

## INITIAL RESULTS OF PROACT IMPLANT: ARE THEY AFFECTED BY THE TYPE OF GUIDANCE USED?

### Hypothesis / aims of study

The ProACT™ device (Adjustable Contenance Therapy, Uromedica, Plymouth, MN, USA) consists of two post-operatively adjustable balloon implants placed via perineal approach bilaterally in a periurethral position at the bladder neck. The Implant of this device can be performed under ultrasound (US) (1) or fluoroscopic (2) guidance. Published results show similar success rates after ProACT implant performed under these two types of guidance (1,2). Nevertheless, no data have been published on possible differences in the learning curve of ProACT implant, in relation to the type of guidance used. Aim of our retrospective study was to evaluate results obtained in the first 20 patients implanted by a single operator either under US or fluoroscopic guidance, in order to assess if the learning curve of the procedure could be affected by the type of guidance used.

### Study design, materials and methods

Database of patients who underwent ProACT implant at our institution was reviewed. Only patients implanted for urinary stress incontinence after radical prostatectomy were considered; patients with history of relapsing urethral strictures or previously treated by means of radiotherapy were excluded from evaluation. Data of the first 20 patients who underwent ProACT implant under fluoroscopy guidance (group A), and of the first 20 patients who underwent ProACT implant under US guidance (group B) were collected. All patients were implanted by the same operator. Patients in group A were implanted before September 2008; patients in group B after that month. The technique used is described in reference 1 and 2 for group A and B respectively. Results available at 6 months follow up were considered. Peri- and post-operative complications were registered as well as number of balloons adjustments and pads used before and after surgery. Patients using no pads or just one pad for rare incontinence episodes (only in case of strong physical activity) were defined "cured"; patients reporting reduction of incontinence episodes and of number of pads used were defined "improved"; the remaining patients were considered "unsuccessfully treated".

### Results

#### RESULTS

Patients' demographics and clinical findings were comparable in the two groups (mean age 71,5 in group A and 72,1 in group B). No intra-operative complication was registered but one case of balloon rupture during implant in group A. Results are reported in table 1.

Tab. 1

	Group A	Group B	p
Number of post-operative complications	4	4	ns
Number of balloons adjustment (mean)	3,3	6,7	0.001
Number of pads used (mean)	1,4	1,8	0.56
Cured	12	6	ns
Improved	3	6	ns
Unsuccessfully treated	5	8	ns

Post-operative complications registered within six month follow up were balloon migration (4 cases), urethral or bladder erosion (2 cases), balloon rupture (2 cases).

The comparison of the number of patients cured and of the number of patients unsuccessfully treated, respectively 12 vs. 5 in group A and 6 vs. 8 in group B, does not produce a significant result ( $p=0,15$ ).

### Interpretation of results

This study have the limitations of a retrospective study, not powered to assess significant differences between the two groups of patients considered. Despite these limitations, the study was able to find a statistically significant difference of the mean number of post-operative balloons adjustment, higher in the group who received the ProACT implant under US guidance (6,7 vs. 3,3). The number of post-operative balloons adjustment can be influenced by the level of precision in balloons placement (the nearer the balloon is placed to the urethra, the less filling is needed to produce its coaptation). Thus, a higher number of post-operative adjustment (e.g. balloons filling) could reflect less precision in balloon implant. This finding cannot be influenced by another bias of this study: the operator was already trained to the implant under fluoroscopic guidance, when he started to perform the implants under US guidance. Thus, possible better results with this latter type of guidance could be due to a higher level of training of the operator: but this is not the case. Furthermore, a higher number of adjustment could produce higher risk of bladder or urethra complications in the long term follow-up, because of a higher pressure on these structures.

Results on incontinence cure, although slightly better in group A, are not significantly different, either considering the number of pads used, or the number of patients cured/improved. This finding could be due to the limitations of the study already underlined.

### Concluding message

Despite several limitations, this study seem to show that fluoroscopic guidance, at least during the learning curve of this surgery, could increase precision in ProACT implant, as suggested by the lower number of post-operative balloons adjustment. According to literature (even in absence of randomized controlled studies comparing results obtained using the two type of guidance) this difference could be minimized and the results improved by the experience of the operator (3). Nevertheless, a better standardization of US guided implant could be useful.

### References

1. Eur. Urol. 2010 Mar;57(3): 430-6.
2. BJU Int. 2005 Sep;96(4):587-94.
3. Eur Urol. 2007 Sep;52(3):680-6.

<b><i>Specify source of funding or grant</i></b>	<b>None</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>Retrospective</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>No</b>