

## **“MACROPLASTIQUE IMPLANTATION SYSTEM” – MIS FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE**

### **Aims of Study**

Urinary incontinence (UI) is a distressing, disabling and costly condition, which causes impairment on several aspects of the quality of life<sup>1</sup>. Periurethral injections are less invasive and easily performed with local anesthesia in outpatient setting. Since the mid-70's researches have been made to find out the ideal bulk agent for periurethral injections. The objectives of the present study is to verify the results of “Macropastique Implantation System”-MIS in female patients with stress urinary incontinence secondary to intrinsic sphincter deficiency (ISD).

### **Methods**

Twenty one women with urodynamically diagnosed stress urinary incontinence secondary due to intrinsic sphincter deficiency were recruited. All the patients were treated on a one day basis. The informed consent was obtained after complete explanation of the procedure. Ages ranged from 33 to 54 (median 48 years), mean body mass index was 25.65 kg./m.<sup>2</sup> (range 19.5 to 29.2), and nine out of 21 patients (42,9%). were in per or post menopausal period. The mean duration of UI complain was 12.3 years (range 2 to 22) and the median parity was three (range 0 to 8). Only four patients (19%) undergone previous surgical treatment for UI. At baseline, the patients were assessed by anamnesis, physical examination, pad usage, urodynamic study (Valsalva Leak Point Pressure – VLPP ) standardized one-hour pad weight test (PWT), Stamey grading of incontinence and “KING'S HEALTH QUESTIONNAIRE” (KHQ)<sup>1</sup>. Follow up was performed at 12 months.

### **Results**

A total of 29 procedures was performed in 21 women; eight out of 21 patients (38.1%) underwent re-injection. The median and mean volume injected was 5 and 6.3 ml respectively (range 5 to 10). The most common adverse effect was transient dysuria and pain at the implantation site. Pad usage was reduced from 4.38 to 1.29 units/day and pad weight test reduced from 53.78 g to 8.07 g of urine ( $p < 0.001$ ). Assessed by VLPP, eight (38.1%) were dry, one (4.8%) improved, one (4.8%) rejected urodynamic study and the remaining 11(52.3%) had urinary leakage at urodynamic study. According to the PWT, 13 patients (61.9%) were cured, four (19%) improved and four (19%) failed. After 12 months follow up, cure was observed in 12 (57.1%) patients by self-assessment and eight (38.1%) by subjective surgeon assessment. Kappa index reported a moderate agreement between surgeon's and patient's perception of cure/improvement. Wilcoxon's matched pair test was statistically significant between baseline and 12 months follow up ( $p < 0.05$ ) for all domains and most of urinary symptoms.

### **Conclusions**

Endoscopic injection of silicone elastomers were used for the treatment of stress urinary incontinence with cure/improvement rates, ranging from 74 to 90% (early follow up) and 48 to 59% at late follow up<sup>2</sup>. The overall success rate of the procedure was 66.7% (cure/improvement), which is comparable to the reported data<sup>3</sup>. Therefore, it makes it difficult to compare our results, since the procedures and outcome methods of assessment are different. Despite of having found 38,1% of objective cure rate in our trial, subjective cure rate was reported as 57.1%. This distinct result clearly shows that depending on the study methodology and the cure criteria used, the final outcome can change widely. In our study, the results from KHQ showed significant difference in all domains and in most urinary symptoms. These subjective results clearly demonstrated patient's satisfaction with the procedure. Injection therapy offers potential advantages over open surgery, including shorter operation time, apart from being minimally invasive and it doesn't increase difficulties in further treatment. Our results are difficult to compare with those published in the literature because patient selection, length of follow up and study methodology varied widely<sup>4</sup>. Due to the high satisfaction rate stated by our patients according to KHQ and patient self-assessment, we encourage the use of this innovative technique for transurethral injection therapy.

### **References**

1. Br J Obster Gynaecol 1997, 104: 1374-9.
2. J Urol 2000, 164: 1619-22.
3. Obstet Gynecol 1998, 92: 332-6
4. Neurourol Urodynam 2000, 19: 127-35.