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DEXTRANOMER BASED IMPLANTS FOR ENDOSCOPIC TREATMENT OF URINARY INCONTINENCE IN BLADDER EXSTROPHY AND PENOPUBIC EPISPADIAS PATIENTS.

Hypothesis / aims of study

Treatment of urinary incontinence in bladder exstrophy and epispadias patients remains a challenging problem. In the last 2 decades endoscopic treatment for urinary incontinence has gained popularity, mainly because it is a minimally invasive procedure compared with open surgery. A number of injectable bulking materials, such as polytetrafluoroethylene paste, silicone paste and cross-linked bovine collagen, have been used for endoscopic treatment of urinary incontinence. Dextranomer/hyaluronic acid copolymer (Deflux, Q-Med AB, Uppsala, Sweden) is a new injectable bulking synthetic material. The aim of our study is to evaluate the efficacy and safety of endoscopic treatment using a new bulking agent (dextranomer/hyaluronic acid copolymer) for urinary incontinence in bladder exstrophy and penopubic epispedias patients.

Study design, materials and methods

Dextranomer/hyaluronic acid copolymer was used as the bulking material. The copolymer is composed of dextranomer microspheres 80 to 120 µm. in diameter suspended in 1% sodium hyaluronan solution. The transurethral endoscopic procedure was performed with the patient under general anesthesia using a videocamera. The urine had to be sterile at the time of treatment. A total of 17 patients (4 females and 13 males), 8 to 23 years old(mean age 12.5) with severe incontinence due to incompetent urethral closure mechanism (12 with bladder exstrophy after bladder reconstruction, and 5 with penopubic epispadias) were enrolled in the study. Exclusion criteria were concomitant vesicoureteral reflux, significant upper urinary tract damage or renal failure, cystometric evidence of detrusor overactivity uncontrolled by anticholinergic medication, poor bladder capacity, and low bladder compliance. The study was performed following approval from the local ethics committee. Each patient or their parent gave written informed consent before the start of the study. Preoperative evaluation consisted of medical history , pad test, urine culture, urinary tract ultrasound, cystography and videourodynamics. Followup at 1 month comprised subjective evaluation of incontinence by the patient and family, pad test, urine culture and renal ultrasound. This evaluation was repeated as well as videourodynamics at 6 months, 1 year and then on a yearly basis. Of the patients 8 had 2 and 1 had 3 treatment sessions to achieve a definitive result. At each evaluation the patients were considered to be cured if they no longer needed protection (that is no urinary leakage) between voidings and they had well-defined bladder emptying intervals of 2.5 hours or more during the daytime or 6 hours or more at night, patients were considered to be improved when they judged themselves to be improved , and used less protection . The results were considered as failure for patients who did not meet the above mentioned criteria. Followup after the last injection ranged from 1 to 24 months (mean 15). A minimum of 1 year follow-up was available for 13 patients, and 2 years follow-up for 10 patients.

Results

The mean injected volume was 4.7 ml. (range 3 to 12) , well-defined bulge was created at the bladder neck or at the pre-sphincteric urethra using a volume of dextranomer/hyaluronic acid copolymer sufficient to obtain a visual well-defined bulge (figure 1,2) . The procedure lasted a mean of 30 minutes (15 to 60). In the postoperative period 2 patients had temporary urethral pain and 5 had a nonfebrile urinary tract infection. At 1 month 15 of the 17 patients (88.2%) were dry or improved. Two patients were subsequently excluded from study for noncompliance with followup. At 6 months 12 of 15 patients (80%), at 1 year 10 of 13 (76.9%), and at 2 years 7 of 10 (70%) were dry or improved. No side effect related to the substance was observed, and no upper urinary tract deterioration was observed as a consequence of endoscopic treatment within the 2-year followup period.

Interpretation of results

The implant procedure for the dextranomer/hyaluronic acid copolymer is similar to that of other injectable materials used for endoscopic treatment of urinary incontinence or vesicoureteral reflux. However, injection of dextranomer/hyaluronic acid copolymer does not require any special equipment, such as a syringe gun, as do other injectable materials(1). Overall improvements obtained with dextranomer/hyaluronic acid copolymer in terms of continence achievement are comparable to those reported with other bulking materials(2). A progressive decrease in continence parameters with time after endoscopic treatment with bulking agents is common. This decrease is more apparent with collagen than with silicone(3). In our study only a slight decrease in continence parameters was observed at 24 months compared with findings at 12 months. However, evaluation of the results after a longer follow-up period is needed .

Concluding message

Endoscopic treatment of urinary incontinence in bladder exstrophy and epispadias patients with dextranomer implant, was effective after 2 years in 70% of our patients.

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figure 1
Intra Operative Picture Before Injection.

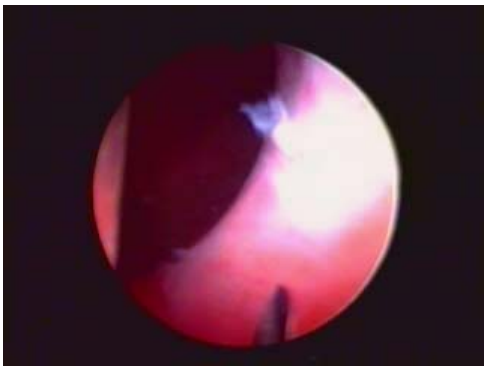

figure 2
Intra Operative Picture After Injection