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MAGNETIC RESONANCE IMAGING TO CONFIRM THE PERIURETHRAL LOCATION OF ZUIDEX™ DEPOSITS

Aims of Study

Urethral injection of bulking agents has long been investigated for the treatment of stress urinary incontinence (SUI) but success rates have been variable. The reasons for this are numerous, and include the choice of injectable agent and lack of a standardised injection technique.

A novel injection device, the Implacer™, was developed with the aim of delivering four transurethral injections of dextranomer/hyaluronic acid (Dx/HA) copolymer with improved accuracy and consistency compared with endoscopic injection (Figure 1). The device, which is intended for use without surgical facilities, is inserted to a depth equivalent to half the urethral length with the four needles held together by a needle cover. The cover is then retracted to release the four needles outwards, holding the mucosa in a fixed position. The syringes are sequentially retracted by 5–10 mm then advanced to penetrate the mucosa thus allowing injection of Dx/HA copolymer. Dx/HA copolymer is a biocompatible material with excellent properties for submucosal injection, having previously been approved for endoscopic treatment of vesico-ureteral reflux in children (Deflux ®, Q-Med, Uppsala, Sweden) as well as for SUI (Zuidex™).

Figure 1. The Implacer™ device, a novel means of administering Dx/HA copolymer injections.

Fig 1a. Assembled Implacer™

Fig1b. Inserted into urethra

Fig 1c. Needle cover with needles covered retracted

A pilot study was recently performed to investigate the safety and efficacy of Zuidex™ treatment for SUI. As a sub-study, Magnetic Resonance Imaging (MRI) was performed to investigate the deposition of Dx/HA copolymer. In particular, we sought to establish the size, positioning and number of deposits present.

Methods

Forty-two female patients aged 18 years or older with urodynamically verified SUI were included in the open, prospective, multi-centre pilot study. All patients had a history of SUI for at least 12 months and had failed prior non-invasive treatment.

Treatment was administered using the Implacer™ device following administration of local anaesthetic. There were two study groups, one for each of two different injection volumes of Dx/HA copolymer: 4 x 1.0 ml (n=32) and 4 x 0.7 ml (n=10). MRI examinations were performed within 3 months of treatment using a 1.5 T Magnetom Vision (Siemens). To localise the deposits, a T2-weighted HASTE sequence with 4 mm slice thickness was used for anatomical description. To evaluate the injected substances, turbo inversion recovery sequences were used in the transversal and coronal planes with 3 mm slice thicknesses and matrix 220 x 256 and 162 x 256 respectively. Volume measurements were performed on a 3D T2-weighted turbo

spin-echo sequence in the sagital plane with 1 mm slice thickness and matrix 162 x 256. Field of view for all sequences: 250–300 mm.

Results

Sixteen patients (8 from each study group) were examined by MRI. These assessments were performed a mean of 35 days after treatment (range 1–92 days).

It proved possible to visualise the Dx/HA deposits by MRI, and the majority were positioned periurethrally in the submucosa, as intended (Figures 2 and 3). Three or more deposits were identified in 11 of the 16 patients (68.8%), and one or two deposits in three patients (18.8%). In only two cases (12.5%) were there no identifiable deposits. Of the 14 patients with identifiable Dx/HA copolymer, 11 (78.6%) had deposits that were located periurethrally in the submucosa; the deposits were localised between the mucosa and muscular layer in three patients.

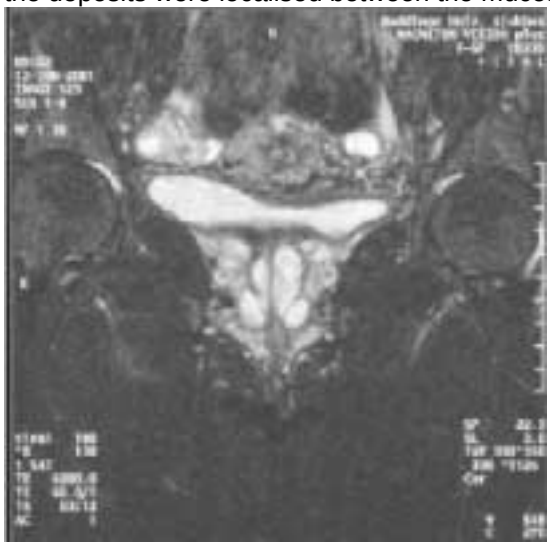

Figure 2. Dx/HA copolymer deposits (urethra, transverse image).

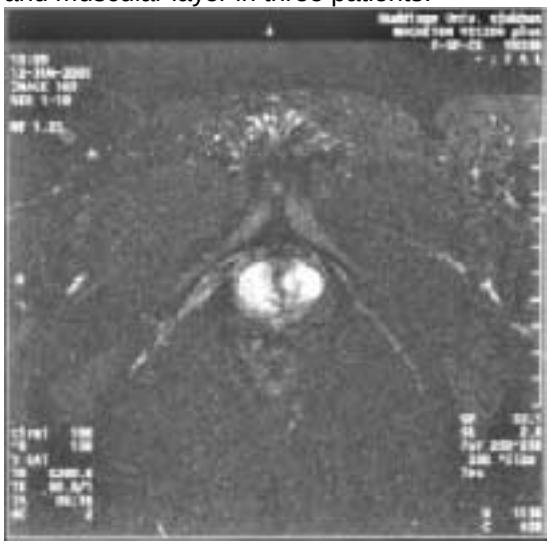

Figure 3. Dx/HA copolymer deposits (urethra, coronar image).

Thirteen of the 16 patients (81.3%) demonstrated qualitative improvement in their incontinence at month 3 post-treatment, both in terms of provocation test leakage and number of incontinence episodes (one patient recorded a decreased number of incontinence episodes but no improvement in the provocation test, and two patients recorded no improvement in either parameter). Three or more deposits were apparent in all three of these patients. Conversely, improvements were noted in both patients with no identifiable deposits.

The size of deposits ranged from 5x5x4 mm to 29x13x17 mm in group A, compared with 2x2x3 mm to 20x24x20 mm in group B.

Conclusions

This study showed that by using the Implacer™, Dx/HA copolymer was deposited into the desired periurethral location in the submucosa, without endoscopic guidance, in the majority of cases. There were some apparent discrepancies between clinical outcome and the number of identifiable deposits. This may be have been due to the small number of patients investigated, but might also indicate a need to refine the MRI procedure that was used.