PRE-CLINICAL EFFICACY AND SAFETY EVALUATION OF PERIURETHRAL HAFSC INJECTION IN THE URINARY INCONTINENCE ANIMAL MODEL

Hypothesis / aims of study
Stem cell-based therapies represent new promises for the treatment of urinary incontinence. This study was performed to assess optimized cell passage number, cell dose, therapeutic efficacy, feasibility, toxicity, and cell trafficking for the first step of the pre-clinical evaluation of human amniotic fluid stem cell (hAFSC) therapy in a urinary incontinence animal model.

Study design, materials and methods
The proper cell passage number was analyzed with hAFSCs at passages 4, 6, and 8 at week 2. The cell dose optimization included $1 \times 10^4$, $1 \times 10^5$, and $1 \times 10^6$ cells at week 2. The in vivo cell toxicity was performed with $0.25 \times 10^6$, $0.5 \times 10^6$, and $1 \times 10^6$ cells at weeks 2 and 4. Cell tracking was performed with $1 \times 10^6$ cells at weeks 2 and 4.

Results
The selected optimal cell passage number was smaller than 6 and the optimal cell dose was $1 \times 10^6$ for the mouse model. In our pre-clinical study, hAFSC-injected animals showed normal values for several parameters. Moreover, the injected cells were found to be non-toxic and non-tumorigenic. Furthermore, the injected hAFSCs were rarely identified by in vivo cell trafficking in the target organs at week 2.

Interpretation of results
Periurethral hAFSC injection provided the pre-clinical efficacy and safety of in the urinary incontinence animal model.

Concluding message
This study demonstrates for the first time the pre-clinical efficacy and safety of hAFSC injection in the urinary incontinence animal model and provides a basis for future clinical applications.

Disclosures
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