731

Adile B[1]
1. villa sofia hospital urogynecolgy department

EFFICACY OF JALURONIC ACID IN URETHRAL BULKING: ONE YEAR FOLLOW UP

Hypothesis / aims of study

First-line treatment for stress urinary incontinence (SUI) is usually non-invasive. Surgery, although effective, is not suitable for all and a clear need exists for the development of a new, minimally invasive approach for the treatment of SUI.
Dextranomer/hyaluronic acid (Dx/HA) copolymer comprises dextranomer microspheres in a carrier gel of non-animal stabilised hyaluronic acid (NASHA).
The gel has no immunogenic properties, and has been shown not to migrate to different organs following submucosal injection.
Dx/HA copolymer is the only injectable agent approved by the US FDA for endoscopic treatment of vesico-ureteral reflux (VUR) in children, and has also gained European approval in the treatment of SUI.
A novel guiding instrument - Implacer ™ has been developed to facilitate reproducible and standardized transurethral injection of Dx/HA copolymer, without the need for surgical facilities.
The aim of this study is to evaluate the safety and efficacy of the Zuidex implacement for the treatment of type II and type III incontinence.

Study design, materials and methods

We evaluated 36 women (median age 51) with type III (MUCP < 20 cm H2O and VLPP < 60 cm H2O) and type II stress incontinence, with fixed urethra demonstrated (Delta Value < 30° at Q-tip test).They were recluted by a complete urogynaecological work-up
(Vaginal profile, Q- tip test, Endoscopy and Urodynamic study, one hour Pad test, Ultrasonography).
We defined as cured patients that were dry after the implant, and as improved those who decreased in number of pads and symptoms.
We underwent all patients an intraurethral injection of Zuidex, in four different points at the bladder nek level under local anesthesia. 21 (58.3%) had undergone previous continence surgery. Subjective and urodynamic assessments were made at 6 months after injection to evaluate success and short term effects.
No catheter was placed after procedure and each patient was invited to void spontaneously after four hours before discharge.
We introduced the Implacer (with the tube covering the needles) so that the top of the tube is located approximately at the mid-urethra level.
It is important that the tube does not move backwards during the insertion into the urethra.
To avoid this apply pressure on the rear end of the tube while inserting.
Pull back the tube to release the needles within the urethra. The position of the needle eyes is then approximately at the mid-urethra
With a firm grip on the hand piece, retract one syringe
5-10 mm and then push it forward to its bottom position in order to penetrate the mucosa.
Inject the contents of the syringe.Leave the emptied syringe in place.Going clockwise, repeat this manoeuvre with the remaining 3 syringes
Remove the syringes with the needles one by one and thereafter the implacer.The syringes,needles and the Implacer must be discarded after the treatment session.

Results

Objective success rates at one year was 64 %(23 pts), significantly improvement 25 %(9pts), failures 11%(4 pts). At the follow-up there was no change in mean bladder capacity, urinary flow rate, bladder compliance and stability; UPP showed a statistically significant increase in functional urethral length and MPCU.

Interpretation of results

Our clinical studies on use of Zuidex in the endoscopic correction of type III and type II incontinence show that up to 64% of patients can be cured or significantly improved. It is easy to use and safe and does not complicate or preclude open surgery at a later date.

References

1. Stemberg AM, Larsson E, Lindholm A, et al. Injectable dextranomer-based implant : histo-pathology, volume changes and DNA-analysis. Scand J Urol Nephrol 1999;33:355-61
2. Stenberg AM, Sundin A, Larsson BS, et al. Lack of distant migrant after injection of a 125iodine labeled dextranomer based implant into the rabbit bladder. J Urol 1997;158:1937-41.
3. Lackgren G, Wahlin N, Stenberg A. Endoscopic treatment of children with vesico-ureteric reflux. Acta Paediatr Suppl 1999;88:62-71