CELL CORDES CLINICAL TRIAL: CELL THERAPY AND SCARRED VOCAL FOLDS

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Origins of vocal folds scarring can be either congenital or acquired, with the last one to be far more common. It leads to a deterioration of a highly complex micro-structure with consecutively impaired vibratory pattern and glottic insufficiency. Patients usually present clinically with vocal fatigue, loss of vocal control and a breathy, little sustainable dysphonic voice, with a considerable impact on the quality of life. The treatment of scarred vocal folds is still an unresolved chapter in laryngology. An ideal approach would be to soften the scar, to improve visco-elastic properties. Adipose tissue-derived stromal vascular fraction (SVF) is increasingly recognized as an easily accessible source of regenerative cells with therapeutic potential in various diseases.

OBJECTIVE: We aimed to measure for the first time the safety, tolerability and potential efficacy of autologous adipose tissue-derived SVF cells local injections in patients with scarred vocal folds.

METHODS: We did an open-label, single arm, at one study site with a 12-month follow-up among 8 patients with disabling scarred vocal folds, refractory to conventional surgical or rehabilitative treatments and with no previous history of cancer. Lesions involved the middle third of the vocal fold, had been evolving for at least 12 months and were source of a Voice Handicap Index score > 60/120. Autologous SVF was obtained from lipoaspirates, using an automated processing system, and subsequently injected into the affected vocal fold(s), on the same day. Primary outcome was the number and the severity of adverse events related to SVF-based therapy. Secondary endpoints were changes in videostroboscopy evaluation, voice recordings (perception, acoustic and aerodynamic data) and quality of life from baseline to 1, 6 and 12 months after cell therapy.

RESULTS: Follow-up of our patients is not finish yet but preliminary results are available. Seven patients aged from 39 to 60 years have been included, 6 women and 1 man. All enrolled patients had surgery, and there were no dropouts or patients lost to follow-up. No severe adverse events occurred during the procedure and follow-up. Some minor adverse events were reported and resolved spontaneously. An improvement in vocal folds vibration, quality of life and perceptive evaluation was noticed. Changes in objective parameters of the functional assessment were variable from one patient to another.

CONCLUSION: This study outlines the safety of the autologous SVF cells injection in scarred vocal folds. Preliminary assessments suggest potential efficacy needing confirmation in a randomized placebo-controlled trial on a larger population.