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THE USE OF SPIRAL COMPUTED TOMOGRAPHY IN PRO-ACT (ADJUSTABLE CONTINENCE THERAPY) IMPLANT FAILURES

Hypothesis / aims of study

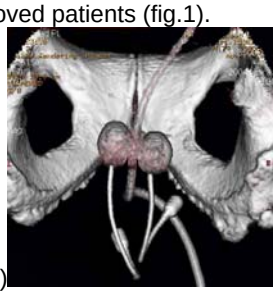
The use of the Pro-ACT™ device was introduced in 1999 for the treatment of post-prostatectomy incontinence (1). The Pro-ACT™-System is made up of two balloons implanted close to the urethra through a perineal approach. The volume of the balloons can be adjusted after implantation through a subcutaneous port in the scrotum. Once the device has been re-filled with non ionic contrast medium , postoperatively, a significant clinical improvement may be achieved due to the "bulking effect". The aim of this study was to evaluate the location of Pro-ACT™ devices in implant failures with the aid of the Spiral Multi Detector Computed Tomography (MDCT) scan.

Study design, materials and methods

A total of 60 male patients affected by post surgical stress-incontinence, due to prostatic surgery, were implanted with the Pro-ACT™ device, over a five year period (September 2000 to March 2006). A total of eighteen consecutive implanted patients were evaluated postoperatively (follow-up: 17-48 months) using pelvic MDCT scan. Thin pelvic collimated scans (1.25 mm) with bone algorithm, completed by multiplanar reformatting (MPR) and volume rendering (VRT) were obtained. A 10 Ch Nelaton catheter was used to better evaluate the urethra and, in 4 cases, to fill the bladder with non-ionic contrast medium (60 ml, 400 mgI/ml). Twelve (67%) of these had had radical prostatectomy and 6 (33%) prostatectomy for benign prostatic hyperplasia (BPH). At clinical follow-up 11/18 patients (61%) were dry or showed a significant clinical improvement and 7/18 (39%) had not improved even though the balloons had been re-filled.

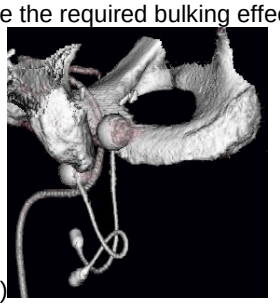
Results

MDTC scan showed the location of ProACT™ devices compared to the urethra, the bladder neck or prostate apex, pubis and pelvis. The Pro-ACT™ devices were over the urogenital diaphragm, close to the urethral wall, in 64% of dry-improved patients (fig.1).



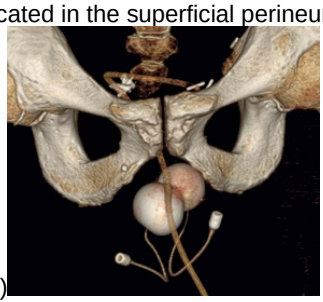
(fig.1)

Whilst, in the other 36% , at least one of the devices was incorrectly positioned, so that only one balloon was able to create the required bulking effect (fig.2).



(fig.2)

Indeed, it was observed that all the "non-improved " patients had devices far from the urethra. Moreover, they were dislocated in the superficial perineum in 86% of cases (fig.3).

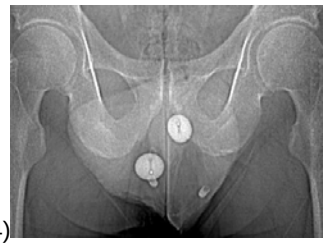


(fig.3)

The scout-view was not able to diagnose mal-positioning in all these cases and only MDCT scan was able to demonstrate the level of dislocation.

Interpretation of results

To the best of our knowledge, to date the post-operative evaluation of the Pro-ACT™ devices has relied on pelvis plain-film, that demonstrate deflating balloons and/or gross dislocations (fig.4).

(fig.4) 

If plain-film results were unremarkable, the devices were progressively refilled until the maximum volume allowed (8 ml), in an effort to arrive at continence. As the early post-operative plain-film evaluation of patients showing no signs of improvement was limited, it was decided to evaluate these patients by MDCT scan, so as to better demonstrate any incorrect positioning of the devices. In some cases it was seen that further filling of one or both balloons was necessary, whilst in others, a new implant, either mono or bilateral, was required. When also the bladder was filled with non-ionic contrast medium, it allowed for the evaluation of the spatial relationship of the devices, not only with the urethra, but also with the bladder neck. Therefore, we are of the opinion that it would be useful to adopt this procedure in the routine MDCT study protocol.

Concluding message

MDCT scan evaluation offers information as to the anatomical location of the devices, allowing for an early identification of the cause for clinical implant failure. The CT data obtained in this study demonstrates that, when Pro-ACT™ devices fail, this is due to the lack of the bulking effect, as the balloon/s is/are too far from the urethra wall. MDCT scan evaluation is well accepted by patients and should be considered when, after two refills, there is no improvement, so as to be able to have an early demonstration of the incorrect position of the devices and thus avoid useless refilling and patient discomfort.

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