

POST RADICAL HYSTERECTOMY URINARY INCONTINENCE: A PROSPECTIVE STUDY OF TRANSURETHRAL BULKING AGENTS INJECTION

Hypothesis / aims of study

Radical hysterectomy (RH) is deemed standard treatment of early-stage cervical carcinoma. This surgical procedure can be performed also in patients with locally advanced disease who respond to neoadjuvant chemotherapy (1). However, bladder dysfunctions are the most common long-term sequela after RH. In particular, de novo stress urinary incontinence (SUI) represents a common complication following type 3 radical hysterectomy, occurring in 21-53% of cases (2, 3). Nevertheless, in clinical practice most of these patients usually do not receive any further treatment. On the other hand, application of mid urethral tension free sling after radical pelvic surgery seems to have some technical difficulties and higher risks of complications (previous radiation therapy and/or chemotherapy). Therefore, less invasive treatment alternatives could be auspicious for this high risk patients group. Recently, urethral bulking agents have re-emerged as effective and minimally invasive procedures to treat SUI due to intrinsic sphincter deficiency (3). The aim of the present study is to prospectively investigate the efficacy and complications of macroplastique transurethral implantation in cervical cancer patients group affected by SUI after RH.

Study design, materials and methods

Patients affected by de novo SUI post type 3 radical hysterectomy, presenting to our Institute, were considered for eligibility in this prospective study. Exclusion criteria were as follows: detrusor dysfunction, residual bladder volume >100 ml, ureteric and/or bladder injuries during primary surgical procedure, hydronephrosis, untreated urinary tract infections, surgery of the lower urinary tract, evidence of current disease, diabetes mellitus, neurological diseases. Preoperative and postoperative assessment included a standardized urogynecological history, urogynecological and neurological physical examination, evaluation of severity of SUI symptoms (with 10 cm grade visual analogue scale), a 3- day voiding diary, urine culture and urodynamic assessment. All patients underwent transurethral implantation using Macroplastique Implantation system (MIS). Patient follow-up was performed 6 and 12 months after surgery. The cure of SUI after treatment was defined as the resolution of SUI symptoms (no incontinent episodes on voiding diary), the resolution of signs (negative cough stress test) and no new symptoms or side effects (urgency, frequency, urge incontinence, urinary tract infections, fistula or diverticulum). Improvement in SUI was defined as persistent stress symptoms but with the number of incontinent episodes decreased on voiding diary without new symptoms or side effects. Failed SUI treatment was defined as persistent stress symptoms with the number of incontinent episodes unchanged or worsened on voiding diary with or without new symptoms or side effects.

Results

A total of 12 consecutive patients were enrolled in this study. At the 12 month after surgery the SUI cure rate was 42% (5 of 12 patients), the improvement rate was 42% (5 of 12) and the failure rate was 16 % (2 of 12). The overall success rate was 84% (5 patients cured plus 5 improved). No intraoperative or postoperative early complications were found. Only 2 patients who failed both had preoperative urethral hypermobility. Subjective patient perception of SUI symptom severity showed significant improvement (mean severity of urinary loss perception 6.4 ± 1.5 vs 2.4 ± 3.2 , $p < 0.05$). The frequency of incontinence on the 3-day voiding diary was significantly reduced at the follow up (13.4 ± 5.6 vs 4.2 ± 7.7 episodes per 3 days, $p < 0.05$).

Interpretation of results

The current study proves that bulking agents urethral injection could be a valid option, without surgical complications, to treat SUI and improve well being of cervical cancer patients after radical surgery. Alleviation of this negative event can play a role in enhancing or preserving the patient's QOL during and after cancer treatment, enabling her to withstand and complete the most effective therapy. Caring for the patient, as well as her cancer, requires that measures to preserve or enhance the quality are incorporated into the patient's treatment plan.

Concluding message

Bulking agents urethral injection could be a valid option to improve well being of cervical cancer patients after radical surgery.

References

1. J Epidemiol Biostat (2001) 6; 7–43.
2. Crit Rev Oncol Hematol (2003) 48; 287-293
3. Cancer (2004) 100; 2110-2117

Specify source of funding or grant	none
Is this a clinical trial?	Yes
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 ethics committee approval because	is a standard treatment for Sui
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes