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DEVELOPMENT, BIOMANUFACTURING AND PILOT CLINICAL TRANSLATION OF AN ALLOGENEIC MSC-DERIVED EXTRACELLULAR VESICLE PRODUCT

Background/Aim. Mesenchymal stromal cell-derived extracellular vesicles (MSC-EVs) are promising cell-free therapeutic agents with regenerative and immunomodulatory properties and significant potential for off-the-shelf clinical applications. This study aimed to develop a clinical-grade allogeneic MSC-derived EV product and assess its therapeutic potential in the treatment of vulvovaginal atrophy (VVA) using clinical and patient-reported outcome measures. **Methods.** Allogeneic MSC-derived EVs were isolated from umbilical cord, adipose tissue, and dental pulp MSCs by differential ultracentrifugation. EVs were characterized by NTA, protein and RNA quantification, ELISA, endotoxin, and sterility testing. Twelve women with vulvovaginal atrophy received a single intramucosal administration of 1 ml of the MSC-EV product containing 3×10^9 particles suspended in physiological saline and were followed for 12 months. Outcomes included vaginal pH, vaginal maturation index (VMI), and Female Sexual Function Index (FSFI). **Results.** The developed MSC-derived EV product contained $3.27 \pm 0.37 \times 10^9$ particles/mL with a mode size of 137.1 ± 3.5 nm and a protein concentration of 242.8 ± 34.2 µg/mL. Expression of CD9, CD63, and CD81 confirmed EV identity. The product contained bFGF, VEGF, IL-6, and IL-1RA, passed sterility testing, and showed endotoxin levels below 0.05 EU/mL. No adverse events were observed following intravaginal administration of the MSC-EV product. One month after treatment, the total FSFI score increased from 1.2 ± 1.2 to 32.8 ± 1.6 , while the Vaginal Health Index (VHI) improved from 10.0 ± 3.6 to 23.1 ± 1.6 and remained stable after 3 months (23.2 ± 1.6). Vaginal maturation index analysis demonstrated a shift from predominantly parabasal cells (43%) before treatment to superficial cells (46%) after 1 month, indicating restoration of vaginal epithelium. Clinical and sexual function improvements were maintained for at least 6 months. **Conclusion.** The developed MSC-derived EV product demonstrated a favorable safety profile and promising therapeutic efficacy in women with vulvovaginal atrophy. Treatment was associated with sustained improvements in clinical and patient-reported outcomes, supporting the potential of MSC-derived EVs as an off-the-shelf regenerative therapy. Further controlled studies are required to confirm these preliminary findings.

Keywords: extracellular vesicles, mesenchymal stromal cells, vulvovaginal atrophy.

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