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THE ADJUSTABLE CONTINENCE THERAPY IN FEMALE STRESS URINARY INCONTINENCE; THE ITALIAN EXPERIENCE

Aims of Study

Since December 1999 a new minimally invasive surgery for female stress urinary incontinence using an implantable, adjustable device called the ACT (Adjustable Continence Therapy) has been used in a multicenter study. The two year follow-up of the Italian multicenter study is presented.

Methods

A group of 37 female patients, affected by type II and III SUI was evaluated before and after the positioning of the ACT . All patients underwent a pre-surgical physical examination, a comprehensive urodynamic study including Flowmetry, Cystomanometry with Valsalva leak point pressure, Pression-Flow study and Urethral Pressure Profile to diagnose and classify the type of urinary incontinence. Quality of life questioners (I-QOL and UDI) was done to asses if the ACT can improve the quality of life of our patients. Mean age was 58,5 (range 21.9 – 84,6). 59% (22 /37) had type II SUI while 41% (15 /37) had type III SUI. 57% (21/ 37) had had prior urogenital surgery

The ACT device consists of an adjustable balloon made by silicon polymers, a subcutaneously positioned titanium port and a two lumen tube in between. Two such devices are implanted into each patient in the same procedure. The balloons are filled during the surgery and are subsequently adjusted, if this is required, with iodated iso-osmotic contrast medium.

The devices are positioned via a percutaneous perineal approach , using either local or regional anaesthesia.. A 2 cm skin incision is made on the medial aspect of each of the labia majora and through these incisions a delivery trocar is directed toward the bladder neck. The trocar is manoeuvred into the desired position using tactile guidance via the vagina with a two dimensional visual confirmation achieved using an image intensifier (I/I). Each ACT device is then inserted via the delivery tool, with the balloon positioned on each side of the bladder neck, proximal to the vesico-vaginal space, below the endopelvic. Each balloon is then filled with only one to two millilitres of the isotonic contrast/sterile water mixture and confirmed as being correctly positioned using the X rays. The injection ports attached to each balloon are then positioned subcutaneously in each labia majora, with the port being placed superior to the introitus.

Results

15 patients reaches 24 months of follow-up. 46,6% of them (7/15) where dry at physical examination and where no pads. Additional 26,6% (4/15) where significantly improved. This group of patients has to where 1 pad/daily but are substantially satisfied whit the outcome of the surgery and do not desire to proceed to further adjustments. 56% (20/37)of the patients required one adjustment to achieve continence, 10% (4/37) two adjustments, 10% (4/37) three adjustments. 24% (9/37) need no adjustments. No cases of urinary retention was reported out of 37 cases. Ona patient has a transient discomfort during sexual intercourse and two patients have urethral pain after surgery treated with non steroid anti-inflammatory drugs.

I-QOL	Base .line.	1 mo	3 mo	6 mo	12 mo.	24 mo
Number of pts.	37	31	26	23	19	11
Mean	32	45	64	63	62	75
SD	18	25	19	26	24	20
p-value		0.0002	<0.0001	<0.0001	< 0.0004	0.00011

Conclusions

ACT offers a viable alternative for the treatment of stress urinary incontinence in patients with prior failed surgical treatments. 73,2 % of our patients where dry or substantially improved, this results includes mainly the patient with sever intrinsic sphincter deficiency and failed previous incontinence surgery. The ability to post-operatively adjust the ACT is clinically relevant and advantageous for these difficult patients, tailoring the appropriate volume to each individual's optimum requirements. The increasing in the quality of life questionnaires after the surgery is statistically significant.

The ACT surgery is really miniinvasive procedure with no operative risk nor contraindications. The preliminary results appears really encouraging especially if we consider that this results contains data of our learning curve. The patients quality of life increase significantly as documents the answers given during the follow-up. The idea to proceed with a “modulating” GSI surgery is feasible however a longer follow up and a bigger number of procedures are required for definitive conclusions.