Pluripotent Fetal Stem Cells in Treatment of the Vascular Factor of Erectile Dysfunction

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Introduction
Existing treatment solutions of erectile dysfunction (ED) do not satisfy patients due to short-term and targeted effects. To achieve prolonged and more pronounced treatment effects, we developed combined ED therapy with the use of 5-phosphodiesterase inhibitor vardenafil and fetal stem cell (FSC) suspensions. We hypothesize that, in contrast to pharmaceuticals that work mainly at the functional level, FSC are able to impact erection at a structural component.

Method
We examined 19 patients with mixed type of ED including vascular component. All the patients underwent complete examination of erection according to international standards. We used IIEF to assess erectile function and pharmacocardiography with 10 mcg of PGE1 to measure cavernous blood flow.

We divided patients into 2 groups:
- Experimental, or FSC, group that received pluripotent FSCs and vardenafil in a daily dose of 10 mg (n = 9);
- Control group (n = 10) that received vardenafil in a daily dose of 10 mg.

Each patient in the experimental group received three types of fetal stem cell suspensions derived from human fetuses following voluntary pregnancy terminations:
1. Containing fetal liver stem cells that were injected i/v and i/cavernously. i/v injection was performed during artificial erections induced by 10 mcg of PGE1 which ensured temporary occlusion of cavernous bodies and created optimal condition for local application of fetal stem cells.
2. Containing fetal brain stem cells administered via pharmacocardiogram.
3. Containing placenta stem cells administered subcutaneously.

Results

![Figure 1: Studied groups were statistically homogeneous with regard to age and erectile function](image)

![Figure 2: Erectile function score improvement was more pronounced in the FSC group compared to the control group](image)

![Figure 3: After treatment, erectile function score (by IIEF) increased 27% on average in the FSC group (p<0.01) vs 17% in the control group (p<0.05) (Figure 2).](image)

![Figure 4: In the FSC group, venous outflow decreased, in contrast to the control group](image)

![Figure 5: Combined therapy including FSC also demonstrated higher long-term efficacy vs vardenafil monotherapy. 40% of patients in the FSC group reported maintenance of adequate erection without pharmacological stimulation 6 months after treatment, which was significantly higher than in the control group (25%)](image)

Conclusion
Combined therapy of ED comprising of vardenafil and cell suspensions containing pluripotent stem cells of fetal liver, brain and placenta had more pronounced positive effect on ED patients than vardenafil monotherapy. In particular:
1. Combined therapy including FSCs led to higher arterial inflow increase along with venous outflow decrease (compared to venous outflow growth in case of vardenafil monotherapy). This resulted in growing positive balance between arterial and venous components of erection in patients treated with FSCs.
2. Erectile function score (IEF) growth was higher in the FSC group (27%) than in the control group that received vardenafil only (17%).
3. The share of patients who had medicine-free sexual life 6 months post-treatment was higher in FSC group than in the control group (40% and 25%, respectively).

Summary
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