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Sandoval C[1], Naser M[1], Valdevenito R[1], Lecannelier J[1], Pattillo A[1], Puga M[1], Guzmán R[1], Manríquez V[1], Abedrapo M[1], Aguilera A[1]

1. *Hospital Clínico Universidad de Chile*

OUT-PATIENT TREATMENT OF GENUINE STRESS URINARY INCONTINENCE: AN INITIAL EXPERIENCE WITH A THIRD GENERATION MIDURETHRAL SLING (MINIARC®)

Hypothesis / aims of study

Stress urinary incontinence has become a highly prevalent disease among women. Surgical techniques for the treatment of this disease have evolved toward minimally invasive procedures, maintaining the same results as classic techniques. MiniArc® (American Medical Systems) is a 3rd generation commercial kit for the treatment of stress urinary incontinence, designed for a minimally invasive surgery thus minimizing complications. The aim of our study is to evaluate the safety and effectiveness of MiniArc® for the treatment of stress urinary incontinence in an outpatient setting.

Study design, materials and methods

A prospective study of 10 consecutive cases treated with MiniArc® followed up to one year with cough stress test and quality of life questionnaires (King's Health Questionnaire). All patients had a multi-channel urodynamic evaluation prior to the surgery, excluding patients with suspected intrinsic sphincter deficiency. The procedure was performed under local anesthesia. The King's Health Questionnaire (KHQ) was applied prior to the surgery and twice after the surgery (median follow up time 90 days, range 30 to 227, and 170 days, range 123 to 395). Cough stress test was performed on all follow-up visits with 300 cc of 0.9% saline solution.

Results

Patients treated with MiniArc® had a 90% cure rate for stress incontinence one year after the surgery. All procedures were performed using local anesthesia. Eighty percent of procedures were successfully performed as out-patient surgery. The mean operative time was 27 minutes. We report no intraoperative complications. Two patients (20%) presented urine retention after the procedure, and were not discharged immediately. One of these patients had spontaneous resolution of retention with normal post-void residue (PVR) at discharge the next day. The second patient required adjustment of the sling prior to discharge, with normal PVR measured a week after. We report one case of de-novo urgency occurring 16 months after surgery. There was a significant improvement in every aspect of the QoL evaluation, as measured with the King's Health Questionnaire. (Figure 1 and Table 1)

Interpretation of results

MiniArc® is a safe and effective treatment for stress urinary incontinence in the short to medium term, and can be performed in most cases as an out-patient procedure with local anesthesia.

Concluding message

We believe that the primary finding of our study is that it shows that third generation minimally invasive procedures for the treatment of tress urinary incontinence such as MiniArc® can be performed safely in an out-patient setting with minimal complications, achieving a significant improvement in quality of life for patients. Regarding its effectiveness there is a lack of prospective, randomized, long term trials that can compare its results with previous midurethral slings, although it appears that "mini-slings" have equal or slightly worse results in the medium term.

Figure 1. Results from King's Health Questionnaire, specified by affected areas (percentage of affection), prior to surgery, and 3 and 6 months after surgery.

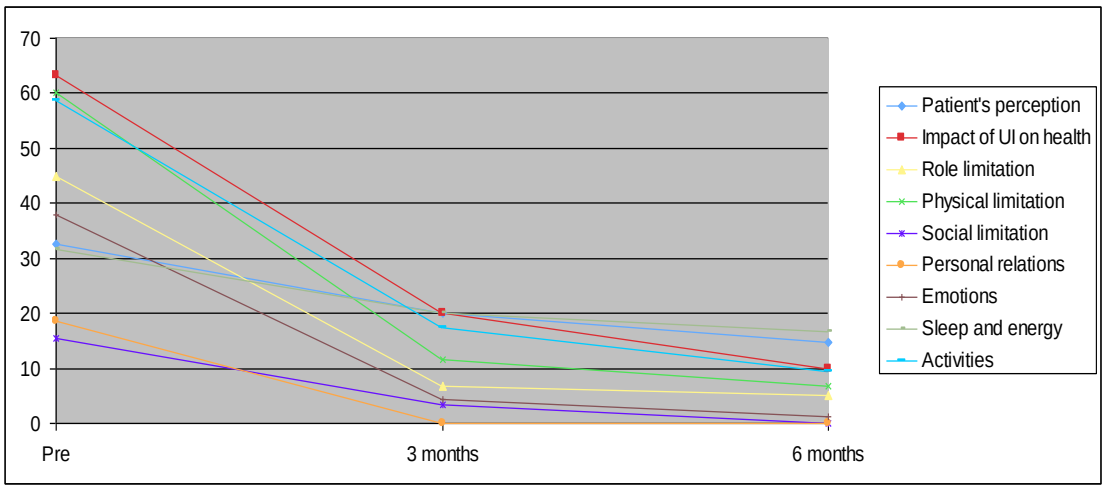

Table 1. Results from King's Health Questionnaire, specified by affected areas (percentage of affection), prior to surgery, and 3 and 6 months after surgery.

	Pre	Post 1 (3 months)	Post 2 (6 months)	p value (Pre vs Post 1)	p value (Pre vs Post 2)
Patient's perception	32,5	20	14,75	0,026	0,011
Impacto of UI on health	63,33	19,99	9,99	0,002	<0,001
Role limitation	44,99	6,67	5	0,001	0,001
Physical limitation	59,99	11,67	6,67	<0,001	<0,001
Social limitation	15,54	3,33	0	0,055	0,014
Personal relations	18,52	0	0	0,027	0,094
Emotions	37,78	4,44	1,11	0,002	0,002
Sleep and energy	31,69	20,01	16,68	0,104	0,041
Activities	58,67	17,34	9,33	0,015	0,003

Specify source of funding or grant	**MiniArc (r) slings and needle kits were donated by the national representative for American Medical Systems.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Hospital Clínico Universidad de Chile Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**