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ULTRASONIC ASSESSMENT OF MINIARC™.

Hypothesis / aims of study

MiniArc™ is a device composed of a suburethral polypropylene tape anchored trough integrated self fixating tips to the obturator membranes. The mechanism of action is based on urethral tension free support and it is intended for the treatment of female stress urinary incontinence (SUI) caused by urethral hypermobility and intrinsic sphyncter deficiency. The ideal position of the tape, according to Ulmsten and Petros theory should be at the mid-urethral level. Aim of this study is to assess the mechanism of action of MiniArc™ tape through an ultrasonographic examination of patients who underwent the procedure.

Study design, materials and methods

We included in this study all the patients from our urogynecology clinic eligible for SUI surgical correction and treated between March and October 2008. MiniArc™ when associated with other procedures was always performed as last step, in order to ensure a correct positioning and avoid a possible displacement. According to our clinical protocol the preoperative assessment of the patients consisted of a clinical and physical evaluation (including Q-tip test) and a urodynamic study (uroflowmetry, cystometry, stress test and pressure-flow study). Postoperative assessment consisted of a clinical and physical evaluation 1, 2, 6 and 12 months after surgery while urodynamics were repeated twice (2^{nd} and 12^{th} month). A perineal ultrasonography (PU) was performed between 2 and 12 months of follow up. PU was performed with patient in lithotomic position at a bladder filling of 100mL by placing the ultrasound probe translabially in order to visualize in a sagittal projection the lower margin of symphys, the urethra, the anterior vaginal wall and the urethrovesical junction (UJ) (1). Images were stored at rest and during Valsalva maneuver at the edge of the effort. Aim of this procedure was to visualize the lower urinary tract and to localize the MiniArc™ tape in the tickness of anterior vaginal wall. For each patient we collected static and dynamic measurements. Static measurments consisted of: (A) total urethral lenght (UL), (B) tape distance from UJ (dUJ), (C) rate R = dUJ / UL. Dynamic measurements (took at rest and during Valsalva) were referred to a Cartesian coordinate system where the origin was a fixed point corresponding to the lowest margin of the symphys. With this methodology we assessed UJ and tape oblique descent according to Pythagoras theorem ($c^2 = a^2+b^2$).

Results

Within the study period 30 patient underwent the procedure and out of this group 29 completed the follow up (1 patient was lost). Population characteristics included a mean age of 56 years (standard deviation: SD = 13.1), mean BMI 27 (SD = 5.2) and mean parity 2 (SD = 1.1). Preoperatively all the patients had a hypermobile urethra (Δ>30°at Q-tip test) and 4 patients (13.3%) had a concomitant correction of anterior compartment defect. Mean follow up at the date of PU was 7.7 months (SD=3.4, min 2 max 12). Clinical results revealed a complete resolution of SUI (patient dry) in 25 cases (86.2%) while in 4 patients (13.8%) SUI was still present. No complications related to MiniArc™ procedure were observed during the study period. Static and Dynamic ultrasonosgraphic findings are showed in table 1.

Interpretation of results

In this descriptive study we correlated the short term clinical outcome of a “third generation” tension free vaginal sling procedure to the ultrasonographic description of tape position and mobility. Static parameters included a measurement of UL that showed a wide range of variability without being correlated to tape position. R represents a valid parameter independent from UL useful to describe the sub-urethral location of the tape in an interval comprised between 0 (tape close to UJ) and 1 (tape close to distal urethra). In our population we found the tape closer to mid-urethra (R=0.5) in the treated group, while in the failure group tape was closer to UJ (R=0.3), that could mean that there is a higher risk of failure when the tape is located too close to UJ. Dynamic parameters revealed a wider displacement of both UJ and tape in the failures group. In both groups of patients it was observed an excursion of UJ wider than the tape. These results seem to explain the mechanism of action of the suburethral sling trough a certain degree of urethral kinking around the tape. In other words the continence could be ensured by an urethral angulation at the fulcrum represented by the tape. This theory was also supported by the subjective observation of urethral kinking during Valsalva maneuver. In this scenario failures related to an unproper tape position can be referred to the lack of kinking, while failures related to tape hypermobility could be related to an insuffucient anchorage of the tips into the obturator membrane. It is important to underline how the nature of the fixating native tissue could change according to the tension required: in fact since MiniArc™ sling lenght is fixed and limited to 8.5cm the surgeon in order to avoid over-tensioning of tape can withdraw the needle before the self fixating tip reaches the obturator membrane. In this case obturator internus muscle or obturator fascia could not represent a solid anchoring structure during the healing process. This could suggest a preoperative evaluation of patients eligible for a specific technique. Once established the efficacy, different approaches should be seen as substitutive and not as competitive. Further comparative studies with larger population are required to confirm these preliminary observations.

Concluding message

This descriptive study hypotized the mechanism of action of a third generation suburethral sling trough an ultrasonographic evaluation and focused on potential risk factors for failure. Despite standardization failures are often related an unproper tape position, perineal ultrasound can help to understand these conditions.

Table 1

Variable (mm)	**Treated**			**Failures**		
	Mean	SD	Min - Max	Mean	SD	Min - Max
UL	32.7	7.7	20.7-49.1	33.8	1.4	32.6-35.3
dUJ	16.3	5.2	5.6-22.6	10.0	5.6	3.7-14.4
R (dUJ / UL)	0.5	0.2	0.2-0.8	0.3	0.2	0.1-0.4

UJ descent	4.8	3.6	0.1-13.7	9.0	11.2	1.6-22.0
Tape descent	4.0	2.7	0.9-11.1	5.9	7.0	1.4-14.0

References
1. Dietz et al., How Important is TVT location? Acta Obstet Gynecol Scand 2004; 83:904-908

Specify source of funding or grant	**None**
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 eithics committee approval because	**Because is an observational study based on ultrasound imaging**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**