259

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TRANSRECTAL ULTRASOUND GUIDED PROACT SYSTEM IMPLANTATION UNDER LOCAL ANAESTHESIA IN PATIENTS WITH POST-RADICAL PROSTATECTOMY STRESS URINARY INCONTINENCE: EVALUATION OF OBJECTIVE PAIN, SUBJECTIVE DISCOMFORT AND PATIENT SATISFACTION

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) may be performed with fluoroscopic (1) or transrectal ultrasound (TRUS) (2) guidance under general or regional anaesthesia. Reasons to develop ProACT system implantation under local anaesthesia include quick recovery after surgery, fast return to a normal diet, decreased use of anaesthesia resources, treatment of patients in poor conditions to receive general anaesthesia due to severe comorbidity and cost advantages. We report our experience in patients who underwent TRUS-guided ProACT system implantation under local anaesthesia in terms of patient satisfaction, objective and subjective pain and discomfort evaluation.

Study design, materials and methods

Between November 2006 and February 2008 we operated on 20 patients (mean age 67.5 years, range 51-77) with post-RP urodynamic intrinsic sphincter deficiency without detrusor overactivity. All patients received analgesic therapy with 100 mg of pethidine (meperidine) on call to the operating room. The ProACT systems were placed after infiltration of 30 to 40 ml of ropivacaine 7.5 mg/ml which was bilaterally released under TRUS-guidance with a spinal needle through a transperineal route. Immediately after the procedure patients went directly back to the ward and were aked to report any reason of discomfort and to complete 3 validated 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). Before discharge from the hospital patients were asked if they were satisfied with having the operation done under local anaesthesia, if they would repeat the procedure and if they would recommend this operation to their families or friends.

Results

Subjective discomfort: 8/20 patients (40%) reported “mild discomfort” during catheter and transrectal ultrasound probe insertion. All patients (100%) reported “mild burning” during administration of local anaesthesia in skin and subcutaneous tissue and “mild discomfort” during administration of local anaesthesia in the pelvic diaphragm. One patient (5%) reported “mild discomfort” due to the stay in the lithotomy position.
Objective pain evaluation: mean VAS was 12.2 mm (range 0-28); mean NPIS was 1.45 (range 0-4); SDPIS: five patients (25%) reported “No pain”, 13 patients (65%) reported “Mild pain”, two patients (10%) reported “Moderate pain”.
Patient satisfaction: all patients declared to be satisfied with having the operation done under local anaesthesia; all patients would choose to have the procedure again and would recommend it to their families and friends.

Interpretation of results

Data regarding subjective discomfort, pain intensity scales and patient approval are satisfactory. In fact, discomfort of catheter and TRUS probe insertion are minimal and generally well tolerated by patients which had a RP and had in their experience one or more TRUS and the indwelling catheter. Burning and discomfort during local anaesthetic administration were minimal as well. Objective data from validated pain scales may be considered more than satisfactory (3).

Concluding message

Our data indicate that TRUS-guided ProACT system implantation under local anaesthesia is very well tolerated. The technique combines the advantages of TRUS-guided ProACT system implantation (excellent imaging of the anatomical landmarks during the entire procedure without radiation exposure) with those of a surgical procedure under local anaesthesia (quick recovery after surgery and decreased use of anaesthesia and operating room resources).

References

(1) BJU Int (2005) 96; 587-594
(2) J Urol (2006) 176; 2109-2113
(3) BJU Int (2002) 90; 481-488

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Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**not required**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**