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MINIARC™: SHORT TERM RESULTS

Hypothesis / aims of study

Aim of this prospective trial is to evaluate the efficacy of MiniArc™ for the treament of female Stress Urinary Incontinence (SUI) looking at subjective and objective cure and complications rate after one year

Study design, materials and methods

MiniArc™ is a single incision device based on a suburetral polypropylene tape anchored trough integrated self fixating tips to the obturator membranes. The mechanism of action is based on mid-urethral tension free support. We consecutively admitted to this study patients from our urogynecology clinic who were eligible for surgical treatment of SUI. Inclusion criteria consisted in clinical stress urinary incontinence and age between 18 and 85 years. Exclusion criteria were occult stress urinary incontinence, previous surgical treatment for SUI, preoperative voiding difficulties and Δ<10°at Q-tip test. Preoperative assessment included clinical history, Visual Analog Scale (VAS) scoring for SUI, physical examination (including Q-tip test) and urodynamic study (uroflowmetry, cystometry and pressure-flow study). Stress test was performed in standing position at a bladder filling of 300mL. According to the number of coughs causing leakage SUI was rated mild (leakage after 5 coughs), medium (leakage after 3 coughs) or severe (leakage after 1 cough). Postoperative assessment included a clinical and physical evaluation (including stress test) 1, 2, 6 and 12 months after the operation while urodynamic studies were performed 2 and 12 months after surgery.

Results

This study included patients who were operated between March and October 2008. During this period 30 patients underwent the procedure. Population mean age at the time of operation was 56 years (Standard Deviation:SD=13, min 31, max 79), mean BMI 27 (SD 5.2, min 19, max 39), mean parity 2 (SD=1.1, min 0, max 6). SUI was associated to pelvic organ prolapse (POP) in 8 patients, while after urodynamic assessment 9 patients (30%) had a diagnosis of mixed urinary incontinence (SUI associated to idiopathic detrusor overactivity:DO). Urgency not related to detrusor overactivity was preoperatively referred by 11 patients (36.7%). Preoperatively SUI was rated medium in 14 patients (46.7%) and severe in 16 patients (53.3%), no patients with mild SUI were treated. Mean preoperative VAS score related to SUI was 9.0 (SD=1.3, min 6, max 10). In 12 patients MiniArc™ was performed with concomitant procedures (when associated to other procedures tape placement was the last surgical step): in 7 cases patients had a vaginal hysterectomy for POP always combined with McCall culdoplasty. In 4 cases an anterior repair and in 2 cases a posterior repair were associated to vaginal hysterectomy. In one case posterior repair was performed without hysterectomy. Other associated procedures not related to POP included 1 laparoscopic myomectomy, 1 laparoscopic bilateral oophorectomy, 1 laparoscopic hysterectomy and 1 operative hysteroscopy. Follow up was completed for 29 patients and only 1 patient was lost. Mean follow up was 7.7 months (SD=3.4, min 2 max 12). Results showed a complete resolution of SUI (patient dry) in 25 cases (86.2%) while in 4 patients (13.8%) SUI was still diagnosed. Two of the patients (6.9%) with SUI showed an objective improvement of incontinence: 1 patient shifted from severe to mild SUI and 1 patient from medium to mild SUI. Mean postoperative VAS score decreased to 1.3 (SD=2.5, min 0 max 5). Postoperatively mixed incontinence was diagnosed in 5 patients (17.2%) while urgency without DO was referred by 5 patients (17.2%): 1 of those patients (3.4%) had de novo urgency while 4 patients were already refferring it preoperatively. In other words 4 out of 9 patients (44.4%) with DO and 7 patients out of 11 (63.6%) who preoperatively referred urgency were cured (See Table 1). No intraoperative complications and no postoperative adverse events were reported during the study period. No patient had subsequent voiding disorders. No vaginal or urethral erosion was reported.

Interpretation of results

In this preliminary study 86.2% of patients was cured and 6.9% improved. No complications were reported and the single incision approach seems to reduce the risk of visceral, vascular and neural injury by reducing the dissection and the path lenght trough the tissues of the polypropylene tape. MiniArc™ was introduced in our clinical practice since march 2008 and this series represents our first experience with the device. It showed good reproducibility and it needed a short learning curve for the surgeons who were previously performing a transobturator technique. Lower Urinary Tract Symptoms (LUTS) other than SUI showed a certain improvement but this finding could be related also to other conconcomitant procedures (i.e. POP surgical treatment). Nevertheless there is a reasonable risk of de novo urgency related to the procedure. De novo urgency could be a transient symptom due to local inflammatory reaction, but the long term safety and effectiveness of this device is not known yet.

Concluding message

MiniArc™ seems to be a safe and effective approach to SUI treatment. Further studies on longer term results and randomised controlled trials comparing it with other procedures are needed to confirm or to confute MiniArc™ efficacy.

Table 1

	Preoperative (30 patients)			**Postoperative (29 patients)**		
	SUI	SUI + POP	Total	MiniArc	MiniArc + POP	Total
Urgency	10 (33.3%)	1 (3.3%)	36.7%	5 (1 de novo 3.4%)	0	17.2%
DO	5 (16.7%)	4 (13.3%)	30%	4 (13.8%)	1 (3.4%)	17.2%

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**

Specify Name of Ethics Committee	**Comitato Etico Azienda Ospedaliera S.Gerardo Monza**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**