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IMPLANTATION OF THE PROACT™ SYSTEM UNDER LOCAL ANAESTHESIA IN PATIENTS WITH POST-RADICAL PROSTATECTOMY STRESS URINARY INCONTINENCE: A FEASIBILITY PILOT STUDY

Hypothesis / aims of study
The implantation of the adjustable ProACT™ system (male Adjustable Continence Therapy, Uromedica, Plymouth, MN, USA) in male patients with stress urinary incontinence after radical prostatectomy (RP) is performed with fluoroscopic (1) or transrectal ultrasound (TRUS) (2) guidance under general or regional anaesthesia. The aim of the present study was to evaluate the feasibility and the potential advantages of TRUS-guided ProACT system implantation under local anaesthesia.
Study design, materials and methods
Between November 2006 and February 2007 we operated on 6 consecutive patients (mean age 70 years, range 66-77) with post-RP urodynamic intrinsic sphincter deficiency without detrusor overactivity. All patients were admitted on the surgery's day and received analgesic therapy with 100 mg of pethidine (meperidine) on call to the operating room. The ProACT systems were placed after infiltration of about 40 ml of ropivacaine 7.5 mg/ml which was bilaterally released under TRUS-guidance with a spinal needle through a transperineal route. During the procedure an anaesthesiologist was available in case of an undesidered event or if general anesthesia was required. Immediately after the procedure the catheter was removed and patients went directly back to the ward without dietary restrictions. Patients were aked to report any reason of discomfort and to complete 3 pain intensity scales: a 0-100 mm linear visual analogic scale (VAS), a 0-10 numeric pain intensity scale (NPIS) and a simple descriptive pain intensity scale (SDPIS – no pain, mild pain, moderate pain, severe pain, very severe pain, worst possible pain). Discharge from the hospital was planned after about 6 hours from the end of the procedure if the patients had no symptoms or signs of complications. A suprapubic ultrasound was performed to rule out urinary retention.
Results
The ProACT systems were succesfully implanted in all cases under local anaesthesia only without any need for general anaesthesia. All patients retained the capability of adequate verbal communication with the staff in the operating theatre. The time to complete the overall procedure ranged from 30 to 40 minutes. We did not observe perioperative surgical or anesthesia-related complications or urinary retentions after catheter removal. Four/6 patients reported mild discomfort during catheter and TRUS probe insertion. All patients reported mild burning during administration of local anesthesia in skin, subcutaneous tissue and in the pelvic diaphragm. The mean VAS score was 12 mm (range 3-21). The mean NPIS score was 1.3 points (range 1-2). SDPIS: no pain in 2/6 patients and mild pain in 4/6 patients. All patients resumed a full, normal diet within hours after surgery and were discharged after 6 hours. All patients declared to be satisfied with having the operation done under local anaesthesia.
Interpretation of results
The whole procedure was associated with minimal patient discomfort and had clear advantages in terms of quick patients' recovery and discharge from the hospital.
Concluding message
Our study indicates that the TRUS-guided ProACT system implantation under local anaesthesia only is feasible, well tolerated and may be performed as a day surgery procedure with the advantage of a faster patients' recovery. Potential advantages are the possibility to treat patients who are unfit to receive general anaesthesia due to severe comorbidity and costs reduction. Other studies with different patient populations and drugs combinations are required to validate our results.
References
(1) BJU Int (2005) 96; 587-594
(2) J Urol (2006) 176; 2109-2113

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HUMAN SUBJECTS: This study did not need ethical approval because not require but followed the Declaration of Helsinki Informed consent was obtained from the patients.