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PERIURETHRAL IMPLANTATION OF PROACT® DEVICE IN TREATMENT OF STRESS INCONTINENCE (MALE). SINGLE-CENTER STUDY ABOUT 79 CONSECUTIVE PATIENTS AND INTEREST OF BLADDER NECK FIBROSCOPY DURING PROCEDURE.

Hypothesis / aims of study

To retrospectively assess the results of proACT® device in the management of stress incontinence in men. To report, for the first time, the interest of a retrovision of bladder neck during implantation.

Study design, materials and methods

Retrospective study upon 79 consecutive men suffering from urinary stress incontinence treated by implantation of ProACT ® devices between 2006 and 2009
A retrovision of the bladder neck was performed in the last 59 cases during implantation by using a flexible cystoscope, to provide a better control in the anteroposterior axle, in addition to fluoroscopy.
74 patients (93,7 %) had postprostatectomy stress urinary incontinence. The average age at surgery was 68,2 years [38 - 83]. The average waiting time between prostatectomy and implantation was 4 years [0 ; 15] . The average pad use per day (PPD) before treatment was 2,45 [0-permanent=8] . 79 patients (100%) had diurnal dribbling , 23 (29,1%) nocturnal dribbling.
The average follow-up period was 14,3 months [1,3 – 44,9]. Improvement scores were evaluated by a visual analogue scale (0 to 100%).
The average “per-device” inflation volume at the time of implantation was 1,17 mL [0,6-2,5].

Results

The average number of postoperative adjustments per balloon stood at 3,6 [0-12].
The average total volume injected into each balloon was 3,77 mL. [0,7-12]. 10 patients failed treatment (12,6%) (5 erosions, 4 insufficient results, 1 bladder perforation). Sixty one patients showed improvement at the end of the follow-up period (77,2%). The average improvement score was 72,9% [0-100].
The average PPD reduced from 2,45 prior to the implantation, to 1,21 PPD (p<1e-06). 33,8% of patients did not use any pad in the end of follow up (25/74) . 53/74 patients were **dry : 68,92%** (according to the definition : dry= 0 or 1 security pad and/or diminution in PPD > 50%).
16 (20%) patients needed device removal because of : 6 erosions , 2 infections, 1 device puncture , 1 device exposition, 4 device migration/misplacement, 1 bladder perforation,1 pain due to the device. All these patients have had a second treatment (6 ProACT® , 10 AUS).
A comparison of these data depending on the use of retrovision is shown on table 1

	No Retrovision	Retrovision	p
Age (yrs)	70,6	67,4	0,04
External Beam Radiotherapy	10%	10,20%	NS
Avg PPD before treatment	1,46	2,68	0,03
Improvement Score	68,40%	70,90%	NS
Removal Rate	25,00%	18,60%	NS
Dry (PPD= 0or1 and/or decrease>50%)	73,3%	71,2%	NS
Avg Follow up (mo)	20,7	12,3	0,003

Table 1 : Pretherapeutic and outcome data depending on the use of retrovision.
Removal rate seemed to be lower when retrovision was used. Results appeared equal between the two groups. The only significant differences concerned : pad use per day before treatment , and average follow up.

Interpretation of results

Overall, the technique had good results. (Dry rate = 69%. Average PPD 2 times lower at the end of follow up.

The follow up was too short , and patients had a PPD significantly higher in “Retrovision” group. It didn’t allowed us to show differences in outcomes and results between these two groups.

Concluding message

With near 69% patients dry ,and an average improvement score= 73% and no irreversible adverse event, the implantation of ProACT® devices for male stress urinary incontinence has become a first intention treatment for mild to moderate incontinence in our institution. Retrovision has not proved its superiority yet.

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 ethics committee approval because	**Retrospective study about an approved device**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**