Periurethral Injection of Autologous Adipose-Derived Regenerative Cells for the Treatment of Stress Urinary Incontinence: Outcome of a Preliminary Clinical Trial in Male Patients

Introduction and Objective: To report a novel cell therapy using autologous adipose-derived regenerative cells (ADRCs) for stress urinary incontinence caused by urethral sphincter deficiency and the early outcomes in 5 initial male patients undergoing periurethral injection of ADRCs for the treatment of urinary incontinence.
Materials and Methods: Five male patients with persistent stress urinary incontinence after prostate surgery received treatment. Four patients had undergone radical prostatectomy for prostate cancer, and one patient had undergone holmium laser enucleation of the prostate for benign prostatic hyperplasia. After liposuction of 250 mL of adipose tissue from the abdomen, we isolated ADRCs from this tissue using the Celution^{TM} system. Subsequently, the isolated ADRCs and a mixture of stem cells and adipose tissue were transurethrally injected into the rhabdosphincter and submucosal space of the urethra, respectively. Outcomes during a 6-month follow-up were assessed by a 24-hour pad test, a validated patient questionnaire (ICIQ-SF), urethral pressure profile, contrast-enhanced transrectal ultrasonography, and MRI. The present study was approved by the Ethics Committee of the Nagoya University Graduate School of Medicine and by the Japanese Ministry of Health, Labour and Welfare, and written informed consent was obtained from the patients.
Results: After injection, urinary incontinence progressively improved during the 6-month follow-up in all patients, i.e., decreased leakage volume in a 24-hour pad test. One patient with moderate incontinence (mean leakage amount per day during 4 consecutive days in a 24-hour pad test: 113.3 g) achieved total continence 14 weeks after injection. In the urethral pressure profile, both maximum urethral closing pressure and functional profile length increased in both patients. In all patients, ICIQ-SF demonstrated a progressive improvement in frequency and amount of incontinence and quality of life during the 3-month follow-up. Ultrasonography and magnetic resonance imaging demonstrated sustained presence of the injected adipose tissue. Enhanced ultrasonography revealed a progressive increase in blood flow to the injected area. No significant adverse events were observed peri- and postoperatively.
Conclusion: This preliminary study demonstrated that periurethral injection of autologous ADRCs is a safe and feasible treatment modality for patients with stress urinary incontinence caused by urethral sphincter deficiency.