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ARGUS T FOR POST PROSTATECTOMY URINARY INCONTINENCE- OUTCOME MINIMUM 12 MONTH OF THE MULTICENTRE TRIAL

Hypothesis / aims of study: To evaluate after minimum one year follow –up (F-up) a group of patient (pt) participating in a multicentre trial that has been treated for post prostatectomy urinary incontinence (PPI) using the transobturator approach to implant an adjustable male sling, Argus T [Tm]

Study design, materials and methods:
From November 2007 and August 2008, 37 consecutive PPI patients (30 post-radical prostatectomy and 7 post adenomectomy) were included in a multicentre trial to be treated with an adjustable male sling (Argus T [TM] - Promedon SA). 5 centres participating in the trial. The mean age was 69 years (58-81); 6 of the 37 had undergone previous unsuccessful anti-incontinence treatment: Suprapubic Argus sling: 1, Pro Act: 3, and bulking agent: 2.The implantation technique was previously described[1,2] and briefly the sling was implanted through a median perineal incision against the bulbar urethra keeping the bulbocavernous muscles in place. The needles that entered outside-in transobutratory, pulled out the cone columns. The tension was adjusted with the washers at a medium of 35.6 cm water (22-45), measured by retrograde urethral pressure (RUP). The Foley catheter remains for 24 to 48 hs. (Fig 1**)** All the pts implanted, completed a full urologic evaluation, a validated International Consultation on Incontinence Questionnaire (ICIQ – SF), 24h pad test, Visual Analogue Scale, urethrocistoscopy, urodynamics with especial interest in RUP, and a global impression (GI) expressed as Dry (D): no pads or one for protection, Improved (I): 1 pad a day, and Failure (F): 2 or more pads daily or sling removal.

Results:
At November 2009 one patient lost contact with the investigator, so there were 36 pts to be evaluated with a mean F-up of 21 month (15-26). All pts had a minimum of 12 months; this time was considered from the implantation or from the sling adjustment. At Inclusion, 29 of the 37 pts presented severe incontinence, moderate in 6 and mild in 1, according with the pad test classification. The Pad test and the ALPP were 1182gr (100-2880) and 46.2 cm of water (4-92). (Table 1)
From operation or readjustment, the ICIQ-SF changed from 18.8 (12-21) to 2 (0-21),
the VAS and RUP changed from 8.9 to 1.3 and from 16.9 to 35.2 cm of water, respectively. Postoperative readjustment was necessary in 5 patients (13.9%)
The GI was Dry, Improved and Failed in 29 (80.6%), 4 (11.1%), and 3 (8.3%) respectively (Table 2)

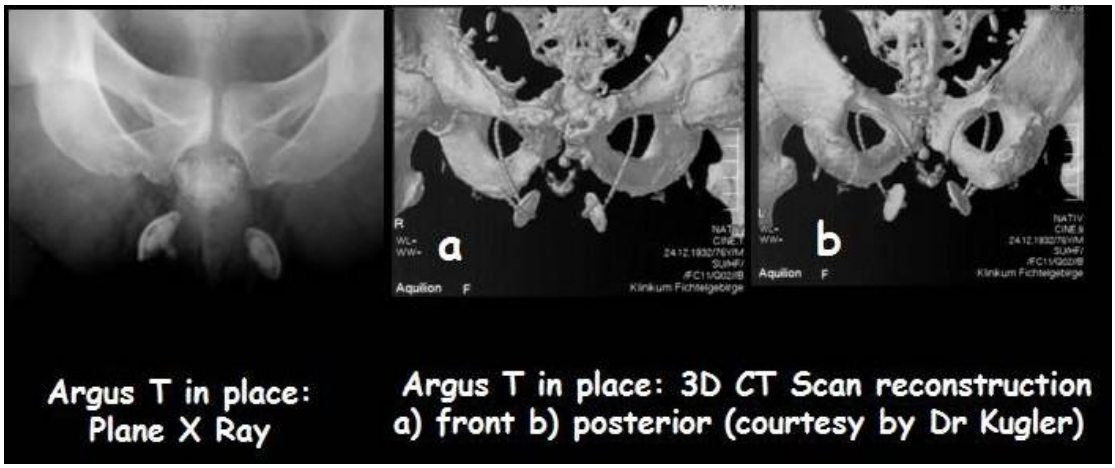

Fig 1: Argus T in place

N 37	Mean	Max	Min
ICIQ	18,8	21	12
VAS	8,9	10	4
VLPP	46,2	92	4
RUP	16,9	29	5
Pad T (gr)	1182,6	2880	100

Table 1: Preoperative evaluation (At inclusion)

N 36			
	Mean	Max	Min
ICIQ	2	8	0
VAS	1,3	10	0
RUP	35.2	45	22
Pad test (gr) Dry	3.8	30	0
Pad test (gr) Improve	25	45	10
G I	**D**: **29 (80.6%) I: 4 (11.1%) F: 3 (8. 3%)**		

Table 2: Follow-up: mean 21 moths (15-26) and minimum of 12 month (12-24)

Complications: 2 pts became infected immediately in the postoperative; one of them needed sling removal, the other cured after local and general antibiotics treatment. 2 patients had acute urinary retention; both are dry and regained spontaneous bladder evacuation; one after sling loosening and the other (with impaired bladder contraction) after a long term (6 month) of self clean intermittent catheterization. Most pts complained of mild or moderate inguinal and or perineal pain lasting less than 30 days postoperatively except one that took more than 2 months to disappear.

Interpretation of results: In the last decade, the male slings are showing a well gained place to treat the devastating condition of the post prostatectomy urinary incontinence. Many models are now in the market and two approaches to implant are recommended: suprapubic or transobturator. Till now none of the approaches or models appear to be efficient or good enough to be qualified as "the best". Even though both approaches using Argus^{Tm} male sling have demonstrated similar good results in 80% of the pts in the medium term follow-up[2]. We assume that the adjustability, during and postoperative time, is a necessary condition in the construction of the slings to control more precisely the bulbar urethral compression to achieve the continence in these pts very difficult to treat, as they are the incontinent post prostatectomy.

Concluding message: Argus male sling can be implanted both, Suprapubic or Transobturatory with almost the same good results, but the transobturatory approach has the clear advantage of its less invasiveness and harmfulness, making this approach the first choice.

References

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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	**Independent Ethic commitee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**