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

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

Results
The selected optimal cell passage number was less than 6 and the optimal cell dose was $1 \times 10^6$ for the mouse model. In our pre-clinical study, hAFSCs-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 cell trafficking in vivo in the target organs at week 2.

Interpretation of results
hAFSCs-injected animals demonstrated normal values for parameters measured, and hAFSCs were found to be non-toxic and non-tumorigenic.

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

References

Disclosures
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Clinical Trial: No Subjects: ANIMAL Species: Mouse Ethics Committee: Animal Ethics Committee of Biotoxtec Inc. and the Ethics Committee of Kyungpook National University School of Medicine