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IS THE MINIARC® MINI-SLING SYSTEM A VALID OPTION IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE?

Hypothesis / aims of study

Ever since its introduction twelve years ago, the retropubic sling of the mid-urethra has become the gold standard technique for female stress urinary incontinence. In spite of the associated risks, this was mainly due to its considerable efficacy. Recent studies have shown that the obturator technique has the same results involving fewer complications. The introduction of the mini-slings of the mid-urethra greatly expands this concept, by reducing the pathway of the tape inside the organism, avoiding going through the obturator foramen, considerably decreasing visceral lesions and by sparing the external incisions.(1) However, we still lack the proper clinical data that will reinsure its efficacy. Our purpose is to evaluate the results after one year's follow-up of the MiniArc® mini-sling system in our patients.

Study design, materials and methods

Retrospective study of a total of 87 women with mixed (MUI) or stress urinary incontinence (SUI) treated by placement of the MiniArc® single-incision sling. These patients underwent surgery between January 2008 and June 2009 at our Department. The parameters analyzed from the patient files were: age, body mass index (BMI), personal history, type of incontinence, anesthetic technique, duration of the intervention, complications (intra-operative, post-operative and up to one year), duration of admission, associated procedures, post-operative cough stress test. Authors then studied one-year follow up cough stress test and subjective results (great or little satisfaction with the procedure) plus QoL evaluation, by using ICIQ-SF test before and after surgery. A descriptive analysis has been performed, as well a comparative study using □*2* Test and Fisher´s Exact Test. SPSS software (V17.0) was used. Results were considered relevant for a p<0.05.

Results

Study group: Mean age: 56.2 years (32-81); Mean BMI: 26.3 Kg/m^2 (18.0-34.9); Nullipara rate 3/83 (3.6%). 75/83 (90.4%) had prior vaginal deliveries; 55/84 (65.5%) had relevant co morbidities; 55/87 (63.2%) had SUI and 32/87 (36.8%) MUI.

Procedure: Patients underwent general anesthesia or sedoanalgesia. Mean duration of surgical procedure was 10 minutes. No intra-operative complications occurred. 59 (67.8%) patients had an outpatient surgery with a mean duration of stay equal to eight hours and 28 (32.2%) were admitted to the infirmary and underwent surgery in the central operating theatre with a mean duration of stay of about twenty four hours. 14 (16.1%) of the women, all included in this last subgroup, underwent another vaginal procedure in the same episode.

Follow-up: 65 (74.7%) of the women did not have any complaints post-operatively. The remaining 22 (25.3%) had transient minor complaints not requiring specific treatment, by decreasing order: local pain (16), urinary retention (5), irritability symptoms (2) and bleeding above 30ml (1). The intensity of pain in those 16 cases was average 2.9 (answers from 1 to 5) in a pain scale ranging from 1 to 10. In 72 (88.9%) cases there were no complications during the one-year period. The complications were, again orderly: recurrent UTI (7), dyspareunia (1) and tape dislocation (1). The stress test was negative in 79 (90.8%) cases, with similar results obtained one year after surgery 68/82 (82.9%). 67/81 (82.7%) patients are very satisfied with the proceeding with overall 72/81 (88.9%) mentioning improvement or complete cure. Average ICIQ-SF score prior to surgery, one month and one year after surgery was respectively 15.09, 2.78 and 3.05.

Comparative study: There were no statistically significant differences between the objective results from the post-operative period and one year after surgery (p=0.13). Using the chronologic order of surgeries, and dividing the target population into two subgroups: earlier surgeries and later surgeries, and comparing its one year results, no differences could be found (p=0.12). Regarding the subjective results, the satisfaction index one year after surgery shows differences according to the type of urinary incontinence (p=0.015), applying the same for the ICIQ-SF scores (p=0.000) with worse results in MUI.

Cough stress test	Negative	Positive
Post-operative	79 (90.8%)	8 (9.2%)
One year	68 (82.9%)	14 (17.1%)
p=0.13		

Cough stress test (at one year)	Negative	Positive
Patients satisfaction (at one year)	High	Low
From January 2008 to May 2008 (first 44 patients)	39 (76.7%)	11 (23.3%)
From June 2008 to July 2009 (last 43 patients)	47 (90.4%)	5 (9.6%)
p=0.12		
ICIQ-SF score (at one year)		
SUI	48 (83.6%)	9 (16.4%)
MUI	20 (69.0%)	9 (31.0%)
p=0.015		
Patients satisfaction (at one year)		
SUI	46 (85.2%)	8 (14.8%)
MUI	13 (40.6%)	19 (59.4%)
p=0.000		

Interpretation of results

This minimally invasive procedure showed to be efficient in the treatment of stress urinary incontinence with high success rates at one-year follow-up (82.9%). This rate is similar to the few existing published papers (69.1%, 77.8%, 85%, 90.2% and 91.4%).(1) (2) (3)

The lack of statistically significant differences between objective results (cough stress test) in post operative period and one year after surgery demonstrates the short and medium term efficacy of this technique.

When analyzing the results in two groups, according to a temporal order of performance, the first and second halves of the population presented different results. In spite of not being statistically significant (76.7% and 89.7%, respectively), these results seem to be very promising, as they suggest that overall success rate might have been potentially penalized by the learning curve period, therefore underscoring this mini-sling's real maximum potential.

The overall satisfaction rate is high, but there are differences related to the type of incontinence showing a connection between urgency symptoms diagnoses before surgery and worst subjective results.

The low morbidity rates, usually presenting as benign and transient symptoms confirm the safety of this mini-sling.

Concluding message

The MiniArc® mini-sling will prove to be a valid option in the future surgical management of female urinary stress incontinence with similar success rates to other first line procedures and fewer complications.

References

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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?	**No**
This study did not require ethics committee approval because	**It was a retrospective study using pacients files. All patiens signed informed consents.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**