The mesh was surgically removed and no incontinence was noted thereafter. Preoperatively, mixed incontinence with detursor overactivity was noted in 10 patients and all of them did not have any storage symptoms at 12 months follow up. De novo urge incontinence developed in 2 (2.4%). The maximum flow rate and post void residual were not different between pre-operative and 12 months follow up. Based on frequency-volume chart, the frequency was reduced from 9.2±3.1 to 7.7±2.0 ($p<0.01$) and the nocturia was reduced from 1.3±1.2 to 0.8±0.9 ($p<0.01$). The I-QoL showed significant improvement in total and three subscale scores at 12 month follow up period (Table 1).

Table 1. Comparison of I-QoL scale scores

	Pre-op	Post-op 12 months	p value
I-QoL total	61.5±20.7	94.4±16.7	p<0.001
I-QoL			
Avoidance behaviors	46.5±23.4	82.7±18.6	p<0.001
Psychological impacts	49.5±25.8	84.1±19.7	p<0.001
Social embarrassment	36.2±27.6	79.1±21.9	p<0.001

Interpretation of results

This study has confirmed that the IVS procedure successfully restores continence in female patients with stress incontinence at 12 months follow up. Continence rate (completely dry) was 86.7%. The incidences of complications such as vaginal erosion are rare. Also, the analysis of I-QoL demonstrates that the IVS procedure improve quality of life significantly in all aspects.

Concluding message

This study demonstrated that the IVS procedure provides a safe and effective means for the treatment of female stress incontinence and improve QoL.

References

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HUMAN SUBJECTS: **This study did not need ethical approval because every involved physicians in this study has doing IVS procedure for the treatment of stress incontinence. So, we did not need ethics committee approval. but followed the Declaration of Helsinki Informed consent was obtained from the patients.**